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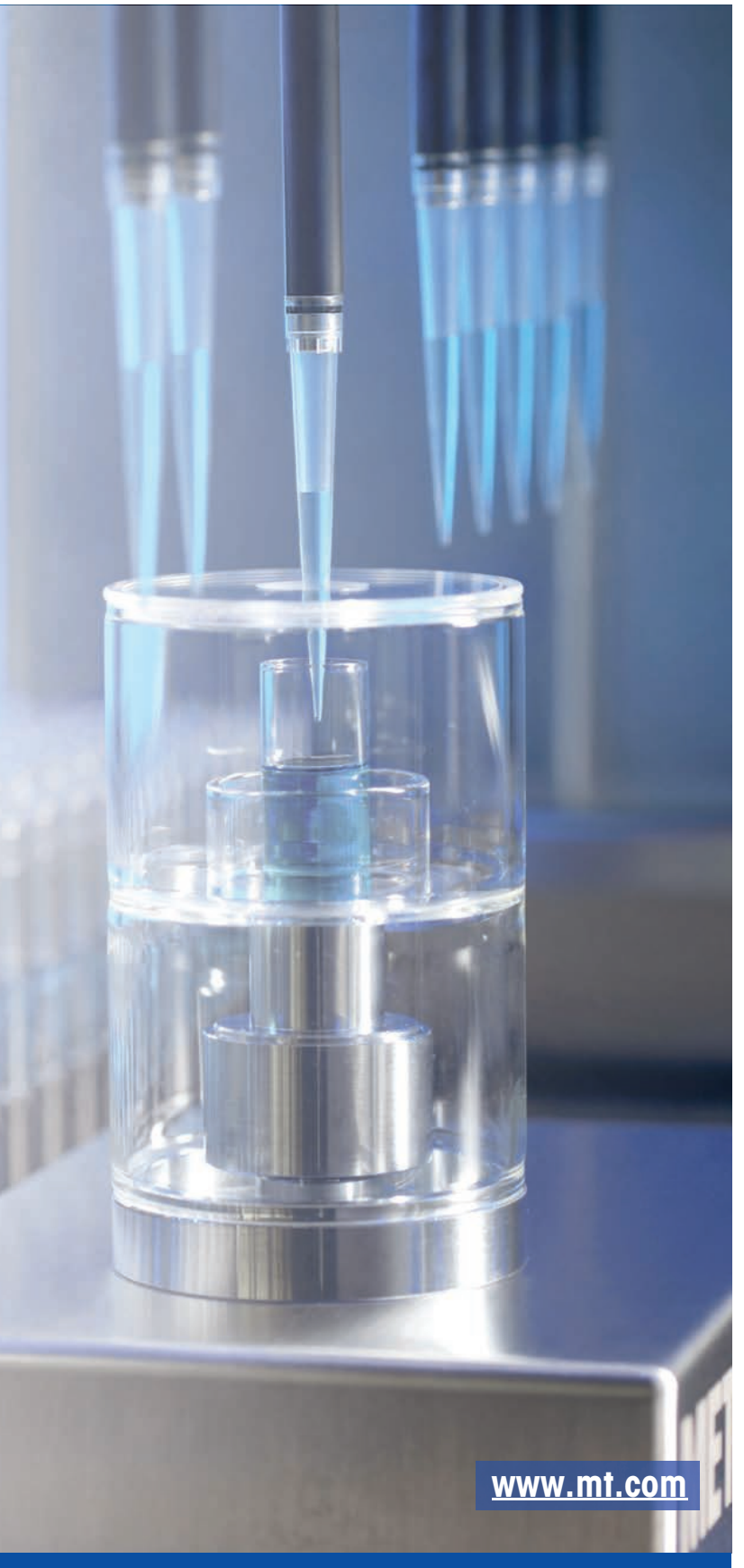
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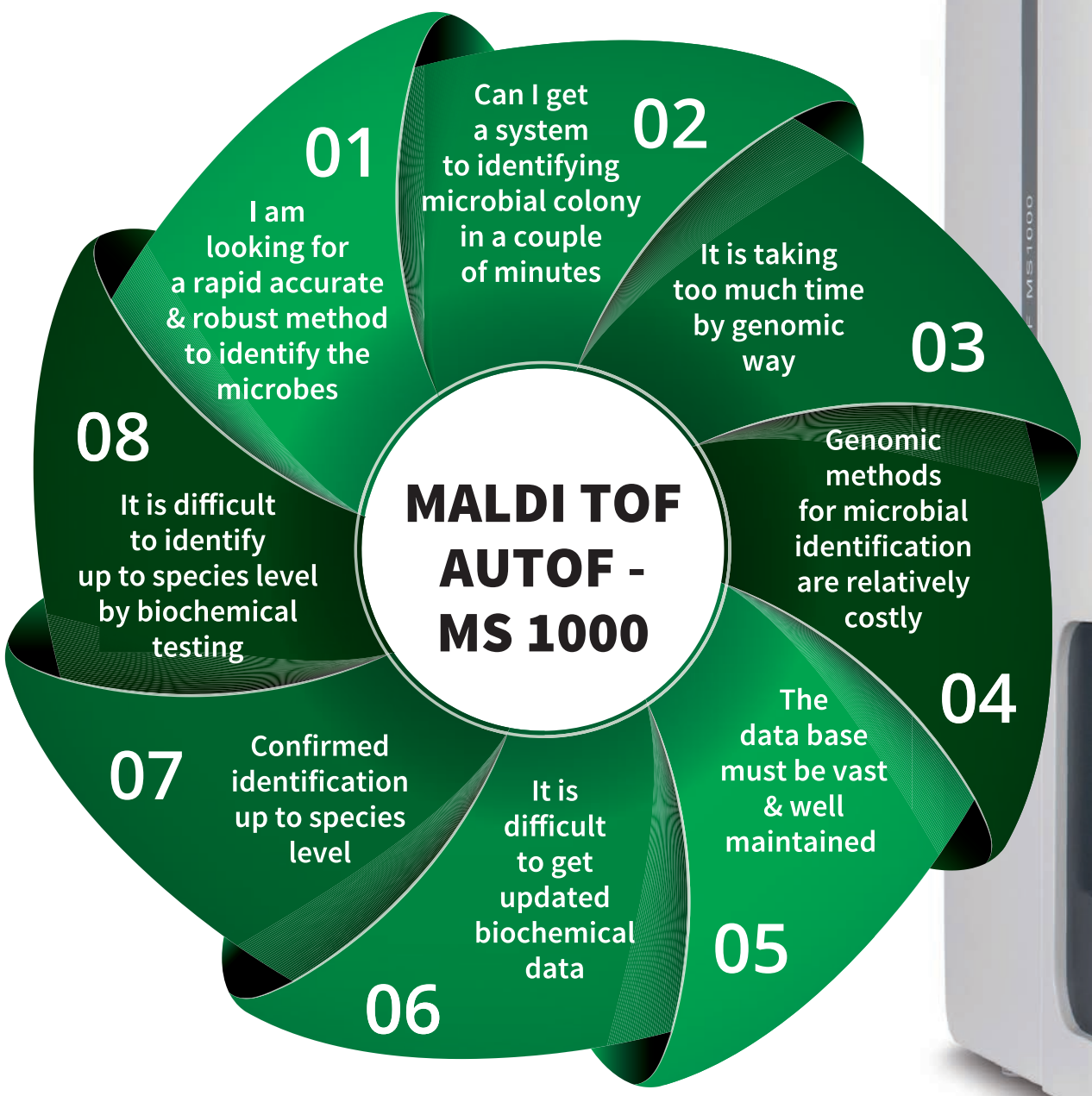
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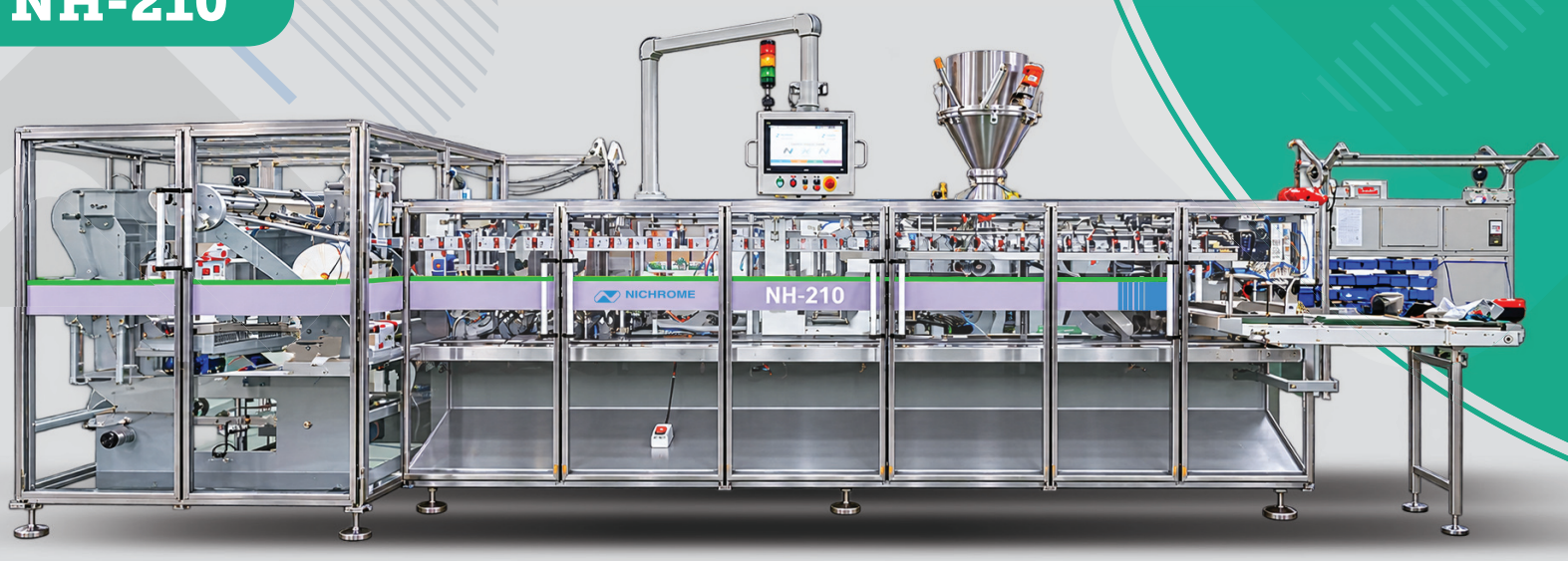
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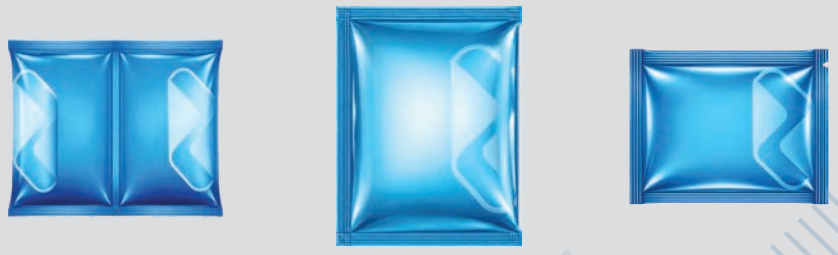
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32 years and counting ...

Every year, as December comes along, I find myself revisiting the days in the run up to the launch of India's first pharma focused weekly newsletter, *Pharma Pulse,* in December 1994. I was the youngest on the team, and watched as our pharma bylines from *Financial Express* flowed into the dummy issues of *Pharma Pulse*. We genuinely believed our sector needed a voice of its own, to advocate for a sector which was struggling to make its mark.

I took a break due to family commitments but rejoined in 2007, this time as Editor. The magazine had been rebranded in 2005 as a fortnightly *Express Pharma*, and the focus had shifted from news to longer reads, analysis and opinions. We had to cease printing during the COVID pandemic but like all media outlets, doubled down on online updates through our websites and digital newsletters. We restarted the print edition post COVID, this time as a monthly. *Express Pharma* @32 spans print, online and conferences. March 2027 will mark the next milestone: the ***Express Pharma World Expo.***

As *Express Pharma* marks its 32nd anniversary this December, it's been a privilege to continue this mission, thanks to the organisational support of *The Indian Express Ltd,* management support, and of course, invaluable team members who demystify complex pharma technology trends and extract insights from business trends. India's pharma sector is today a global force to reckon with, making affordable medicines for citizens well beyond its borders.

As we continue to track the sector, we look forward to working even more closely with industry leaders in 2027, highlighting persistent pain points, tracking new challenges, and looking for new technologies and solutions to enable the next wave of innovation and growth.

That's the theme for our 32nd anniversary edition: how can we help Indian Pharma Inc scale new heights and what's the strategic vision for global leadership? This edition curates industry voices in various formats: thought leadership articles, interviews, round tables on automation, cold chain logistics, and more.

As it is also the CPhI/PMec India 2026 special edition, the issue offers a peek of what will be at this year's event: for instance, smarter technologies, going beyond mere manufacturing muscle, with an emphasis on quality standards and compliance.

Pharma leaders will have to cope with increasing regulatory pressure. On the pricing front, the trade margin rationalisation on 137 non-scheduled anti-cancer medicines needs to be closely tracked as it might alter the economics and possibly access, defeating the intent.

The government continues to focus on improving manufacturing quality through various proposed amendments but more guidelines do not necessarily translate into better implementation. Industry suggestions and clarifications submitted within the 30-day period will also need to be considered, and if found appropriate, incorporated in the final amendments.

For instance, MoHFW's recently proposed amendments to the Drugs Rules, 1945 include the mandate that drug manufacturers have to formally authorise a person with 'appropriate qualifications and experience' for batch release of drugs and maintain prescribed records for every batch manufactured.



Express Pharma @32 spans print, online, conferences and from March 2027, the next milestone: the Express Pharma World Expo. As we continue to track the sector, we look forward to working even more closely with industry leaders in 2027

While the proposed amendments aim to strengthen accountability in the drug manufacturing process by introducing an explicit regulatory requirement for the authorisation of personnel responsible for batch release, comments from experts like Rama Venugopal on *LinkedIn* point out that terms like 'appropriate qualifications and experience' leave scope for vague interpretations, as what is deemed appropriate to the manufacturers might not be appropriate for users/consumers.

In the same vein, Sathish Babu Munaga, Sr GM-Quality, Naprod Life Sciences suggests that besides defining the minimum qualifications and experience required for the authorised batch-release person, the amendment should clarify the scope of responsibility. As he points out, clarity is required on whether the Batch Release Certificate (BRC) constitutes final QA batch disposition or merely documents GMP compliance, ensuring alignment with existing Schedule M requirements and avoiding duplication of release responsibilities.

Similarly, take another MoHFW draft notification seeking public comments on the proposal to immediately suspend manufacturing licences of drugs declared Not of Standard Quality (NSQ) on specified critical quality parameters, till satisfactory Corrective and Preventive Action (CAPA) is submitted. Importantly, the proposed amendment does away with the current process of issuing a show-cause notice before the suspension or cancellation of a manufacturing licence. As a PIB notice pointed out, this process sometimes resulted in a time gap between the NSQ declaration and initiation of regulatory action, allowing an NSQ drug to remain in circulation, posing potential risks to public health and making effective recall more challenging.

Again, the intent is exemplary: to ensure uniform implementation of the Act across the country and ensure root cause analysis and effective CAPA before continued marketing of the drug, especially in the case of medical products which are repeatedly not meeting the quality standards. But, experts point out that the draft does not differentiate between minor quality deviations and serious contamination issues. A manufacturer might consider suspended particles a minor failure, but a regulator will differ.

As we close 2026 and look ahead, we hope 2027 will strengthen our current position, bring more opportunities, and above all, give us the confidence to take bolder bets.

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The platform for India Pharma Inc's next leap

Scheduled as a three-day event **(March 3-5, 2027)**, the expo is not just a traditional trade show, but a media-powered business platform built to facilitate high-value conversations, enable partnerships and accelerate decision-making across the pharma ecosystem

India's pharma industry is at a turning point. Long defined by its scale and cost advantage, the sector is now being reshaped by more complex forces like biologics, stricter regulatory expectations, shifting global supply chains, and the growing importance of innovation-led growth. The next phase will demand not just capacity, but capability.

Recognising this shift, Express Pharma is launching Express Pharma World Expo, a new industry platform designed to bring together the people, ideas and technologies that will define the future of Indian pharma.

Scheduled as a three-day event (March 3-5, 2027, the expo is not just a traditional trade show, but a media-powered business platform built to facilitate high-value conversations, enable partnerships and accelerate decision-making across the pharma ecosystem.



Why this platform, why now

As regulatory scrutiny tightens and global competition
intensifies, Indian pharma companies are being pushed to rethink manufacturing quality, compliance readiness, and innovation strategies. At the same time, emerging areas such as biosimilars, specialty pharma and digital transformation are opening new opportunities.

What has been missing is a credible, neutral platform that can bring all stakeholders together, not just to showcase solutions, but to address the sector's most pressing challenges in a structured, outcome-driven manner.

This is what *Express Pharma* aims to build. A space where industry dialogue translates into business action.

Who will attend

The expo is expected to attract over 10,000 professionals from across India's major pharma hubs, including Mumbai, Hyderabad, Ahmedabad, Pune, Bengaluru, Chennai, and Baddi.

Attendees will include:

- CXOs and business leaders from pharma and biopharma companies
- R&D, manufacturing, plant, and operations heads
- Quality, regulatory, and compliance leaders
- Engineering, technical services, and project heads
- Packaging, validation, and cleanroom specialists
- EHS and sustainability leaders
- Supply chain and procurement strategists
- CDMO and contract manufacturing leaders
- Digital and technology transformation heads

Alongside them will be regulators, policymakers, investors, and solution providers, enabling a cross-functional, decision-making ecosystem under one roof.

The expo floor

The exhibition floor is designed to reflect the full pharma value chain, with participation from:

- API, excipients and KSM manufacturers
- Processing and manufacturing equipment providers
- Packaging solution companies
- Quality, validation, and analytical technology firms
- Engineering, project, and infrastructure specialists
- Cleanroom and controlled environment providers
- Utilities, water, and waste management solution c ompanies
- EHS and sustainability solution providers
- Digital, automation, and Pharma 4.0 technology companies
- Supply chain and contract service organisations

This breadth ensures that the expo is not limited to one segment, but captures the interconnected nature of modern pharma manufacturing and operations.

Turning presence into progress

The focus here is on structured engagement, ensuring that interactions are relevant and outcome-oriented.

Attendees can expect to:

- Gain insights into regulatory trends, global market access, and emerging technologies
- Discover cutting-edge solutions across manufacturing, packaging, and digital transformation
- Engage directly with decision-makers and industry leaders
- Identify new partnerships and business opportunities
- Benchmark their operations against industry best practices
- Stay ahead of shifts shaping the future of pharma

Conversations that matter

At the heart of the event is a leadership conference curated to address the most critical issues facing the industry.

Key themes include:

- Regulatory intelligence and global compliance readiness
- Strategies for global market access
- Innovation in biosimilars, specialty pharma, and advanced therapies
- Manufacturing excellence and scale-up capabilities
- Pharma 4.0, AI, and digital transformation
- Supply chain resilience and risk management
- Investment, partnerships, and growth opportunities
- The future positioning of Indian pharma on the global stage

These discussions signal a broader shift, from volume-driven growth to quality, innovation and reliability as differentiators.

Beyond an event: Building an ecosystem

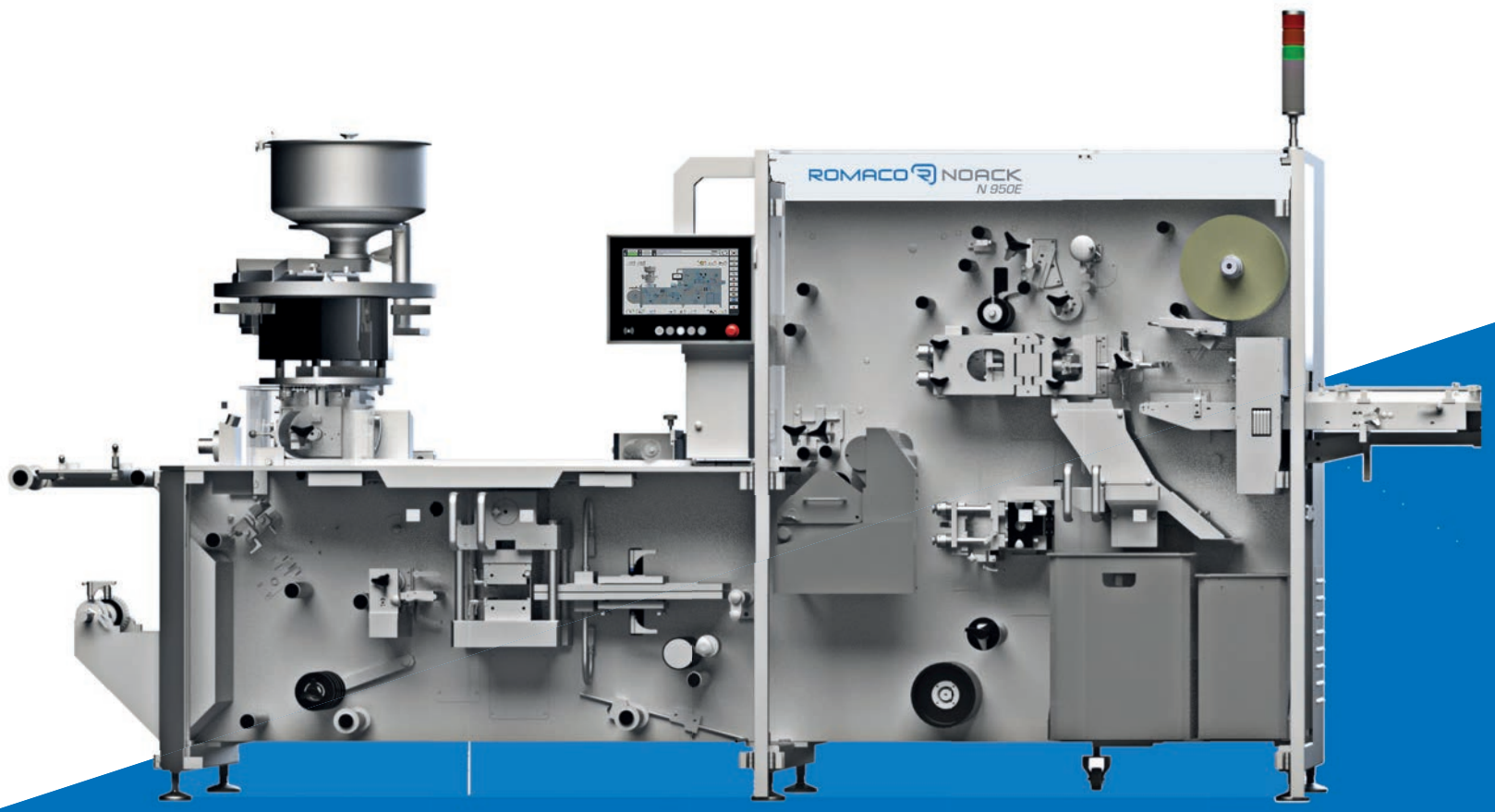
Backed by Express Pharma's editorial, digital, and events ecosystem, the platform is designed to enable year-round engagement, extending conversations, insights, and business connections well beyond the event itself.

The launch of this platform is tied to a larger industry question: how can India move from being the 'pharmacy of the world' to becoming a global hub for innovation, quality, and advanced manufacturing?

By convening the right stakeholders and focusing on actionable outcomes, Express Pharma World Expo seeks to play a catalytic role in that transition.

In an industry where the next leap will be defined by collaboration as much as competition, the value of such a platform lies not just in who attends, but in what emerges from the conversations it enables.

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INTERVIEW

Uttar Pradesh steps up its pharma investment push

With nearly Rs 10,000 crore in investment intent and major pharmaceutical infrastructure projects underway, Uttar Pradesh is looking to strengthen its position as a pharma manufacturing destination. **Kritika Sharma,** MD and CEO, Uttar Pradesh Promote Pharma Council (UPPPC); Special Secretary, Medical Education Department, Govt of UP, shares the state's plans to attract investors, expand manufacturing capabilities and build a stronger pharmaceutical ecosystem, in an interaction with **Viveka Roychowdhury**

What is the current status of the pharma sector in Uttar Pradesh?
Uttar Pradesh is among the largest pharma markets in the country, with a share of nearly 17 per cent of national pharma sales by value. The State's manufacturing base is predominantly formulation-led. It has approximately 400 formulation units and 41 bulk drug units. These are spread across established pharma clusters in Gautam Buddh Nagar (136 units), Ghaziabad (70), Lucknow (55), Meerut (45), Kanpur Nagar (41) and Moradabad (37).

The key strategic priority now is to reduce dependence on imported Active Pharmaceutical Ingredients and Key Starting Materials by building domestic bulk drug capacity. Industry confidence in this direction is clearly visible. At Pharma Conclave 1.0, held in Lucknow in February 2026 and inaugurated by the Hon'ble Chief Minister, investment intent of nearly Rs 10,000 crore was announced and 11 MoUs in pharmaceuticals and medical devices were exchanged.



> The key strategic priority now is to reduce dependence on imported Active Pharmaceutical Ingredients and Key Starting Materials by building domestic bulk drug capacity. Industry confidence in this direction is clearly visible

What is the strategy, schemes and funding for attracting pharma investment?
The State's strategy rests on three pillars: a competitive incentive framework, ready-to-use pharma land, and a strong research and talent base. Invest UP acts as the State's nodal investment promotion and single-window facilitation agency. UPPPC functions as the dedicated sectoral body for pharma, biotech and medtech, undertaking targeted investor outreach, project hand-holding and institutional partnerships.

The principal instrument is the Uttar Pradesh Pharmaceutical & Medical Device Industry Policy, 2023. The policy covers MSME units as defined by the Government of India and large units with investment up to
Rs 100 crore. Its main incentives are:

- **Capital subsidy:** 15 per cent of eligible investment up to
Rs 200 crore, disbursed in five annual instalments.
- **Special package for parks:** units in Bulk Drug Parks and Medical Device Parks receive a ten-year interest subsidy.
- **Green incentive:** this is particularly relevant to API manufacturers. It provides a 50 per cent capital subsidy on the cost of Effluent Treatment Plants, capped at Rs 2.5 crore.
- **Other benefits:** stamp duty and electricity duty exemptions, and incentives for private pharma parks.
- **Larger projects:** investments above Rs 100 crore by FDI, Fortune Global 500 and Fortune India 500 companies may also avail benefits under the State's FDI and Fortune 500 Investment Promotion Policy, 2023.

On funding, the Lalitpur Pharma Park is being developed by the State through UPSIDA from its own resources, so its centre: state funding ratio is 0:100. The Medical Device Park at YEIDA is the State's centrally assisted park. Under the Department of Pharmaceuticals' scheme "Promotion of Medical Device Parks," final approval for financial assistance of Rs 100 crore was granted to Uttar Pradesh for common infrastructure facilities. Land and other physical infrastructure are borne by the State through YEIDA. A 250-acre Pharma Formulation Park is also planned in Sector-7 near Noida International Airport to provide export-oriented formulation capacity.

What is the progress at the Lalitpur Bulk Drug and Formulation Park, and which companies have signed up?
The Lalitpur Pharma Park

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extends over 1,472.33 acres. Phase I covers 352.91 acres and Phase II covers 1,119.42 acres. An Expression of Interest has been floated for Phase II, and the State is backed by an overall pharma land bank of nearly 8,000 acres. On the Hon'ble Chief Minister's direction, red- and orange-category bulk drug units are being encouraged to locate at Lalitpur.

Phase I infrastructure is at an advanced stage. Roads (3.3 km) are 85 per cent complete. Power, street lighting and ICT are 80 per cent complete, and storm drainage is 78 per cent. The sewerage network and the Fire Fighting and Emergency Response Centre are each 63 per cent complete, and the Administrative Building is 55 per cent complete. Most components are targeted for completion by October 2026. Several works are already complete: the entrance gate, the potable (4 km), purified (3 km) and reuse (8.5 km) water networks, the 1.97 km boundary wall and the truck parking.

To support export logistics, an MoU was signed with the Jawaharlal Nehru Port Authority in March 2026 to facilitate EXIM trade and port-linked industrial development. A proposal for improved national highway connectivity has also been sent to PWD for inclusion in the FY 2026–27 work plan.

Industrial plots are offered at Rs 1,990 per sq m, equal to Rs 80.53 lakh per acre. Anchor units receive a 10 per cent discount, at Rs 1,791 per sq m, and a further 2 per cent rebate applies on one-time full payment. Of the 28 plots covering 216.55 acres, 23 plots (75.60 acres) are earmarked for formulation and 140.95 acres for bulk drugs.

Five formulation plots totalling 6.65 acres have been allotted to:

- I.J. Pharmaceuticals Pvt. Ltd. (1.05 acres)
- JBJM Parenterals Pvt. Ltd. (1.04 acres)
- Atul Kumar Gupta (1.55 acres)
- Ripe Lifesciences Pvt. Ltd. (two plots of 1.54 and 1.47 acres)

The bulk drug segment remains open for anchor API investors.

> UPPPC has signed strategic MoUs with BIRAC, NIPER, IIT BHU, the Indian Pharmacopoeia Commission (IPC), Medical Excellence JAPAN (MEJ) and PI-RAHI to strengthen the State's pharma, biotech and MedTech ecosystem. These partnerships cover research and innovation, startup incubation and entrepreneurship, and academia–industry collaboration

What is the status of the Biotech Park in Lucknow and the MedTech Park in YEIDA Sector-28?

The Medical Device Park in Sector-28 of YEIDA is being developed over 350 acres. YEIDA is the State Implementing Agency nominated by the Department of Pharmaceuticals. In-principle approval was received on 24 September 2021, and the Detailed Project Report was approved by the Government of India on 4 January 2022. About 195 acres, or 55 per cent of the area, are earmarked for allotment to manufacturing units. The park is equipped with advanced testing laboratories and an ASCA certification facility to reduce dependence on overseas testing. These will also benefit pharma packaging and drug–device combination manufacturers.

The Biotech Park, Lucknow serves as the State's incubation and research platform for biologics and biosimilar enterprises. It is also the base of UPPPC, which links start-ups and researchers directly with investment facilitation.

What collaborations has UPPPC signed with academia and knowledge institutions?

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On 14 July 2026, UPPPC signed an MoU with the Indian Pharmacopoeia Commission to advance quality standards and strengthen the regulatory framework. Under it, the two bodies will promote research, innovation and industry–academia collaboration, and organise joint training programmes and workshops. These are essential for building GMP and export-grade compliance among pharma units.

The State's research anchors include CSIR-Central Drug Research Institute, NIPER Raebareli, the National Institute of Biologicals and the Indian Society for Clinical Research. Their leadership advised the State on strengthening scientific capability at Pharma Conclave 1.0. NIPER Raebareli has itself entered into MoUs and technology transfer agreements with pharmaceutical companies, which give the State's industry a direct route to institutional research.

Does UP have the pharma talent to support these expansions, and how will UPPPC ensure it?

Uttar Pradesh has one of the largest pharmacy education pools in the country. Dr. A.P.J. Abdul Kalam Technical University alone has 100 colleges offering B.Pharm and 64 offering M.Pharm, alongside premier research institutes such as CSIR-CDRI, Lucknow. NIPER Raebareli, an institute of national importance, has CSIR-CDRI as its mentor institute and adds postgraduate and doctoral specialists in pharmaceutical sciences.

To ensure that trained manpower is available when units commission, UPPPC is pursuing a four-pronged approach:

1. Policy-backed skilling: the 2023 Policy supports training programmes aligned with pharma and medical device requirements and industry-driven skill development initiatives.

2. In-park training infrastructure: the Administrative Building at Lalitpur includes a dedicated Skill Development and Training Centre and a Safety Audit Centre.

3. Regulatory and quality upskilling: this will be delivered through the IPC partnership, covering pharmacopoeia standards, pharmacovigilance and quality assurance.

4. Demand-led curriculum: UPPPC will work with AKTU, NIPER Raebareli and ITIs to map allottee companies' requirements in API chemistry, sterile manufacturing and quality control, so that industry-ready cohorts are available as production begins.

Alongside manpower development, UPPPC is strengthening the State's clinical and academic research capacity. Under the UP-SHRUTI mission, it has developed the Uttar Pradesh Integrated Medical Research Application System (UP-IMRAS), a single-window digital application designed to ensure transparent, streamlined and time-bound clinical research approvals across more than 80 institutions. UPPPC has also introduced 22 uniform Ethics Committee Standard Operating Procedures (SOPs) and is strengthening research infrastructure, including Medical Research Units (MRUs) and Clinical Trial Units (CTUs), in medical colleges. These initiatives, supported by structured training aligned with global clinical research standards, aim to build a robust, ethical and quality-driven research ecosystem that supports clinical research, medical device innovation, technology validation and the growing biotechnology, MedTech and pharmaceutical industries in Uttar Pradesh.

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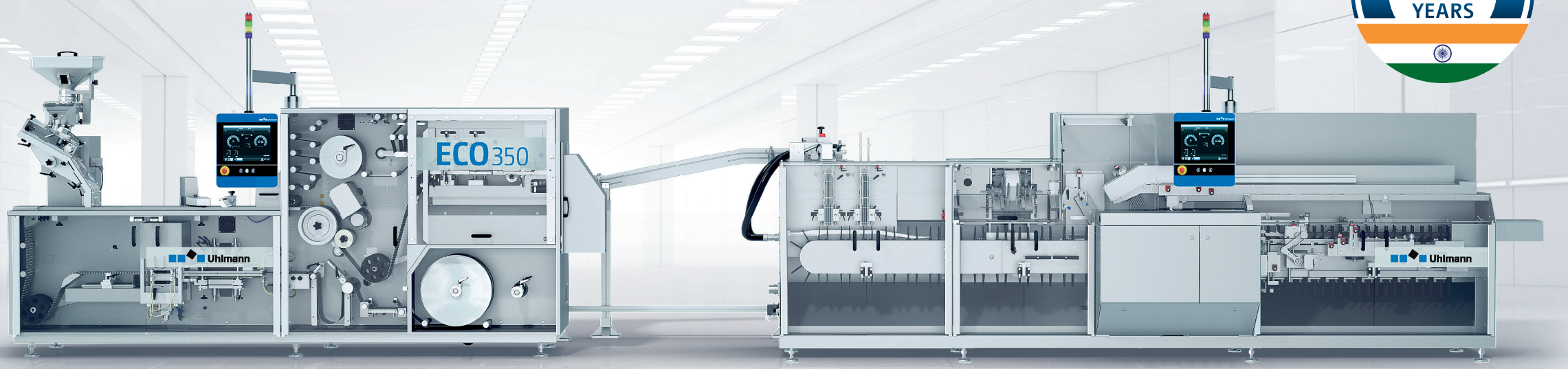
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INTERVIEW

The transition from volume to value creation is required

Dr Praveen Khullar, Executive Director, VerGo Pharma Research Laboratories, discusses Goa's CDMO landscape, export market opportunities, complex manufacturing and the need for technology transfers to strengthen the state's pharma industry, in an exclusive interview with **Neha Aathavale**

You have moved from a large MNC environment such as Sanofi to leading VerGo, an Indian CDMO. How has this transition influenced the way you approach pricing and business strategy?

Working in a CDMO in Goa is a very different kind of a ball game. The reason is that here, you have to not only look into the implementation of corporate decisions, but also actually make the decisions. The role shifts from being an implementer to creating new knowledge, new ideas, new business and new geographies. There is a greater focus on business development and strategy. In a multidimensional approach, strategies are made at the global level and then cascaded down to the region, country and site. However, in our Indian CDMO, we have to actually build the strategies. It is not a top-down approach. Decision-making takes place at the site level, so it is easier to implement an idea quickly. You need not go to so many committees or seek approvals from different stakeholders. A small group can discuss an idea, and if they find that there is a significant technical, financial and strategic advantage, they can implement it in a very short time. So, this is an advantage in terms of decision-making time. If you take responsibility, you also have accountability. So, I think working in a CDMO is a more engaging kind of a job because you are the creator, the implementer and, ultimately, the stakeholder and client-holder for the decision. This makes it a 360-degree engagement and gives you the freedom to apply new ideas and explore new business opportunities, which I feel is a much more fulfilling professional experience.



> We are not focused on volume; we are focused on the value chain, particularly that of the most highly regulated markets

In my own organisation, we are a 100 per cent export-oriented CDMO. So, our strategies focus on regulated markets, primarily the UK, Europe, Canada, Australia and New Zealand. Almost every product we develop, manufacture and supply is intended for the global market. So, we are not an India-focused CDMO. We are not focused on volume; we are focused on the value chain, particularly that of the most highly regulated markets. This involves meeting high standards of PMT, manufacturing products that meet quality standards and global compliance requirements, and supplying them for testing across global markets. So, that is our focus and our business model.

Your long association with GPMA has given you a wider view of Goa's pharma industry. Has this industry-level perspective changed any of the decisions you make at VerGo?

I think the pharma industry is a very dynamic industry. It is driven by global regulatory compliance because, as an export-oriented industry, we are not driven only by Indian laws. We are driven by the global landscape of regulatory compliance and new initiatives. We like to keep ourselves abreast of new developments across the world, including new guidelines, new expectations, new quality norms, new equipment, new packaging norms and safety norms, and understand how these need to be incorporated and implemented.

So, GPMA helps foster connections between the global regulatory landscape and Indian laws, while supporting stakeholders, including the government, administration and pharma industry stakeholders, in coming together to brainstorm and identify the compliance requirements that need to be implemented. Training is also done, and GPMA acts as a bridge between the global regulatory landscape and pharma industry stakeholders.

So, for us, the objective is to spread knowledge, understand expectations, meet those expectations and help each other through our learnings, so that one learning or one company's experience can also help other companies.

I think, as a small state, we have a very close network of pharma industry stakeholders, the government and the FDA. It helps us ensure that there are no gaps in understanding or in awareness of new initiatives. We connect with other companies, which also use the GPMA platform to spread knowledge beyond Goa. We invite industry participants and encourage

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brainstorming not only at the local level, but also at the national and international levels.

Through GPMA, we discuss the current industry landscape, including technology, automation and data management.

When we hold GPMA sessions, seminars and conferences, we invite various stakeholders, innovator companies and startups. These interactions help us understand new ways of learning and operating, as well as how to manage cost and quality. This collaboration through GPMA provides new indicators and ideas, which I also use to assess their applicability and see how they can be applied elsewhere. I think many of these initiatives and learnings have given us a good starting point for implementing changes to update our quality, operational efficiency and understanding, while strengthening the knowledge of team members, which helps us achieve the best outcome.

Goa's pharma industry has a strong export orientation and significant exposure to international markets. Which international markets do you think Goa's pharma companies should explore further, and why?

Indian pharma industries are primarily focused on the US because, in recent years, Indian pharma companies have supplied 40 per cent of the pharma industry's products there. There have been disruptions over the last few years. I think the US market still accounts for the largest share in terms of value. The next market is Europe, followed by developing countries, including those in the Asia-Pacific region.

I think focusing on Europe is one of the areas to consider. We need to look at the top five companies or countries in Europe and explore how we can collaborate with them. This is a new destination. I would also say that Canada is a very good market, and Australia is a good market.

Japan has the highest level of regulation, making it very difficult to enter that market.

By increasing your capability, skills, automation and level of scientific expertise, you can break these barriers through collaboration and achieve compliance to supply and export to Japan, which is among the markets with the highest value and quality standards in the world. However, you have to ensure that you have the necessary capabilities, resources, infrastructure and people who understand all the rules and regulations.

So, to answer your question, I think Europe is a major destination. Exploring Japan or a market such as New Zealand could also add value. The US is experiencing some stagnation in terms of value, and there are other issues in that market. Europe is comparatively easier to enter.

Australia, New Zealand and some Asian countries are good destinations to explore because India has a cost advantage, an understanding of quality requirements and the ability to compete effectively.

International cooperation treaties can help facilitate decision-making and make cooperation between countries easier. This EU-India FTA will help people and trade move forward, followed by commercialisation. Less effort will be required, while greater exposure and deeper market penetration will become possible. So, the government is not restricting these requirements; it is facilitating exports.

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Goa has traditionally been known for its manufacturing and export base. With the growing role of CDMOs, do you see an opportunity for the state to move further up the value chain into development, technology transfer and more complex manufacturing?

The pharma industry should focus on technologies that are not easy to replicate. Simply copying generic products using basic technologies is not the best approach. There is a time when you find that moving into generic-plus products, lower-WD systems and platform technologies gives you added value, differentiation and an edge over the competition.

Technology transfer is important for products that involve process difficulties, environmental considerations, manufacturing challenges, time constraints and the quality control required.

If you can find a product that only a limited number of CDMOs can manufacture, that can be the most important part because it provides added value. You also become a selected or preferred partner. If you have to make commodity items such as tablets, capsules and powders, there may be thousands of companies that can do it.

But if you can make something that is more difficult to manufacture, such as an insulin pen or certain medical devices, the competition will be limited because there are few players. If you have the expertise to manufacture these products, the potential is significant. I think the transition from commercialisation and volume to value creation is required. So, the focus should be on technology adaptation, the technology transfers that are required, and identifying new types of automation, machines and equipment, as well as cost-effective, environmentally friendly and safe processes.

I think these are very important areas. So, I would say that technology transfers and complex products should be a focus for me.

Having seen Goa's pharma industry evolve over several decades, what is one immediate capability you think the state needs to build now to stay competitive in global markets?

The pharma industry is growing. So, I think the most important issue is how to expand the pharmaceutical industry. This includes providing additional manufacturing sites and the required infrastructure, such as road networks, rail networks, water systems and single-window clearances for new investment. I think this is very important.

Expanding operations and developing the necessary infrastructure and facilities in Goa are also important. If you can speed up these processes, expansion will become easier. More facilities should be provided to support expansion within existing manufacturing sites.

If you can allow a higher floor area ratio (FAR) to enable more construction on the plot, that will help. The government should consider these requirements. In pharma, you have to get around 30-40 different licences.

If single-window clearance and online clearance systems can be implemented, the speed of clearances can support more growth and help increase value and market penetration. So, if Goa's manufacturing sites have to grow, the government needs to provide industry-friendly single-window clearances and the necessary infrastructure.

Roads, transportation, electricity and high-quality water are the lifelines for industrial operations. And I am sure that the Goa government is already doing a lot of things in this regard.

We have the distinct advantage of being on the west coast. So, shipping, air travel, airport access, train connectivity and road connectivity are quite good. Goa is very well connected and has the potential to become a hub for exports to markets across the world.

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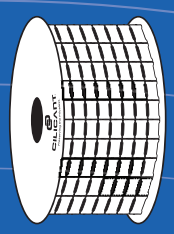


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INTERVIEW

Cilicant: Protecting drug stability through active packaging built on science, precision and scale

As pharmaceutical formulations become more complex, active packaging is taking on a greater role in protecting drug stability and enhancing product shelf life. As a key player in this space, Cilicant is navigating this shift while looking to strengthen its global position. **Manish Jain,** Founder and MD, Cilicant, shares his perspective on industry trends, India's opportunities, innovation priorities and the company's growth ambitions, in an interaction with **Express Pharma**

How do you look at the growth of the active packaging industry, and what key trends are driving its growth and shaping future opportunities?

The biggest change is not in volume; it is in how the industry sees active packaging. For years, a desiccant was a small line item, bought on price and added at the end of the packaging line. Today, pharma companies understand that the canister or sachet inside the bottle is part of the product's stability. If it underperforms, the drug can fail its shelf life; no matter how good the formulation is.

Three trends are driving this shift. First, formulations are more sensitive: more oxygen-sensitive molecules, more combination products, more nutraceuticals and diagnostics that degrade in ways a simple desiccant cannot handle. Second, global supply chains are longer and cross several climatic zones, so the internal pack environment must hold for months under conditions nobody fully controls. Third, regulators and customers expect documented, consistent performance from every component that touches the product.

The opportunity is therefore shifting from selling material to solving stability problems; and that favours manufacturers who invest in science, compliance and work closely with formulators. That is precisely the space Cilicant has chosen to compete in.

What emerging technologies will have the biggest impact on active pharmaceutical packaging over the next five years?

I see four areas shaping the future of active packaging.

The first is precision humidity control; regulators that maintain a target humidity range rather than absorbing everything, which is critical for gelatin capsules, probiotics and many modern formulations.

The second is multi-functional sorbents that handle moisture, oxygen and odour together, so a single insert can replace two or three; thereby reducing complexity in the packaging line.

The third is traceability built into the component itself. Last year, we began manufacturing laser-marked desiccant canisters in India, making India one of the few countries with this capability. Information is engraved directly onto the canister with no inks, labels or adhesives; so it is permanent, machine-readable and free of a contamination source.

The fourth is automation and data; high-speed dispensing, in-line verification and better monitoring of the pack environment will reduce human error, which remains a common cause of market complaints.

Together, these technologies make active packaging more predictable; and predictability is what pharma companies are really buying.

How are evolving global regulations and quality standards influencing packaging manufacturers serving international pharma markets?

Compliance today is about more than just certificates. Customers audit change control, raw material traceability, batch-to-batch consistency and how quickly a manufacturer responds to a deviation. Global customers also expect the same documentation and the same response whether they buy from India, Europe or the US.

In India, the gap is that active packaging still lacks a comprehensive regulatory framework; Japan, the US and China have clearer rules. Through the Active Packaging Association of India, we are advocating for standards that keep substandard and unsafe materials out of the market. Clear rules protect patients, and they place more trust in manufacturers who have already invested in doing things properly.

How can the active packaging industry balance product protection, regulatory compliance and environmental sustainability?

Protection comes first; a sustainable pack that lets a medicine degrade is not sustainable at all. On the other hand, active packaging solutions used with the intent of extending shelf life is itself a sustainability contribution, because every batch that does not degrade is material, energy and money not wasted.

Beyond that, the work is in design. We favour mono-material and separable formats so the active component does not contaminate recycling streams. Kraft paper sachets with natural clay desiccants are a good example for non-pharma uses. Laser marking removes inks, labels and adhesives from the canister altogether. And we avoid unnecessary mixing of materials so the pack is easier to recover.

Compliance sets the boundaries. In pharma, every material change has to be validated, so sustainability improvements must be introduced with the same discipline as any other change. The companies that get this right will build sustainability into the design stage rather than adding it at the end.

What opportunities does India have to strengthen its position as a global hub for active pharmaceutical packaging?

India has significant opportunity in this space. It already supplies a significant share of the world's generic medicines, yet when we started in 2011, most pharma-grade desiccants used here were imported. That gap is closing. Indian manufacturers can now offer global-standard quality, regulatory documentation and technical support, with the cost structure and responsiveness that come from being close to the world's largest generics base.

To become a true hub, three things

matter. First, quality systems that match the best in the world, without exceptions. Second, investment in R&D and indigenous capability, so we are not only assembling imported technology; laser-marked canisters are one example of what is possible. Third, a clear national regulatory framework for active packaging, which would give global buyers additional confidence in Indian manufacturers.

Cilicant has always worked on strengthening these critical cornerstones and contributing to initiatives that help deliver the best to its customers.

Since founding Cilicant in 2011, what have been the biggest milestones in the company's journey, and what lessons have shaped your leadership?
When Cilicant was established in 2011, it was effectively a one-person company with a clear purpose: to serve the pharmaceutical industry. Desiccants were available in India, but most were not suitable for pharma, and those that were, came largely from abroad. So, the first milestone was not a sale; it was building the certifications and quality systems that allowed us to supply pharma companies properly. That took time, but it shaped everything after.

The next milestones looked at resolving our customers' problems, moving beyond moisture into oxygen absorbers. Filing our Type III DMF with the USFDA and our Master File with Health Canada. Growing to multiple cGMP facilities in India. Launching Accuflip to solve over-desiccation. And, becoming the first in India to manufacture laser-marked desiccant canisters.

One of the key lessons is that we must focus on building systems first, then scale. We grew without external funding, which forced discipline. Every expansion was backed by process, people and quality. And the second one was to listen to customers closely, because our best products came from the problems they brought to us.

How is Cilicant expanding its portfolio beyond traditional desiccants to address emerging customer needs?
Our business is solution-oriented, not product-oriented. We start with the customer's stability problem and work back to the chemistry and format.

For moisture, we offer silica gel, molecular sieve and custom blends in canisters, pouches, tablets and reels, including FREXIL compressed desiccant canisters that resist dusting. For precise humidity, Accuflip holds the pack at a defined relative humidity rather than over-drying it. For oxygen, the Oxabide range, including the compact Oxabide canister, protects oxidation-sensitive formulations. For odour and sensory quality, especially in nutraceuticals, products like FRESHCANT combine moisture control with aroma management.

Around these, we offer laser-marked canisters for traceability, desiccant dispensing equipment so the insert is placed correctly at line speed, and technical support with trials and dosage recommendations. Outside pharma, the same science serves food, agri-exports, diagnostics and electronics, including ethylene scavengers that extend the life of fresh produce such as mangoes.



> Our ambition is to be the premium active packaging partner for the world's most demanding pharmaceutical and healthcare customers. Premium, for us, means three things: performance that is proven, quality that is consistent, and support that helps customers get their products to market with confidence

What are Cilicant's key growth priorities over the next three to five years, and how will it strengthen its global presence and competitive positioning?
We already supply customers in more than 30 countries across North America, Europe, Africa and the Middle East. The next phase is about more depth.

The first priority is to be the preferred, long-term partner rather than an alternative supplier. So, our focus is on regulatory documentation, audit readiness, consistent quality and responsiveness that match or exceed what they get from other multinational suppliers.

The second priority is presence. We are investing in local technical and commercial teams. The third priority is co-development. The strongest relationships start early, when a formulation is still in development. If we help solve a stability challenge at that stage, we become part of the product's dossier and its success.

Our ambition is to be the premium active packaging partner for the world's most demanding pharmaceutical and healthcare customers. Premium, for us, means three things: performance that is proven, quality that is consistent, and support that helps customers get their products to market with confidence.

R&D is central to that. We continuously invest in sorbent science, precision humidity control, combined moisture and oxygen solutions and more sustainable formats, along with the testing and stability support customers increasingly expect from us.

Manufacturing is the other pillar. As we scale, we will add more capacity and automation, but the principle stays the same: systems before scale. Every new line must meet the same cGMP and ISO standards as our first. We will also keep expanding our presence in regulated markets and in adjacent segments like nutraceuticals and diagnostics, where the same expertise applies.

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INTERVIEW

AI in clinical trials: From detection to prevention

AI could help identify risks earlier, improve site selection and streamline clinical trial processes, but its effectiveness will depend on reliable data, regulatory clarity and human oversight. **Rob Goodwin,** Chief Operating Officer, Parexel, and **Sanjay Vyas,** President of Patient Safety Services & Clinical Logistics and Managing Director, India, Parexel, discuss with **Viveka Roychowdhury** how AI could strengthen patient safety and compliance, and what India needs to scale its use in clinical research. Edited excerpts



Rob Goodwin



Sanjay Vyas

CDSCO cancelled the registration certificates of seven clinical trial ethics committees in July 2026 for non-compliance with GCP guidelines and the New Drugs and Clinical Trials (NDCT) Rules, 2019. Can AI help red flag such issues before the regulatory audits catch them?

Sanjay Vyas: The cancellations show that regulations, audits and monitoring are working in the interest of patients. They also help weed out non-compliant players.

At the World Patient Safety Congress recently, I spoke about the limitations of pharmacovigilance that begins after an adverse event has been reported. By then, the patient has already experienced the harm. We need to move towards prevention by combining real-world data, pharmacogenomics and AI.

AI will not solve the problem on its own. It can aggregate data and present it meaningfully, allowing subject matter experts to focus on the issues that need attention.

Consider the example of carbamazepine, an epilepsy drug associated with severe adverse events in patients with a particular genetic marker. Taiwan proactively introduced genomic screening to identify people at risk before treatment began. Physicians could then consider alternative treatments for patients with the relevant marker. This helped bring adverse events associated with the drug down to zero in that context.

This illustrates how AI, genomic information and real-world data can work together to anticipate risks.

The US real-time clinical trials (RTCT) initiative follows a similar principle. Instead of waiting for data to be compiled at the end, it enables data to be reviewed as it is reported. If something appears inconsistent, the issue can be flagged for investigation. I hope India will move towards this approach as well.

Rob Goodwin: It is positive when a regulator intervenes to stop non-compliant activity. Patients entrust us with their bodies, and quality, compliance and integrity must underpin everything we do, whether at clinical trial sites, sponsor companies or CROs.

I think AI is going to help us, but it's just not AI alone. We talk about artificial intelligence. We talk about human interaction.

AI can help identify issues before they occur or detect emerging trends sooner. Today, monitors visit trial sites, review data and assess whether investigators and their teams are complying with protocols. Often, however, they identify problems after they have happened.

AI can help us recognise patterns earlier. For example, if one site reports more or fewer adverse events than others, the data could prompt questions about what is happening there and whether events are being underreported.

The value lies in integrating data with human oversight. I do not see a future in which people no longer interact with sites or regulators. AI can provide a clearer view of what is happening across the clinical research value chain, enabling people to intervene sooner.

I think that if regulators are not stepping in, then it sends a different signal to industry, that it's okay to be not compliant, to have protocol deviations, to not follow GCP.

So, you want to always be thinking that if that's me, what would I expect? And so, I think it's very positive.

Vyas: AI can process

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millions of data points, but subject matter experts must review the findings. This is why Parexel believes in keeping the human in the lead, including to identify possible errors or hallucinations.

Our real-world evidence and medical teams recently developed a white paper on cell and gene therapy. The analysis found that patients with pre-existing mental health conditions had a higher likelihood of post-treatment mental trauma following a particular cell and gene therapy.

Such insights can help sponsors identify patients who may need closer monitoring. There may not always be an alternative treatment, but knowing the potential risks allows physicians to make informed decisions about the level of care required.

The objective is to use data to make proactive decisions before harm occurs. I am optimistic that AI could eventually help inform decisions even before a dose is administered.

Goodwin: Data curation will be critical to avoid hallucinations and make the findings reliable. One exciting possibility is the use of digital twins in clinical trials.

If we can confidently simulate patient groups, we may be able to reduce the number of participants required in some trials and accelerate development. Recruitment remains one of the biggest reasons clinical trials take time.

Better-curated data could also support simulations for bridging studies and help us understand which patients are most likely to respond to a particular molecule. This could reduce trial failures and support more precise medicine.

However, this will require strong governance, privacy safeguards, ethical use of data and appropriate standard operating procedures.

What's India's current share of global clinical trials? Does industry's growth strategies match the regulatory framework, the infrastructure, the talent, etc., to deploy these new technologies like AI at scale with guardrails in place?

Goodwin: I am optimistic because clinical development is becoming a global activity rather than a predominantly Western one. Regulators around the world, including in India, are increasingly looking at how their countries can participate in global medicine development.

Regulators have an important responsibility to protect patients, and the industry must recognise the historical experiences that influence public trust in clinical research. That trust cannot be taken for granted.

At the same time, technology is changing how research can be conducted. India has moved from paper-based submissions towards electronic submissions, making information easier to access and review. Looking at the changes over the past 35 years, it is difficult to imagine how much more the industry could change over the next decade.

Regulations may increasingly converge across countries, but competitive advantage will depend on patient populations and unmet medical needs.

India is also considering how applications for first-in-human studies could be submitted to regulators and ethics committees simultaneously. Such approaches could help address delays and make the process more efficient.

Vyas: We need to be practical about India's position. Around 10 per cent of global clinical trial applications are approved in India, but this includes both interventional and observational studies. The number of interventional studies remains relatively small.

Only 3 per cent of India's population participates in clinical trials, so awareness and education remain important. In the US and Europe, clinical trial advertisements appear in the media and on television. In India, people may still perceive clinical research as experimentation rather than a structured, regulated process.

There are, however, signs of progress. The Sugam portal has helped move applications online, and regulators are exploring AI tools for submissions and data evaluation. The real-time clinical trials approach is another example of the direction in which the industry is moving.

India's regulators are looking at developments in the US and Europe, and initiatives are beginning to take shape. The challenge is to bring these elements together and translate them into practice.

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The BioShakti programme is another development to watch, particularly in terms of how it will support the proposed expansion to 1,000 clinical trial sites and the use of technology to clean and evaluate data.

The opportunity is not simply to deploy AI, but to combine it with training, data quality and governance. India is also considering AI guidelines for clinical research, while the Digital Personal Data Protection (DPDP) Act represents an important step towards stronger data protection.

India's digital health initiatives could eventually support patient tokenisation, allowing individuals to decide who can access their health data, when it can be shared and how it can be used for clinical trials or drug development.

That would put patients in the driver's seat. But the different elements still need to come together.

Goodwin: Data tokenisation is an important goal globally. Bringing together information from different sources and systems requires common standards and governance.

Patients may be concerned about how their data will be used, particularly if it falls into the wrong hands. However, many people affected by diseases such as breast cancer are willing to share their information to help others with similar conditions.

Clinical trial participation is not always intended to benefit the individual patient directly. A trial may or may not help them, but the information gathered can support better treatment decisions for others.

People are the reason clinical research progresses, not AI alone. Regulators and other stakeholders will need to respond to the growing opportunities while maintaining the safeguards that patients expect.

Mr Goodwin, you were Senior Vice President of Clinical Development and Operations at Pfizer, before you joined Parexel. Give us a sponsor perspective on the use of AI in clinical development. What are the pain points it addresses?

Goodwin: Having worked on the sponsor side, I understand what clients need. Sponsors want trials that are reliable, high-quality, ethical and compliant.

Many of the bottlenecks in clinical research have remained unchanged for decades. These include identifying the right sites and patients, as well as eliminating unnecessary manual work.

AI can help identify patient populations more effectively by analysing available records in a compliant manner. It is not necessarily recruiting patients itself, but it can help determine where suitable populations are located.

At Parexel, AI-enabled site selection has reduced the time needed to identify suitable sites by approximately 50–60 per cent.

AI can also help identify sites using a broader range of quality information rather than relying only on historical performance, which may not predict future outcomes.

Another area is document writing. Clinical study reports represent a company's work to regulators, and documents must remain faithful to the facts. AI can help produce initial drafts of protocol documents, clinical study reports, informed consent forms and other materials, reducing the time required to prepare them by up to 30–40 per cent in some cases. Human experts then review and refine the drafts.

Protocol development is another opportunity. A protocol defines the trial's parameters, including primary and secondary endpoints, inclusion and exclusion criteria, and other requirements.

AI can compare a proposed protocol with existing studies, identify differences in washout periods and eligibility criteria, and highlight changes in standard care. This can help prevent protocol deviations. More than half of protocols, particularly in oncology, may be revised before a study begins, so identifying issues early is valuable.

AI can also extract metadata from protocols and support the creation of submission data tabulations. In the longer term, standardised specifications could allow sites to collect

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data within their existing systems, instead of requiring sponsors to introduce new tools.

This could make trials easier to conduct without compromising quality or compliance. Sponsors want to be the partner of choice for sites, and a smoother process can help achieve that.

Mr Vyas, can you give us the CRO perspective?
Vyas: From a CRO perspective, AI is already delivering practical benefits. At Parexel, we have seen a 50 per cent reduction in the site selection process through AI.

We are also using AI to prepare initial drafts of clinical study reports and protocols. This helps medical writers identify potential issues earlier and make corrections before protocols are implemented. Similar applications support periodic benefit-risk evaluation reports (PBRERs) and development safety update reports (DSURs).

AI is being deployed as a series of targeted solutions rather than as a single, organisation-wide platform. The aim is to identify gaps in existing processes where technology can make a difference.

Patient selection is one such area. AI can map inclusion and exclusion criteria against information about disease burden and patient populations worldwide, helping identify feasible sites. This makes site selection more predictable than relying on historical data and manual assessments alone.

Parexel's integrated data delivery (IDD) model is another example. Traditionally, CROs have often cleaned up trial data towards the end of a study. With IDD, queries can be raised as data arrives from sites, allowing issues to be addressed earlier.

We have tested this model in at least 12 studies, and all have shown shorter timelines for the later stages of data cleaning. There may still be queries at the end, but much of the work has already been completed.
Goodwin: CROs can be agile in deploying AI because they work with a broad range of customers and see different processes and challenges.

We are moving towards a model in which tools are developed by the people who use them. Medical writers, for example, can use AI to automate and improve their daily work. These tools can then be validated through appropriate frameworks before being deployed more widely.

This approach, sometimes described as citizen development, allows practical experience to inform technology. Medical writers need to understand both their work and how to use AI effectively.

CROs can then work with sponsors to implement these tools in their environments. This creates opportunities to develop solutions more quickly and flexibly than traditional technology development models.

Looking ahead, what does India need (in terms of data, digital infrastructure and governance) to use AI effectively in clinical research? What are the policy support steps needed? What are the specific changes needed in the New Drugs and Clinical Trials (NDCT) Rules, 2019 to increase India's share of global clinical trials?
Vyas: Education remains my top priority. Patients need to understand what clinical trials are, how they are conducted and how they work.

From an AI perspective, regulators should develop clear guidelines, drawing on approaches adopted by the US FDA and the European Medicines Agency (EMA).

India has made progress with guidelines for medical devices using AI. A similar framework could be extended to investigational drugs and clinical research, clarifying acceptable uses of AI, reporting requirements and the oversight needed.

For instance, if AI is used to develop a protocol or generate an aggregate report, the US FDA requires information about how the data was generated, who reviewed it and who signed off on it. Clear guidance of this kind would help Indian organisations understand what regulators expect.

There are many AI tools available, but their usefulness depends on how they are applied to real-world situations and how their outputs are reported and reviewed. India is still approaching some of these questions on a case-by-case basis.
Goodwin: Industry can help regulators develop practical guidance. At Parexel, we were fortunate to hire Dr Tala Fakhouri, who helped create the US FDA's AI guidelines. We adapted that experience to develop our own standard operating procedures and governance framework.

She now works with other organisations to help them prepare for AI adoption. Every organisation needs policies, procedures, ethical-use guidelines and trained employees.

Indian regulators could seek industry feedback on best practices, including approaches that have not worked as intended. They could then incorporate those lessons into guidance, publish it and invite further feedback.

AI is advancing faster than many expected. Without appropriate policies and procedures, adoption could become inconsistent. Regulators need to approach AI governance with the same seriousness they have applied to issues such as privacy.
Vyas: The question is whether AI can improve the information available to human decision-makers. It should help them narrow down the options and make better decisions, not remove human oversight.

Regulators need to remain open to innovation while ensuring that governance is strong. AI has advanced in months rather than years, and the frameworks governing its use must keep pace.

As agentic AI develops, some tasks currently handled by several people may be performed by AI, with fewer people focusing on quality control and escalation. But human oversight must remain strong, and the validation of outputs will be critical.
Goodwin: There are developments we cannot yet anticipate. Technology is moving quickly, and younger generations increasingly expect it to be part of everyday life. We will have to adapt faster than we have in the past.

Does industry need to self regulate to weed out the black sheep/non-compliant sites/ECs/CROs etc? Are organisations like the Indian Society for Clinical Research (ISCR) already doing this at some level?
Goodwin: Trade organisations already help the industry work towards better practices. Through CRO associations, organisations can share experience and learn from each other without disclosing trade secrets.

Self-regulation develops when organisations understand what good practice looks like and recognise when others are not following the required procedures.

The objective is to ensure that everyone has sound governance and strong standard operating procedures. One non-compliant player can damage the reputation of the entire industry, so it is in everyone's interest to maintain high standards.

The same principle applies in India. Industry associations have a role to play in encouraging compliance and supporting better practices.
Vyas: Alongside ISCR, organisations such as ICMR have a role to play. I believe ICMR could take a broader role in oversight, rather than leaving the responsibility solely to the DCGI.

Industry associations can also explore initiatives such as certification programmes for clinical trial sites. The Association of Clinical Research Organisations (ACRO), of which Parexel is a member, has started discussing questions with ISCR along the lines of doing some certification programs for the sites if the government is not doing it? Can we initiate something on our side which qualifies that these are the good sites to work with?

This is about cooperation rather than competition. If one organisation fails to perform, the entire industry suffers.

For anyone working in clinical research, compliance and patient safety must be part of the organisation's culture. Patients need confidence that trials follow established procedures and quality standards.
Goodwin: These cannot remain slogans. Standards must be measurable and visible so that patients, regulators, scientists, study nurses and physicians can see and understand them.
Vyas: The CRO registration process introduced by CDSCO is a positive step. Parexel was the first organisation in the industry to receive the registration, and the process involved a thorough review of our documentation and audit trail.

The process is helping weed out non-compliant players. It also reinforces the need for organisations to remain audit-ready at all times.

In that sense, the registration process is helping raise standards across the industry.

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INTERVIEW

LoopBac is built for complex proteins, at any scale from micrograms to kilograms, without a bioreactor

India's pharma and diagnostics industries continue to depend on imports for several specialised proteins and biological raw materials. Loopworm wants to address this gap with a silkworm-based manufacturing platform that promises lower costs, shorter development timelines and flexible production scales. **Ankit Alok Bagaria,** Co-founder & CEO, Loopworm, outlines the opportunity and the challenges ahead, in an exclusive interaction with **Lakshmipriya Nair**

What is the biggest gap in today's protein-manufacturing market that Loopworm is trying to address?

Every recombinant protein today is made under a trilemma. You want speed to market, the precision to make a complex protein correctly, and a price the buyer can afford. No conventional system gives you all three, especially for applications other than human therapeutics:

- Bacterial systems are fast and cheap, but they can't fold complex proteins or add the post-translational modifications that diagnostic and therapeutic proteins need.
- Transient expression in eukaryotic cells delivers quality, but yields are low and every new protein is expensive to bring up.
- Stable mammalian cell lines are precise but slow to develop and capital-heavy. A sophisticated facility can run to hundreds of millions of dollars before it sells its first gram.

In this industry, capacity comes from steel. If you need more, you build another bioreactor. Those economics favour large batches of a few blockbuster molecules, and everything else gets squeezed. That includes viral antigens and virus-like particles for diagnostics, kinases and membrane proteins for drug discovery, and cytokines, growth factors and specialty enzymes. A research lab needs these in micrograms and a kit maker in kilograms but conventional manufacturing does not serve these segments well. Minimum order quantities are set by the size of the vessel, not the size of the need.



The result is concentrated, fragile supply. Indian labs routinely import research-grade proteins from a small group of overseas suppliers. Material sometimes degrades in transit, and research cycles slip by months. India makes about 60 per cent of the world's vaccines by volume, yet holds roughly two per cent of the global biotech market. That is because the value in biotech sits in innovation, not in high-volume, low-risk manufacturing.

This matters beyond the lab. The Lancet Commission on Diagnostics estimates that 47 per cent of the world's population has limited or no access to essential diagnostic tests. Cost is a large part of that, and limited local R&D, manufacturing and distribution of diagnostics is one of the reasons tests remain unaffordable in low and middle-income countries.

LoopBac is built for that gap: complex proteins, at any scale from micrograms to kilograms, without a bioreactor.

Silkworm-based protein production has been explored in scientific research before. What makes LoopBac different? Is the advantage in cost, yield, speed or range?

The Silkworm protein expression platform is proven. What we've built is an industrial process around it, and the bio-informatics capability to predict the outcome and map the process before lifting a single test tube in the lab for any potential protein candidate.

We use transient expression rather than genetically modified silkworm lines, so moving from one protein to the next doesn't mean breeding a new strain. We've engineered the end to end process around automated handling. That gives us an advantage on three fronts, and each one changes what our customers can do.

On cost, LoopBac needs roughly a tenth of the upstream capital of a conventional set-up. Our production cost comes in up to five times lower, depending on the molecule. There's no fleet of bioreactors to build and no cell-culture media to buy, and capacity grows by increasing the number of Silkworms. For buyers, that changes the economics of whole workflows.

On time to market, a new protein moves through our R&D in weeks. Compare that with stable mammalian cell lines, where classical development can take up to 8-24 months to reach a manufacturing stage. For a diagnostics company responding to a new pathogen or variant, that gap decides whether its test reaches the market while it's still needed. The gain also compounds, because every protein we make sharpens the process for the next one.

On order size, we can produce anywhere from micrograms to kilograms, a span of nine orders of magnitude, on the same process. The unit of production is a single silkworm, so scaling up means



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running more of them, not re-optimisation of the process parameters for a bigger vessel. A drug-discovery team can order exactly the milligrams it needs of a custom protein without paying for a full production run. A kit maker can validate at small scale and move to commercial volumes on the same process.

So the advantage isn't one number. It's a lower cost per functional gram of complex protein, delivered fast, at whatever scale the customer actually needs.

How does the cost compare once purification and quality testing are included? What data can you share?
Most of our advantage is upstream. We need no bioreactor capex, no cell-culture media and no single-use consumables, because the organism does the work a steel vessel and its supply chain do in a conventional plant.

Downstream, the purification chemistry is broadly the same as for any recombinant protein. We start from concentrated biomass rather than large culture volumes, though, so much of the saving carries through. Quality testing (identity, purity, endotoxin, bioactivity) costs roughly the same per batch whatever the host. It is a fixed cost that larger batches dilute.

All in, our manufacturing cost comes to between half and one-fifth of conventional routes, depending on the molecule. We share molecule-level information and performance data with partners under NDA.

Which proteins are you targeting first for pharma, and why?
We're deliberately not starting with human diagnostics and therapeutics. That path runs through years of clinical work, and it isn't where a new manufacturing platform should prove itself. Our first products will be aimed at where the gap is large and the regulatory barriers are low.

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Animal health is a natural next step. Our animal nutrition business already supplies functional ingredients that support gut health and immunity in shrimp, fish, poultry and pets, to customers in more than 10 countries. LoopBac extends that work from what animals eat to how their diseases are detected and prevented: viral antigens and virus-like particles for diagnostic kits, vaccine candidates and specialty enzymes. It uses the same silkworm and builds on our understanding of where farm economics break. From there, the platform moves up to antigens and VLPs for diagnostics, kinases and membrane proteins for pharma R&D, and in the long term to vaccine antigens and therapeutic proteins.

The need is large and pressing. The productivity of animal agriculture not only affects livelihoods and economy, but also food security. Zoonotic risk makes animal disease a public-health issue, not only a farm one. Over 60 per cent of existing human diseases and 75 per cent of emerging ones are zoonotic.

There's a feed-security angle too: an animal lost to disease late in the cycle takes every kilo of feed it has eaten with it. Pets are the same story at the premium end, where owners increasingly expect the diagnostics and preventive care they would want for themselves.

How far has the technology progressed? What still needs to be proven at pilot scale?
We've proven expression, and now we're proving manufacturing. We have expressed 4 complex proteins, with Green Fluorescent Protein as the first proof of concept. We are now at pilot scale. Though we are confident in our in-house prevalidation studies, every protein still needs to be verified in terms of quality and efficacy with 3rd party labs or potential customers to establish its commercial viability for the desired application. We're working through these one molecule at a time, and are actively seeking collaboration & partnership opportunities.

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What will it take for pharma companies to adopt the platform?
Pharma companies and diagnostics buyers have already adopted the insect cell based bio-reactor platform. Our Silkworm platform is just an advanced version of it, built using similar vectors, which already has a track record of crossing regulatory barriers. Instead of licensing such gene delivery vectors, we have built it in-house from scratch. The commercial facility with global standards and approvals, the detailed credible 3rd party validation, with the obvious commercial benefits will convince them to adopt the platform.

Our job is less about persuasion and more about removing their risk. We're also clear about where silkworm-expressed proteins fit. They can carry insect-type glycans. So we choose molecules where that doesn't matter or can be managed, rather than claiming one host suits everything.

Batch consistency at scales is something we've already built. Our nutrition business takes a variable biological raw material and delivers it to specification for customers in more than 10 countries, from a facility certified to ISO 22000, GMP+, HACCP and EU TRACES. The recombinant line builds on that discipline, raised to pharma standards.

Could Loopworm reduce Indian pharma's dependence on imported specialised proteins?
Yes, in specific places rather than across the board. The realistic opportunity is in proteins that sit inside Indian products but come from abroad: antigens and enzymes for diagnostic kits, growth factors for cell culture, and antigens for veterinary vaccines. At ADMI's AGM in August, a Department of Pharmaceuticals Joint Secretary raised concerns about 70–80 per cent import dependence on IVD products and called for localising raw materials. That is the opening.

On price, our cost structure lets us compete with imports because we don't carry bioreactor capex and opex or imported consumables or even license/royalty fees given to technology partners which normally creates a margin crunch. On reliability, being domestic changes the equation. Buyers get rupee pricing, shorter lead times, no customs delays, and supply that isn't exposed to someone else's shortage. Our capacity also grows by increasing the number of silkworms rather than commissioning new vessels, so it can follow demand closely.

Therapeutics are a longer game. Replacing imported drug substances will happen through partnerships, over years.

What is the business model for LoopBac, and when will it generate meaningful revenue?
We're taking two routes, in sequence. The first is custom manufacturing: a diagnostics company needing a viral antigen gives us the gene, and we express it in silkworms, purify it and supply the protein. That is our fastest path to revenue manufacturing molecules the market actually wants. The second is our own portfolio, built around molecules where demand repeats.

We've funded this deliberately. Animal nutrition is operationally profitable and pays for itself. So we aren't forced to monetise the science before it's ready. The bigger idea is that the silkworm is the platform, and recombinant proteins are one of the things it can make. Nutrition proved we can industrialise it. LoopBac is where that capability reaches healthcare.

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INTERVIEW

Addressing the gaps in India's generic medicines market

Rajesh Kumar, CEO, Generic Remedy in an interview with **Kalyani Sharma,** discusses the challenges of building trust in generic medicines, strengthening pharmacy networks and maintaining quality while keeping medicines affordable

India has expanded access to affordable medicines through government & private company initiatives. What are the key gaps that still need to be addressed to make generic medicines more widely accepted and accessible?
The government has played an important role in expanding access to affordable generic medicines. It has also created greater awareness around the category. The next phase will involve building upon this base. The three main aspects that require attention: acceptance, availability and awareness.

There is still a perception among some consumers that a lower-priced medicine means lower quality. This needs to change. Consumers need clearer information about generic medicines, their active ingredients and the quality standards they follow.

Availability is another gap. It should not be limited to dedicated outlets. A wider pharmacy network can improve access. Organised private pharmacies can complement initiatives. They can strengthen retail reach, inventory availability and last-mile access.

The goal should be simple. Quality medicines should be affordable, available and trusted by consumers.



Affordability has been one of the biggest advantages of generics, but concerns around quality and efficacy continue to influence prescribing and purchasing decisions. What is driving this trust gap, and how can the industry address it?
The trust gap is largely driven by perception. Consumers are familiar with pharmaceutical brands. They often associate a higher price with better quality. But price does not automatically mean better therapeutic value. Generic medicines contain the same active pharmaceutical ingredients as their corresponding branded medicines. They are intended to provide the same therapeutic effect when they meet the applicable standards.

The industry needs to communicate this more clearly. Quality also has to be visible through credible manufacturing standards and consistent products.

Doctors and pharmacists have an important role here. They can help consumers to be better informed about their choices. In the end, trust lies in experience. If the consumers continue receiving high quality medications, clear pricing and proper availability, the perspective towards generics will change.

How do you see the role of private pharmacies and organised generic pharmacy chains evolving alongside the government's network? Can the two models complement each other in improving access?
Absolutely. There is room for both models. The requirement is much larger than any single retail network. The government has played an important role in bringing affordable medicines into the public conversation. It has also expanded access through dedicated outlets. Private pharmacies and organised generic chains can build on this. They can add retail reach, local availability, technology and stronger supply-chain systems.

They can also serve consumers who value neighbourhood access or online ordering. The focus should not be on competing for the same space. It should be expanding access. Smaller pharmacies will continue to matter because of their neighbourhood presence and customer relationships. Effective networks can help with better stock and replenishment programs. Together, these approaches can help build a greater network for medicines access.

What are the biggest challenges for manufacturers and pharmacy networks in maintaining quality while keeping generic medicines affordable, particularly as input costs and regulatory requirements increase?
The biggest challenge is to maintain quality while taking into account the total cost of the logistics chain. Input costs are only one part of it. Manufacturers have to manage quality systems and regulatory compliance. Pharmacy networks have to manage storage, inventory, logistics and replenishment. None of these areas can be compromised simply to achieve a lower price.

The answer is better operating efficiency. Accurate demand planning can reduce excess inventory and stock-outs. Strong supplier management can improve consistency. Better distribution planning can also reduce avoidable costs. From a pharmacy-retail perspective, quality has to remain consistent from sourcing to the point of sale.

The Indian pharmaceutical industry is a major supplier of generics globally. What lessons from India's export-oriented generic industry can be applied to improve the domestic market's quality, pricing and distribution?
One important lesson is that scale works only when it is supported by consistency. India's global generic industry has built its position through manufacturing capability, quality systems, regulatory discipline and cost efficiency. The domestic market can apply the same discipline. Quality should remain consistent whether a medicine is being supplied internationally or sold to an Indian consumer.

There is also a lesson in supply-chain planning. Efficient procurement, inventory management and distribution can help control costs. They can also improve availability.

From my experience in pharmacy retail and distribution, the domestic market needs to focus more on what happens after manufacturing. The last-mile supply chain matters just as much when the objective is to make quality medicines affordable and consistently available.

Looking ahead, what policy or regulatory changes would have the biggest impact on strengthening India's generic medicines ecosystem and improving access to quality medicines?
Consistent regulatory standards must be maintained. Quality oversight also needs to remain strong across the market. At the same time, consumers need clearer information about generic medicines, their active ingredients and the standards they meet. The distribution side also deserves greater attention. Improved supply chain management can assist in eliminating stock outs. Improved retail infrastructure can enhance availability due to the growth of pharmacy chains.

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INTERVIEW

The industry needs to stop treating drug formulation, packaging, delivery and manufacturing separately

Vinayak S. Joshi, Country Manager – India, Stevanato Group, explains to **Neha Aathavale** why an integrated approach to drug containment, delivery systems and manufacturing is key to managing the growing complexity of injectable therapies and supporting India's pharmaceutical growth

India's pharma industry is moving towards more complex injectables, biologics and drug-device combination products, each bringing new demands on primary packaging. How is Stevanato Group adapting its solutions to these evolving requirements, and where do you see the greatest opportunities for the company in India over the next few years?

As injectable therapies become more complex, primary packaging can no longer be considered independently from the drug formulation, delivery device and manufacturing process. Biologics and other advanced therapies may involve higher concentrations, larger volumes or more demanding dosing regimens. At the same time, the shift toward self-administration is increasing the need for delivery systems that are reliable, intuitive and suitable for scalable production.

Stevanato Group is responding through an integrated approach that combines primary drug containment, analytical and testing services, drug delivery systems, and manufacturing equipment. This allows us to support customers in evaluating the complete combination product from an early stage, rather than optimising individual components separately.



> Our role is not simply to supply an individual component or a piece of equipment. It is to work collaboratively with customers, identify potential risks and interdependencies, and help them build solutions that can progress successfully from development to commercial production

In India, we see strong opportunities to support pharmaceutical companies developing increasingly sophisticated injectable products for both domestic and international markets. These opportunities include high-performance, ready-to-use primary containers; flexible device platforms; inspection and assembly technologies; and analytical services that help customers evaluate compatibility and performance early in development.

Our objective is to help customers reduce development risk, manage technical complexity and build scalable solutions that can support the progression from development to commercial production.

Stevanato Group offers integrated solutions across the drug development lifecycle. How important is this end-to-end approach in the Indian market, where pharma companies must balance cost competitiveness with quality, regulatory compliance and product integrity?

An end-to-end approach is particularly relevant when companies need to balance development speed and cost competitiveness with quality, regulatory requirements and long-term product performance.

Decisions related to the formulation, primary container, closure system, delivery device and manufacturing process are closely interconnected. If the container or device is selected only after the formulation has been finalised, it may become a constraint rather than a development lever. Early collaboration allows potential compatibility, usability and manufacturability challenges to be identified before they lead to redesigns, delays or additional investment.

Stevanato Group brings together expertise in glass primary packaging, analytical services, drug delivery systems, inspection and assembly equipment. By considering these elements as part of one development strategy, we can help customers simplify technical coordination, reduce integration challenges and support a more efficient path toward commercialisation.

For Indian pharmaceutical companies, this approach can also

facilitate the transition from development and clinical supply to larger-scale commercial production. Flexible and scalable technologies are increasingly important, particularly when manufacturers need to process different container or device formats and address the requirements of multiple products and markets.

Ultimately, cost competitiveness should not be viewed simply in terms of the price of an individual component. It should also take into account development risk, manufacturing efficiency, product quality, supply reliability and the total cost of bringing a combination product to market.

As Indian pharma companies expand their presence in global markets, expectations around packaging quality, delivery systems and product safety continue to evolve. How is Stevanato Group working with Indian customers to help them meet these expectations, and what role do you see the company playing in the next phase of India's pharmaceutical growth?

As Indian pharmaceutical companies expand internationally, packaging and delivery systems need to support increasingly demanding expectations concerning product integrity, device compatibility, patient usability and manufacturing consistency.

Our approach is to engage with customers early and evaluate the product as an integrated system. This includes assessing the interaction between the drug formulation, primary container, closure components and delivery device, together with the requirements for filling, inspection, assembly and commercial manufacturing.

For combination products, attributes such as mechanical resistance, dimensional tolerances, gliding performance, needle-shield configuration and device compatibility should be assessed as early as possible. Analytical and testing services can help generate the technical evidence required to support container selection, understand system performance and reduce integration risks.

We also see growing demand for ready-to-use container solutions and flexible manufacturing platforms. These technologies can help companies manage different formats, improve operational efficiency, and scale from development to commercial production without completely redesigning the manufacturing process.

Another trend is related to the growth of complex formulations, requiring pharmaceutical companies to select container materials, performance levels, and configurations that align with the physicochemical properties of their products. To address this challenge, Stevanato Group offers its EZ-fill® RTU syringe platform, featuring two product performance levels, Nexa® and Alba®. The portfolio covers capacities ranging from 0.5 mL to 5.5 mL, including the newly introduced Alba® 5.5 mL format designed specifically for high-volume drug administration applications.

In the next phase of India's pharmaceutical growth, we believe Stevanato Group can act as a long-term technology partner, helping customers manage the increasing



interdependence of containment, delivery and manufacturing. Our proprietary device portfolio is designed to address different requirements and stages of therapy through complementary technologies, ensuring compatibility with drug containment solutions for seamless integration. For example, we do this with our Alina® and Deora® pen injectors. Alina® is a variable-dose, disposable pen injector platform designed for subcutaneous drug delivery. The platform can accommodate doses from 0.01 mL up to 0.75 mL and includes multiple pre-configured variants developed for GLP-1 and potentially for a broader range of therapies requiring repeated administration and variable dosing. Deora® is our new proprietary pen injector platform, recently added to our DDS portfolio, targeting incretin-based therapies and supporting other originator and biosimilar drug development programs. It is a multi-use, fixed-dose pen injector featuring a simple pull-push mechanism for dose setting and delivery, eliminating the need for manual dose selection: the user pulls to set the dose, then pushes to inject.

In a nutshell, by combining global expertise with close collaboration in the Indian market, we aim to support customers in developing robust, scalable solutions for products intended for patients around the world.

You have worked with organisations such as L&T, Pall Life Sciences, Becton Dickinson and West Pharma, gaining experience across different aspects of the pharmaceutical and life sciences value chain. Looking back at this journey, what has most significantly shaped your understanding of customer needs, and how does that perspective influence the way you lead Stevanato Group's business in India?
Working across different parts of the pharmaceutical and life sciences value chain has shown me that customers rarely face isolated technical challenges. Their decisions are influenced by a combination of product performance, regulatory expectations, manufacturing capability, supply-chain reliability, commercial priorities and timelines.

What has shaped my perspective most is the importance of understanding the customer's complete objective, rather than focusing only on the immediate product or technology being discussed. A technically strong solution must also be practical to industrialise, scalable for future demand and aligned with the customer's broader development and commercialisation strategy.

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This perspective influences how I lead Stevanato Group's business in India. I encourage our team to engage customers early, listen carefully to both their current requirements and their longer-term ambitions, and connect them with the appropriate expertise across our organisation.

Our role is not simply to supply an individual component or a piece of equipment. It is to work collaboratively with customers, identify potential risks and interdependencies, and help them build solutions that can progress successfully from development to commercial production.

Having spent over 25 years in the industry, what is one significant shift you believe the industry has yet to fully appreciate, and how are you preparing your team and business to respond to it?
One significant shift is the need to stop treating the drug formulation, primary container, delivery device and manufacturing process as separate development decisions.

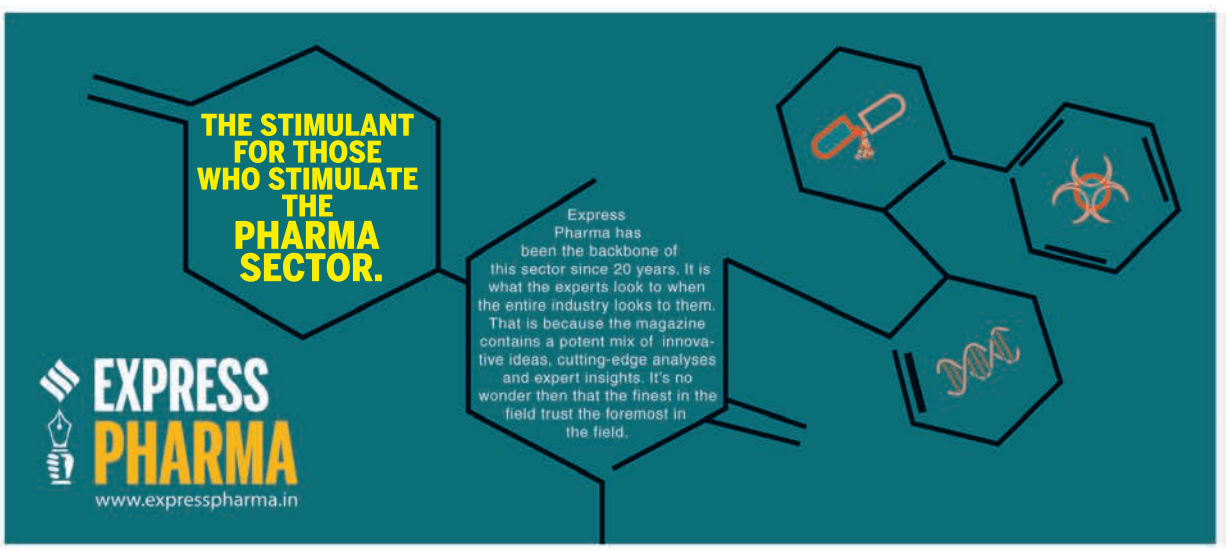
The industry increasingly recognises the importance of combination-product thinking, but these choices are still sometimes made sequentially. When packaging or delivery-system decisions are addressed too late, they can limit device options, create additional testing requirements, complicate manufacturing or increase development risk.

This becomes even more important as biologics and other advanced therapies move toward higher concentrations, more complex dosing regimens and greater use of home-based self-administration. The appropriate solution must balance formulation needs, container performance, device usability, regulatory considerations and scalable manufacturing from the beginning.

We are preparing our team by strengthening collaboration across primary packaging, analytical services, drug delivery systems and manufacturing technologies. We are also encouraging earlier and more strategic discussions with customers, focusing not only on their immediate technical requirements but also on how the product may evolve throughout its lifecycle.

The future will require flexible platforms rather than one-size-fits-all solutions. Different patient populations, treatment phases, dosing requirements and geographic markets may require different delivery approaches. Our responsibility is to help customers anticipate that complexity and create solutions that remain robust, adaptable and scalable over time.

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INTERVIEW

Moving from supplying ingredients to becoming a partner in formulation development

Jaynil Doshi, Director - Techno Commercial, PIOMA Chemicals, discusses the company's evolution from excipient distribution to application-driven solutions, its focus on technical and regulatory capabilities, and the growing role of functional excipients in complex formulations and advanced drug delivery with **Neha Aathavale.**

How has Pioma Chemicals' role in India's pharma excipients market evolved, and what are the company's strategic priorities for expanding its presence in the pharma value chain?
Pioma Chemicals began its journey in 1989 as a trading company supplying raw materials to the pharmaceutical and personal care industries. Over the years, our role has evolved considerably. Today, we see ourselves not merely as an excipient distributor, but as a solution-oriented partner to pharmaceutical manufacturers, combining global sourcing, a broad functional excipient portfolio, technical support and regulatory documentation.

Our focus is increasingly on the functionality behind the excipient rather than simply the chemistry. A pharmaceutical manufacturer is not only looking for HPMC, a carbomer or a disintegrant. They are looking for a specific delivery of drug, release profile, rheology, stability, manufacturability or formulation performance. Pioma's pharmaceutical portfolio already spans areas including film coating, controlled-release polymers, binders, disintegrants, rheology modifiers, suspending agents and other functional excipients.

Going forward, our priority is to deepen our presence in these value-added and application-driven excipient categories, while strengthening technical capabilities, supply reliability and documentation support. The objective is very clear: to move further from being a supplier of ingredients to becoming a partner in formulation development.

As pharma formulations become more complex, how is PIOMA working with manufacturers to address challenges around excipient functionality, formulation stability, bioavailability and drug delivery?
Complex formulations require much more than simply selecting a pharmacopeial grade. Two excipients may meet similar compendial specifications and yet behave differently during processing or in the finished formulation. This is where understanding functionality becomes extremely important.

At Pioma, our technical approach is built around working with formulation teams on product selection, formulation development and troubleshooting. Our pharmaceutical communication already positions our technical team around formulation support and troubleshooting, and our cellulose portfolio, for example, covers multiple functional roles including binders, film formers, controlled-release polymers, thickeners and stabilisers.

We therefore try to understand what the formulator actually wants to achieve, whether it is controlled release, better suspension stability, improved rheology, efficient film formation or more consistent processing, and then recommend the appropriate excipient or grade.

I believe the future of excipients will increasingly be about performance and



functionality rather than specification alone. Our role is to help customers translate excipient functionality into a more robust and reproducible formulation.

India's pharma industry is seeking to strengthen its position in regulated markets. How is PIOMA helping manufacturers meet global quality and regulatory requirements, particularly through excipient sourcing, documentation and supplier qualification?
For manufacturers supplying regulated markets, the excipient is no longer viewed as just another raw material. The reliability of its source, traceability, documentation and consistency of supply become extremely important.

Our approach begins with selective sourcing. Pioma's quality policy specifically commits us to partnering with approved and reliable manufacturers and suppliers with robust quality systems, while maintaining traceability, documentation and regulatory compliance throughout the supply chain. Equally important is documentation. Our customers increasingly require structured vendor qualification and supporting regulatory information, and Pioma has built regulatory documentation support into its organisational structure alongside technical support, sourcing and supply-chain functions.

We also recognise that qualification is not a one-time transaction. Our role is to create a dependable link between the excipient manufacturer and the pharmaceutical customer, helping ensure that quality consistency, traceability, documentation and communication are maintained throughout the relationship. This is particularly important when customers are developing products intended for multiple global markets.

What have been the key leadership lessons from building and expanding PIOMA, particularly in managing supplier relationships, technical expertise and customer trust?
One of the biggest lessons has been that this business is ultimately built on long-term relationships and credibility. Pioma is a family business, and with the second generation now taking an increasingly active role, our outlook is naturally long term. We want to build on the relationships and values established over the years, while bringing in fresh technical capabilities, new products and a more application-driven approach. With both our principals and customers, we believe relationships must go beyond transactions. Technical knowledge, transparency and consistency are equally important in building lasting trust.

Ultimately, being a second-generation family business means we are not looking at the next transaction; we are looking at the next generation of relationships.

Looking ahead, which developments in pharma manufacturing, complex generics and advanced drug delivery are likely to reshape demand for excipients in India, and how is Pioma Chemicals preparing its portfolio and capabilities to address these needs?
We see the next phase of pharmaceutical development being driven by complex generics, modified-release formulations and advanced drug-delivery systems, increasing the need for excipients that offer consistent performance and greater functionality.

At Pioma, we are strengthening our portfolio with specialised and multifunctional excipients that address specific formulation challenges, rather than simply adding more products. Alongside this, we continue to strengthen our technical and regulatory capabilities. Our aim is to combine the right products with application knowledge, dependable sourcing and strong documentation, enabling Pioma to play a larger role in India's evolving pharmaceutical value chain.

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INTERVIEW

From wastewater to the Arctic: Tracking pharma pollution

What can Arctic waters reveal about pharma pollution? **Dr Manoj P Rayaroth,** Assistant Professor, GITAM (Deemed to be University), Vizag, is investigating emerging contaminants in environments ranging from Visakhapatnam's coastline to the fjords and glacier meltwaters of Svalbard. He discusses the movement of drug residues, their environmental risks and the challenges of detecting and removing them, in an interaction with **Lakshmipriya Nair**

Medicines, personal care products and other chemicals often find their way into water bodies. What happens to them once they enter the environment? Do they break down, or can they remain there for years?
The persistence of pollutants in nature depends on their chemical nature. Most pharmaceuticals may be converted into other forms or degraded by microorganisms. However, they do not break down completely or rapidly. Instead, they may undergo transformation. If a pollutant has a chemically stable structure, it may become difficult to break down and may fall into the category of persistent organic chemicals.

Nature behaves like a complex chemical system with different reaction conditions, such as light, oxidising and reducing species, ions, organic matter, and many microorganisms. Therefore, pharma products can be converted into other forms (often called transformation products), depending on the environmental conditions and the physicochemical properties of the pollutants. Pollutants undergo degradation/transformation through direct and indirect photooxidation. In direct photooxidation, pollutants directly absorb light and undergo oxidation. In indirect photooxidation, reactive oxygen species formed through photosensitisation reactions oxidise the pollutants. The presence of organic matter and nitrite ions often enhances the indirect photooxidation of pollutants. Biodegradation by microorganisms is another natural degradation pathway. Redox reactions are also part of global biogeochemical cycles and may transform pollutants into other products.

The transformation may lead to the formation of products that are even more toxic or persistent.

Where does pharma pollution come from, and how concerned should we be about its impact on aquatic life and human health?
The major sources of pharma pollution are hospital waste, pharma industries, sewage treatment plants, and septic tanks, which are the major source of pollution. Agricultural runoff from animal waste and manure, as well as urban runoff from domestic waste, are the non-point sources of pollution. Since these pollutants are not completely removed by conventional water treatment methods, many pharmaceuticals contaminate our water resources.

In the aquatic environment, pharma products harm organisms by acting as endocrine disruptors and impairing reproduction. Antibiotic pollution contributes to the development of antibiotic-resistant pathogens and the spread of antibiotic resistance genes in the environment, threatening the effectiveness of treatments against infectious diseases. Other direct effects of pharma products include hormonal imbalances and reproductive and developmental abnormalities.



You recently participated in the 17th Indian Arctic Expedition in Svalbard. What were you looking for in the fjord waters and glacier meltwater, and why is the Arctic an important place to study these contaminants?
Environmental pollution by emerging pollutants is a global concern, and recent studies have reported the presence of different emerging pollutants in the Arctic environment. These pollutants enter this pristine environment from lower latitudes through ocean currents, rivers, and atmospheric transport. The pollutants can become trapped in Arctic ice. Arctic ice melting is considered one of the major indicators of global climate change, which further enhances the release of these pollutants into Arctic seawater. Therefore, the major objective of my Arctic project was to identify and quantify pharma pollutants in seawater and glacier meltwater.

As glaciers melt and the climate changes, could pharma residues and other pollutants be released into the oceans in new ways? What are you hoping to understand through your research?
Glaciers act as reservoirs for many pollutants that are deposited through condensation, particle capture, and the freezing of water-based aerosols. It has been reported that these trapped pollutants can persist in glaciers for extended periods. Therefore, glacier meltwater acts as an additional source of pollution in the ocean. The fate of pollutants within glaciers and under such extreme environmental conditions is also not well understood. In my study, I am trying to identify the pollutants in glacier meltwater and investigate their release into the fjord.

You will analyse the Arctic samples using high-resolution mass spectrometry at GITAM. How does this technology help you identify contaminants that might otherwise go undetected?
HRMS techniques are used for the trace-level detection (ng/L) of pollutants across different environmental matrices. There are two major approaches used in mass spectrometry to identify contaminants: targeted and suspect/non-targeted analysis. HRMS provides highly accurate mass measurements (molecular weight), along with fragmentation patterns and elemental compositions of compounds. These details can be used to identify the chemical structures of unknown compounds by comparing them with available chemical databases. This approach is particularly useful for identifying previously unknown contaminants in complex environmental samples.

Targeted analysis, on the other hand, is used to detect pollutants that are already known. In this method, the instrument is configured to look for specific compounds based on their molecular weight and characteristic fragmentation patterns. In this project, I am adopting both targeted and non-targeted approaches to ensure that we do not miss any potential pollutants during the analysis.

You also study emerging pollutants in the coastal waters of Visakhapatnam, in collaboration with the University of Montreal. What are you learning about the presence and movement of these pollutants along India's coastline?
We are collaborating with the University of Montreal, Canada, through a collaborative project funded by the Scheme for Promotion of Academic and Research Collaboration (SPARC), Ministry of Education, Government of India. In this project, we are focusing on emerging contaminants, such as microplastics and fluorinated chemicals, in the seawater of Visakhapatnam.

We have identified per- and polyfluoroalkyl substances (PFAS), also known as 'forever chemicals'. This research has provided important insights into the occurrence and

sources of PFAS in the marine environment. We targeted 77 PFAS compounds in seawater and sewage water, of which 38 were detected, with higher concentrations observed in sewage water. Our research concluded that approximately 41 per cent of PFAS contamination in coastal waters could be attributed to sewage discharge. This research helps us understand the sources of PFAS in coastal waters. We are currently working on microplastics (MPs) to investigate their occurrence and potential impacts on the marine environment.

From a pharma industry perspective, how big is the challenge of drug residues entering the environment? Are current wastewater treatment systems doing enough to remove them?

Wastewater treatment is a major challenge, particularly when it comes to the incomplete removal of pollutants. The concentration of pollutants in the influent can be very high, and wastewater treatment plants (WWTPs) are likely to remove only a portion of them. In such cases, pharma residues may still be present at significant concentrations in the effluent of WWTPs. The pharma components are having different physicochemical properties and many other co-exisiting components, that also affect the removal efficiencies in WWTPs.

In many industries, wastewater monitoring is largely focused on routine parameters such as colour, total dissolved solids (TDS) and organic matter. While these checks help assess basic effluent quality, they may not reveal the presence of emerging pollutants and other chemical contaminants. Conventional wastewater treatment methods may also not be sufficient to remove these substances completely, allowing some residues to enter the environment through treated effluent. This makes it important for industries to go beyond routine monitoring and adopt more comprehensive testing and treatment practices. Alongside effective wastewater treatment, proper solid waste management is equally important to minimise the release of pollutants into the environment.

What needs to change to tackle pharma pollution? Where should the responsibility lie—with drug manufacturers, wastewater treatment facilities or regulators?

The first and most important step is to strengthen regulations governing pharma pollutants in industrial effluents and ensure that industries regularly monitor these contaminants. It is equally important to adopt appropriate wastewater treatment methods to ensure that these chemicals are effectively removed before treated water is discharged into the environment. Advanced oxidation processes (AOPs), membrane-based technologies, adsorbents and hybrid treatment processes can help improve the removal of pharma pollutants. At GITAM, we are working on different AOPs to study the removal of various organic pollutants.

In my opinion, tackling pharma pollution requires a collective effort from drug manufacturers, wastewater treatment facilities and regulatory authorities. Drug manufacturers need to focus on minimising chemical waste generation, adopting appropriate treatment methods and regularly monitoring pollutants in their effluents. Treatment facilities must ensure that their processes effectively remove these contaminants, while regulatory authorities need to ensure that discharge standards are properly monitored and enforced. Ultimately, preventing pharma pollution requires us to look beyond treating wastewater after contamination and focus equally on preventing these pollutants from entering the environment in the first place.

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INTERVIEW

Strengthening clinical trial operations through better site readiness

Dr Krishna Sai Penumarthi, Clinical Research Manager, Advanced Foot Care and Advanced Research Institute (ARI), discusses improving clinical trial execution, strengthening research quality, integrating trials into physician practices, the role of AI in trial operations, and opportunities to expand India's clinical research capabilities in an interview with **Kalyani Sharma**

You have worked across pharmaceutical sponsors, CROs and clinical research sites. What are the biggest operational gaps affecting clinical trial execution today, and where is there the greatest scope for improvement?

Having worked with pharmaceutical sponsors, CROs, and research sites, one thing I've noticed is that there's often a gap between how a clinical trial is planned and what actually happens at the site level. A protocol might look great on paper, but when it comes to execution, things like patient availability, staffing, documentation requirements, and day-to-day clinical responsibilities can make it much more challenging than expected.

I've experienced some of these operational challenges firsthand. When I took over research operations at Advanced Foot Care, one of the challenges was managing a significant backlog of outstanding data queries across our clinical studies. Data queries are a normal part of clinical research, but when they accumulate without timely resolution, they can affect study timelines and data quality. I worked closely with the team to understand where the delays were happening, improve our internal workflows, and establish a more consistent process for reviewing and resolving queries. Over approximately six months, we brought the number of outstanding queries down from 2,322 to 173, a reduction of more than 90%.

For me, it was a great example of how the right operational approach can make a real difference without compromising research quality.

I think one of the biggest improvements we can make as an industry is involving research sites much earlier in the planning process. The people managing trials at the site level understand what is practical, what patients can realistically manage, and where challenges are likely to arise. When sponsors, CROs, and sites work together from the beginning, we have a much better chance of preventing avoidable problems instead of spending time fixing them later.

As clinical trials become more complex, how can research sites strengthen quality systems, data integrity and inspection readiness without increasing timelines and operational costs?

One thing I've learned from my experience is that quality and inspection readiness have to be part of everyday research operations, not something we start worrying about when an audit or inspection is announced. I always look at it like a snowball. Small documentation gaps or unresolved issues may not seem like much initially, but if they're not addressed regularly, they keep building up until they become much bigger problems.

During my time at Arizona Cardiovascular Research Center, I supported two FDA inspections and several sponsor audits. At Seres Therapeutics, I also worked on



trial master file quality and electronic documentation workflows. These experiences reinforced how important it is to have clearly defined processes, properly trained staff, and consistent documentation practices rather than trying to catch up when an inspection is approaching.

At the site level, time is money. When documentation is maintained properly, responsibilities are clear, and issues are resolved as they arise, coordinators spend less time correcting errors, responding to avoidable queries, or preparing for last-minute inspections. I believe the best way to manage costs and timelines is to build quality into daily workflows, so inspection readiness becomes a natural part of how the site operates.

You are developing an integrated research model that brings clinical trials into established physician practices. How can this model improve patient recruitment, trial diversity and access to investigational therapies, and what challenges need to be addressed for wider adoption?

One thing I've noticed in clinical research is that we often expect patients to come to research facilities, even though many are already receiving regular care at specialist clinics closer to home. That's one of the reasons I'm helping develop an integrated research organisation (IRO) model in the US.

The idea is fairly simple. Instead of building new research facilities from scratch, the model involves partnering with established physician practices that already have experienced doctors, clinical equipment, and patient population. We then bring in the research infrastructure they need, including trained coordinators, regulatory support, quality systems, and study management. This allows suitable clinics to participate in clinical trials while continuing their regular patient care.

I believe this approach could make recruitment more practical, reduce some of the barriers patients face, and potentially improve trial diversity by reaching communities that traditional research sites may not always serve. The NIH's CARE for Health initiative reflects a similar direction of bringing research into everyday healthcare settings.

Of course, the biggest challenge is making sure these clinics are genuinely research-ready. Physician engagement, staff training, informed consent, data quality, and regulatory oversight all need to be in place. For me, expanding access only makes sense if we're maintaining the same standards of research quality and patient safety.

AI is increasingly being explored for clinical trial monitoring, data management, safety surveillance and regulatory processes. Which applications offer the most immediate value, and what safeguards are needed to ensure accuracy, accountability and regulatory compliance?

I think one of the biggest opportunities for AI in clinical research is helping teams identify problems early, rather than waiting until they become bigger issues. Research teams spend a lot of time reviewing data, managing queries, tracking protocol deviations, and ensuring regulatory compliance. AI could help identify patterns, flag inconsistencies, and bring potential issues to our attention much earlier.

This is actually something I've explored in my own research. In my paper on agentic AI for clinical trial operations, I proposed a framework where AI systems could identify potential compliance issues, assess their risks, and recommend corrective and preventive actions before problems escalate. The idea is to move from reacting to issues after they happen toward identifying risks earlier and addressing

them proactively.

One thing I strongly believe in, and something I've also emphasised in my research paper, is the human-in-the-loop approach. I've always advocated for keeping human judgment at the center of AI-driven processes, especially in clinical research. No matter how advanced AI becomes, I don't think it should independently make decisions that affect patient safety or regulatory compliance. It should help research professionals analyse information, identify risks, and make informed decisions faster, while the final judgment and accountability remain with qualified people. Of course, proper validation, data privacy, audit trails, and regulatory safeguards are equally important. For me, AI should make human decision-making better, not replace it.

Your work includes clinical research in diabetic foot ulcers and advanced wound care. What are the key challenges in generating robust clinical evidence in these areas, and how can better-designed trials support the development of new treatment options?

Working on diabetic foot ulcer and advanced wound care studies has taught me that wound healing isn't always predictable. Two patients with similar wounds can respond very differently depending on their circulation, infection, diabetes control, and the care they're receiving.

That's what makes these studies challenging. We need to make sure things like offloading, wound measurements, patient selection, and standard care are consistent, so we can actually understand how well a treatment is working.

I've also explored advanced wound therapies through a published comparative case report on decellularised human dermis and standard wound care. While early findings can be encouraging, I think larger, well-designed trials are what really help us understand which treatments work, who benefits most, and whether the results last.

Drawing on your experience in the US clinical research ecosystem and your long-term interest in India, what changes in research infrastructure, regulatory processes and physician participation would help India strengthen its clinical trial capabilities and attract more drug development programmes?

Having studied in India and worked across the US clinical research ecosystem, I see tremendous potential for India to expand its clinical trial capabilities. But I believe we also need greater investment in research and development. Initiatives like Atmanirbhar Bharat and the government's PRIP scheme are encouraging steps toward building India's own pharmaceutical innovation capabilities.

I also think India already has a strong foundation of medical professionals, academic institutions, and people with research knowledge. The opportunity is to translate more of that knowledge into practical clinical trial experience. Physicians need trained coordinators, regulatory support, reliable data systems, and quality processes so they can participate in research alongside their regular patient care. That's also the thinking behind the integrated research organization model I'm helping develop in the US.

Initiatives like ICMR's INTENT network are moving in the right direction. I would love to see more practical, standardised guidance that shows interested clinics how to become research-ready, from staff training and documentation to ethics oversight and day-to-day trial operations. Alongside consistent implementation of India's existing clinical trial regulations, stronger R&D investment and practical site-readiness guidance could help India expand research beyond major hospitals, attract more drug development programs, and make clinical trials accessible to more patients.

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Stevanato Group

INTERVIEW

Changing face of pharma careers: What graduates need to know

As India's pharma industry evolves, pharmacy graduates are finding opportunities beyond traditional roles in manufacturing and quality control, with fields such as pharmacovigilance, clinical research, regulatory affairs and data-driven drug safety gaining attention. However, bridging the gap between academic knowledge and industry expectations remains a key challenge. **Shailendra Bhadauria**, Chancellor, Pratap University discusses emerging career pathways for pharmacy students, the importance of practical training and industry internships, and how AI and digital technologies are reshaping pharma careers in an exclusive interview with **Swati Rana**



How is pharmaceutical education in India evolving to meet the changing needs of the industry?

Pharmacy graduates today can choose from several career paths. Many still go into manufacturing and quality control, while others are finding opportunities in clinical research, drug safety and regulatory affairs. Students may not know much about these fields when they first join a pharmacy course, so it helps to introduce them to these options during their studies.

In the classroom environment, students gain the necessary knowledge, but there are other difficulties when one works within the industry. The students should be able to learn through practical experiences how certain things are done, comprehend the nature of their jobs, and learn from individuals who have practical experience in the industry. This way, it will be easier for the students to transition into the industry.

What career opportunities are emerging in pharmacovigilance, and how can pharmacy graduates prepare for this field?

A medicine's safety needs to be monitored even after it has been approved for use. This is what makes pharmacovigilance an important area for pharmacy graduates. The work involves reviewing reports of suspected side effects, checking the available information and ensuring that safety concerns are recorded correctly.

Students considering a career in this area should make sure that they get thorough knowledge about pharmacology. They must be prepared to go through scientific literature and prepare scientific reports. Internship or specialised training will assist them in understanding the nature of the job prior to applying for a job in drug safety. This is a profession which requires careful reading every day.

What career paths are available to students pursuing D.Pharm, B.Pharm and M.Pharm, and how do their opportunities differ?

D.Pharm, B.Pharm and M.Pharm lead to different opportunities, and students should understand what each qualification offers before making a choice. D.Pharm can lead to pharmacy practice, subject to registration and eligibility requirements. B.Pharm opens up options in manufacturing, quality control, pharmaceutical sales and other industry functions.

M.Pharm provides the possibility of specialisation. Based on the subjects they have, they can decide whether to conduct research, formulate, go for technical jobs or become teachers.

It also depends on when they want to start working and if the chosen career demands additional studies. There is not one way that would work for all. The only important thing is to know the options and follow a goal-oriented program.

Beyond traditional roles in manufacturing and quality control, what emerging career options should pharmacy students explore?

While manufacturing and quality control are common professions among pharmacists, there are other areas to consider as well. There are many options such as pharmacovigilance, clinical research, regulatory affairs, medical writing, and clinical data management that should be considered as well.

The types of activities differ in each case. For example, medical writing requires students to prepare different scientific papers, and in regulatory affairs, students will have to learn all the requirements for pharmaceuticals. Pharmacovigilance is about medicine safety. Students who know about these professions earlier have much more time to choose what to do.

The best way to begin learning is to talk to someone working in the profession. It takes only a few minutes to figure out whether this activity suits you or not.

What technical and soft skills do pharmaceutical employers expect from fresh graduates today?

The skills needed will vary from job to job. For laboratory positions, the skills needed are an understanding of testing techniques and laboratories. Skills needed for drug safety jobs include an understanding of drugs, side effects of drugs, and their reporting.

Good communication skills, working together with other people, and taking responsibility are some other skills that are needed by fresh graduates. These skills are sometimes forgotten by students as they concentrate only on scoring marks.

It is not expected from any employer that a fresher will know everything. Basic knowledge along with good learning capacity and a good attitude towards work can be a good start. It is a necessity in this field to check things and follow procedure.

How can universities bridge the gap between academic learning and industry requirements?

One of the problems that the students have is how the learning done in class is connected to the profession. It is possible that the students may be well informed about the theories involved in a certain process, but they do not know how to apply this knowledge at a pharmaceutical company.

In order to solve this problem, universities can help students practice more during class and get involved in case studies and discussions with industry experts. While guest lectures are important, the students need chances to apply the knowledge and see how they can improve themselves.

This task can also be partially solved by employers. By telling what requirements the pharmaceutical companies have for the new graduates, they can help the universities change their learning approach accordingly.

What role should internships, industry collaborations and practical training play in preparing students for employment?

An internship enables students to learn about what comes after class. They have a chance to witness how people work, how documentation takes place and how duties are carried out within the professional arena. An internship might even reveal to them whether or not a certain profession is indeed as it appeared to them.

For the experience to benefit them greatly, they need

guidance and exposure to specific activities. This is not as beneficial as simply completing the internship for the sake of putting something on their CVs.

Collaborations between industries and educational institutions could provide similar benefits to students through visits and other forms of interaction. Through this process, students are able to appreciate what a job entails prior to application.

How are AI, data analytics and digital technologies creating new opportunities in pharmacovigilance and other pharmaceutical fields?

The utilisation of artificial intelligence in pharmaceutical practices is evident in areas where a lot of data has to be processed. One example is pharmacovigilance, where digital means will help process safety reports and detect any patterns for further analysis. Data processing will also be useful when studying clinical trial data.

Although these tools make the process somewhat easier, they do not eliminate the need for thorough investigation. Detection of a pattern in a report does not necessarily indicate that the drug was responsible for an occurrence of such a reaction. Analysis of information is still required from experts in science.

Students in pharmacy practice must be able to use digital tools and learn the processes related to the use of data within their specific field. Not everyone has to be skilled in computer science, but not using these digital tools can turn into a disadvantage in the future.

How is Pratap University adapting its pharmaceutical programmes to improve student employability and prepare graduates for emerging roles?

At Pratap University, emphasis is placed on developing the knowledge base required by the student for a career in pharmaceuticals and how such knowledge is applied within the field. The students also need to appreciate the fact that there are many more career paths available besides what is familiar.

Pharmaceutical drug safety, research and regulatory affairs are some of the fields where students can venture in as they make their decision on their career path. Familiarising themselves with these different fields will give students an idea of whether to look for employment or go for further studies.

Being prepared for employment requires students to recognise the fact that getting a degree does not end all learning. Students continue to learn through experience, but a solid academic base is vital for making a good start.

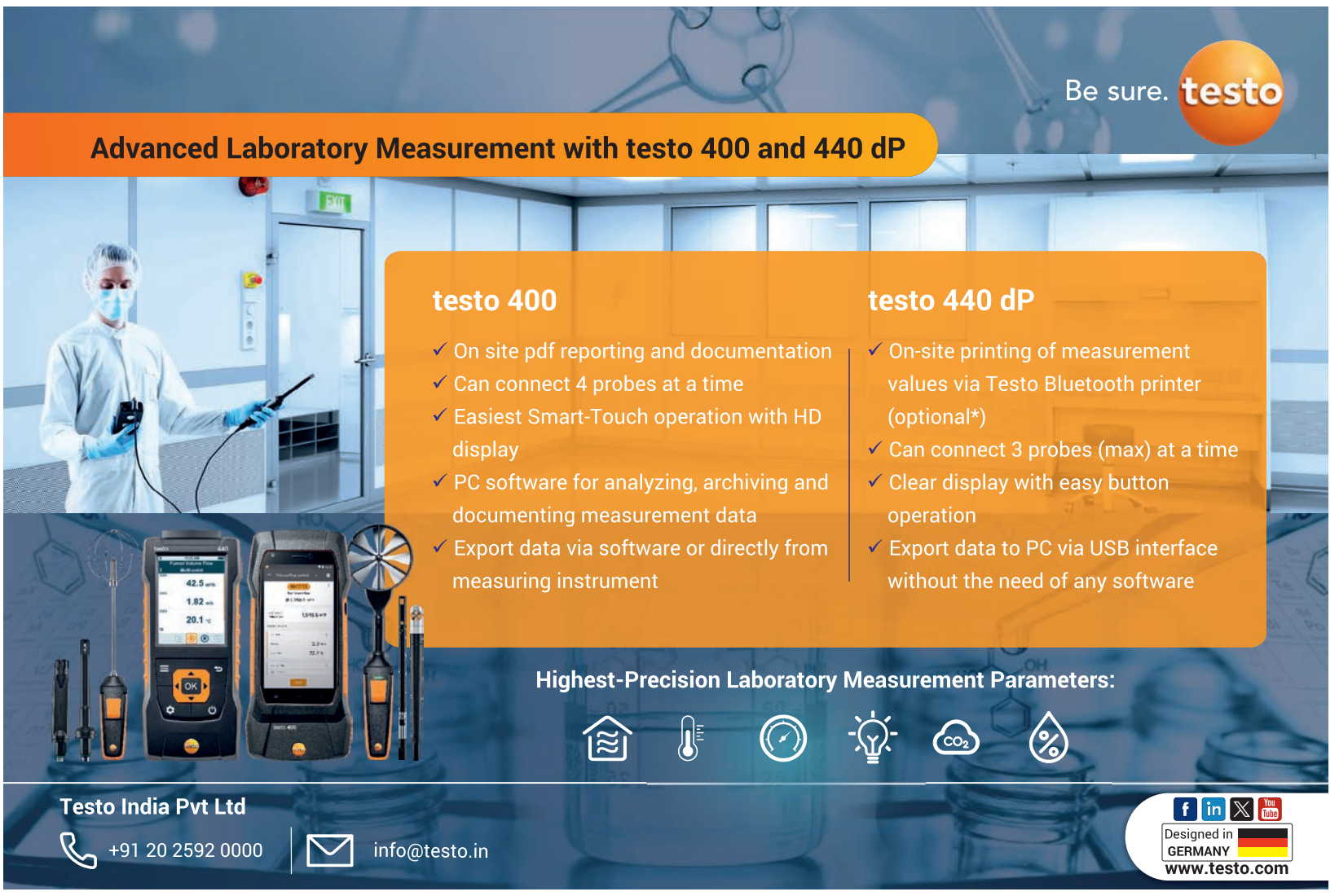
Which pharmaceutical career areas are likely to see the strongest growth over the next five to ten years, and what advice would you give aspiring pharmacy professionals?

Some of the sectors that should be considered include pharmacovigilance, clinical research, regulatory affairs, and biopharmaceuticals. There could also be potential for AI and data analysis to create job prospects in various sectors within the pharmaceutical field. The rate of growth will be dependent upon industry investments, research activities and regulatory changes, and thus it would be presumptuous at this point to declare a winner.

From a student's perspective, taking time to explore some of these areas will be more beneficial than guessing what job will be in high demand a few years down the line. Internships, talking to experts in the field, and extra training will enable them to learn more about the profession and what it entails.

One's first job does not necessarily mean being committed to that sector forever. People's interests and opportunities change over time, and a student who understands the subject and takes the job seriously will be in a better position to make such decisions.

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Stevanato Group

INTERVIEW

We are much more than a pharmaceutical equipment manufacturer

Vishal Wagh, Director, Adam Fabriwerk, discusses the company's focus on integrated process engineering solutions, the growing demand for advanced sterile and biopharma manufacturing systems, and India's role in pharma engineering with **Neha Aathavale**

What are you most excited to show at CPhI & P-MEC this year, and what problem does it solve for your customers?
At CPhI & P-MEC India 2026, we are excited to showcase Adam Fabriwerk's expanding capabilities in integrated process engineering solutions for pharma sterile manufacturing and biopharma applications.

Our focus is on demonstrating how we are moving beyond conventional equipment manufacturing towards delivering complete, integrated process solutions. These include large-volume parenteral (LVP) processing systems, high-capacity compounding vessels, advanced mixing technologies, process skids, buffer and media preparation systems, CIP/SIP solutions and automated process systems.

We are particularly focused on solutions for complex formulations such as Propofol, biologics, biosimilars and other high-value injectable products, incorporating inline high-shear mixers, high-pressure homogenisers and advanced process instrumentation.

The fundamental challenge we address is helping pharma manufacturers achieve consistent product quality, process reliability, higher manufacturing efficiency and regulatory compliance while reducing operational complexity.

Our objective is to provide customers with a single engineering partner capable of taking responsibility from process understanding and equipment design through manufacturing, automation, integration and commissioning.

What's the biggest change you're seeing in pharma right now? How is it shaping your plans?
The pharma industry is undergoing a significant transformation, particularly in sterile manufacturing and biopharma production.

We are witnessing a shift from conventional batch-oriented manufacturing towards more integrated, automated and data-driven manufacturing environments. Regulatory expectations are becoming increasingly stringent, while pharma companies are demanding greater process control, traceability, product safety and manufacturing flexibility.

Another important development is the rapid growth of biologics, biosimilars, vaccines, monoclonal antibodies, plasma-derived products and advanced therapeutic molecules. These products require sophisticated processing technologies and a much higher level of engineering integration.

For Adam Fabriwerk, these developments are shaping our investments in engineering capabilities, automation, advanced mixing technologies, hygienic equipment design and integrated process systems.

We are also strengthening our capabilities to address global regulatory expectations, including EU GMP Annex 1, ASME-BPE, GAMP 5 and 21 CFR Part 11 requirements.

We believe the future belongs to equipment manufacturers who understand not only mechanical engineering but also the science of pharma manufacturing and the regulatory environment in which their customers operate.



Where are technology, automation or AI making the biggest difference in your business today?
Automation and digital integration are fundamentally changing how pharma processing equipment is designed, operated and monitored.

At Adam Fabriwerk, we are focusing on intelligent process automation, integrated control systems and real-time monitoring of critical process parameters such as pH, temperature, dissolved oxygen, conductivity, pressure, weight and mixer speed.

Our automation philosophy is built around process consistency, electronic data integrity, traceability and seamless communication between upstream and downstream manufacturing systems.

We are integrating PLC/SCADA-based automation architectures with 21 CFR Part 11-aligned functionalities, electronic batch records and secure process data management, as required by individual project specifications.

We also see significant opportunities in Process Analytical Technology (PAT), including online analytical sensors and emerging technologies such as Near Infrared (NIR) spectroscopy, which can support real-time process understanding and improved manufacturing control. AI will increasingly complement these capabilities through predictive maintenance, process optimisation, anomaly detection and intelligent analysis of manufacturing data.

Our approach is practical: technology must deliver measurable improvements in process reliability, product quality, operational efficiency and compliance rather than simply adding complexity to manufacturing systems.

Where will your next phase of growth come from? What will it take to get there?
Our next phase of growth will be driven by three strategic areas: advanced sterile processing systems, biopharma manufacturing infrastructure and international market expansion.

We see substantial opportunities in large-volume parenterals, complex injectable formulations, biologics, biosimilars, vaccines, plasma fractionation and downstream processing.

We are also strengthening our capabilities in integrated process skids, super skids, buffer and media preparation systems, bioreactor support systems and customised solutions for complex manufacturing requirements.

Geographical expansion will remain equally important. We are working towards strengthening our presence across the Middle East, Africa, Europe, the Americas and other emerging pharma markets through strategic partnerships and closer engagement with customers.

Achieving this growth will require continued investment in engineering talent, manufacturing infrastructure, digital technologies, global service capabilities and strategic technology partnerships. Most importantly, we must continue building customer confidence through engineering quality, execution excellence and the ability to deliver complex projects reliably.

How does India fit into your growth story?
India is central to our growth strategy, both as our manufacturing base and as an increasingly important global engineering and technology hub.

The Indian pharma industry has established itself as a global leader in generics, vaccines and pharma manufacturing. As Indian companies increasingly move towards complex injectables, biologics, biosimilars and high-value pharma products, the demand for sophisticated process engineering solutions will continue to grow.

At Adam Fabriwerk, we see India as a platform from which we can design, manufacture and deliver globally competitive pharma processing systems.

Our experience in executing large-scale projects, including high-capacity processing vessels, integrated process skids and complex automation systems, demonstrates the growing capabilities of Indian engineering companies.

We strongly believe that Indian manufacturers must move up the value chain from supplying individual equipment towards delivering complete, technologically advanced and globally compliant process solutions.

Our ambition is to strengthen the Adam Fabriwerk brand internationally and establish Indian pharma engineering as a benchmark for quality, innovation and execution.

Five years from now, what will the leaders in your space be doing differently?

Five years from now, leaders in pharma process equipment manufacturing will be distinguished by their ability to combine process engineering, digital intelligence, automation and regulatory expertise.

I believe we will see greater adoption of integrated manufacturing platforms, advanced PAT applications, real-time process monitoring, predictive maintenance and data-driven process optimisation.

Equipment design will also evolve further towards improved cleanability, reduced product hold-up volumes, lower contamination risks, energy efficiency and greater flexibility for multiproduct manufacturing facilities.

The boundaries between equipment manufacturers, automation specialists and process technology providers will increasingly converge. Customers will expect their engineering partners to understand the complete manufacturing process rather than simply supply vessels or skids.

Another important differentiator will be global execution capability. Companies will need to provide consistent engineering standards, documentation, validation support, lifecycle services and technical support across international markets.

At Adam Fabriwerk, we are preparing for this future by strengthening our integrated engineering approach and developing solutions that are intelligent, scalable, sustainable and ready for the next generation of pharma manufacturing.

Who would you love to meet at CPhI & P-MEC, and what would a great partnership look like?

CPhI & P-MEC provides an excellent opportunity to connect with pharma manufacturers, biotechnology companies, CDMOs, technology providers, engineering consultants and global equipment manufacturers. We are particularly interested in meeting organisations developing complex injectable formulations, biologics, biosimilars, vaccines, plasma-derived products and other high-value pharma products.

We also see opportunities to collaborate with international technology companies specialising in mixing, homogenisation, filtration, process instrumentation, automation and advanced manufacturing technologies.

For us, a successful partnership is one built on complementary technical strengths, transparency, mutual trust and a shared commitment to customer success.

We are not looking simply for transactional relationships. We want to develop long-term strategic collaborations that allow us to jointly deliver innovative and technically differentiated solutions to pharma manufacturers worldwide.

What's one thing you'd like visitors to remember about your company after CPhI & P-MEC?

I would like visitors to remember that Adam Fabriwerk is much more than a pharma equipment manufacturer. We are an engineering partner committed to solving complex pharma processing challenges.

Our strength lies in understanding the complete process, translating customer requirements into robust engineering solutions and integrating equipment, automation and process technologies into reliable manufacturing systems.

From large-volume parenteral processing to advanced biopharma applications, we aim to deliver solutions that help our customers manufacture critical medicines with greater confidence, consistency and efficiency. Our philosophy is simple: Engineering Excellence. Process Innovation. Global Partnerships. We are proud to represent India's growing engineering capabilities on the global pharma manufacturing stage, and we look forward to building the next generation of pharma processing solutions together with our customers and technology partners.

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Stevanato Group

INTERVIEW

European technology meets local expertise and dedication

The Indian pharma industry has long since expanded beyond the domestic market and now serves, to a large extent, international customers as well – and this trend is on the rise. Already, around 30 per cent of the world's generic products are supplied by the Indian pharma industry. How is this global scope changing the needs of Indian pharma companies, and what do technology suppliers need in order to support them and succeed in this environment? **Nicola Magriotis,** Chief Sales Officer, Romaco Group, **Sanjeev Nimkar,** Managing Director, Romaco India and **Amol Nikam,** Director of Customer Service, Romaco India, answer these questions in conversation with **Swati Rana**



Nicola Magriotis



Sanjeev Nimkar



Amol Nikam

Given the growing importance of the European and US markets for Indian pharmaceutical manufacturers, what changes are taking place in terms of technological requirements?
Nicola Magriotis: There is a significant shift here away from production that is cheaper in the short term – but compromises on aspects such as performance and product quality – towards more economical and higher-quality manufacturing in the medium and long term. This is not only due to international requirements, but also a matter of competitiveness. European machinery therefore remains popular among Indian pharma manufacturers, especially those who export worldwide.
Sanjeev Nimkar: Our customers are very pleased with our high-performance machines, which are extremely efficient, deliver very high output whilst maintaining consistent product quality, and achieve excellent OEE figures. This pays off not only in the production of generic medicines and OTC drugs, but also in specialised medicines such as oncology and ophthalmic products, or entirely different areas such as sterile powder filling.
Amol Nikam: What is certainly becoming increasingly crucial is a high degree of automation, as there are certain manufacturing concepts used by our Indian customers that only work if

the equipment can keep up. One example of this are so-called 'dark factories', where manufacturing takes place automatically in pitch-black production halls and technicians only ever need to access the equipment from outside. This results in enormous energy savings and also supports the sustainability initiatives of the Indian government and the pharmaceutical industry. Tableting technology from our most popular brand, Kilian, are already being used in this context.

You mentioned automation – do technological innovations play a major role for Indian companies?

Nicola Magriotis: Absolutely. International markets are dynamic and constantly evolving; to keep pace with them – or even to stay ahead – Indian players need the advanced capabilities that new technologies offer. That is why we do not rest on our laurels, but continue to develop our technologies. Kilian, which has recently celebrated its 150th anniversary, exemplifies this success story of constant innovation, and this is recognised in the Indian market.

Sanjeev Nimkar: We are currently developing, for example, various AI applications that will enable us, amongst other things, to further improve our service. Some AI systems are already in use, such as our AI-based vision inspection and pinhole detection system for blister packs, which we will be presenting at PMEC India. We are furthermore increasingly integrating the possibilities offered by robot technology. For example, our MicroRobot powder/liquid filling machine uses anthropomorphic robots to manage all operations and vials transfer. This allows us to further increase the level of automation in our solutions.

Amol Nikam: But it is not just about new equipment. We are taking our customers – who are using previous-generation machines that are still functioning well – along with us on this journey. Wherever possible, we carry out retrofits or upgrade their machines with operator terminals, data integration and so on. This allows manufacturers to remain competitive without having to automatically invest in a completely new production line.

Is technological progress the key to the global success of the Indian pharmaceutical industry?

Nicola Magriotis: Not exclusively. For us at Romaco, it is above all about developing genuine solutions for and with our customers. This means staying closely in touch with the market and systematically gathering feedback from our customers. We receive very, very positive feedback here in India – well over 90 per cent of customers say they are very satisfied – but what is just as crucial for us is the impetus to improve.

Amol Nikam: For example, we received feedback that the delivery of format parts and spare parts was taking too long. We have therefore addressed these challenges by setting up local production of format parts in India and establishing a spare parts and logistics centre operating as a customs warehouse in Chennai, which enables us to process customs clearance more quickly and thus deliver faster.

Sanjeev Nimkar: And that is just one example. We have also expanded our network of engineers and technicians, so that our experts are present in all pharmaceutical hubs in India – such as Hyderabad, Ahmedabad, Baddi, Mumbai and Goa – and can provide assistance quickly. Consequently, Indian companies benefit from local expertise and European technology.

So, is the key to providing optimal support to Indian pharma businesses a combination of 'local-to-local' and international resources?

Nicola Magriotis: Absolutely. I think this is also where the trust that Indian pharma businesses place in us comes from. We offer them advanced, high-quality European technologies, whilst also delivering technical expertise and support locally – for example, at our Experience Centre in Hyderabad.

Amol Nikam: And it is about more than technical expertise; our team members also understand the local mindset and culture and are attuned to the needs of Indian manufacturers. This makes many things easier and bridges the gap between the requirements of the global and Indian markets.

Sanjeev Nimkar: One of the biggest drivers of our positive growth is the motivation of our Indian team. Everyone here is truly committed to getting the best out of things and helping our customers move forward. I would therefore like to take this opportunity to thank my team. Today, twice as many Romaco machines are in use at customer sites in India as there were eight years ago, and we see this success as an incentive to continue giving our all and to further develop our presence in India.

Meet Romaco at PMEC India, Booth 9A32

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Stevanato Group

INTERVIEW

The businesses that endure will be those that deliver consistently

Abhijeet V. Shetty, Vice President, Transchem Corporation Pharma, discusses the evolving pharma excipients market, customer expectations, sustainable partnerships and the role of service-led growth in India's pharma ingredients business. In an exclusive conversation with **Neha Aathavale**



With over 17 years of experience in the pharma industry, what key shifts have you witnessed in India's pharma ingredients market, particularly in the demand for excipients, and how have these changes shaped your approach to business development?
The market has changed, but the customer's priorities have not changed nearly as much. Excipients have remained a relatively resilient business, supported by their essential role in pharma formulations. What was once a market dominated by a few established players is now increasingly fragmented, with new entrants competing aggressively on price

But there's a difference between being cheaper and delivering better value. Customers need reliable logistics, technical support, help during formulation trials and someone who picks up the phone even after the sale. At Transchem, our focus is simple: don't just win the order; earn the next one.

You currently lead a Rs 330 crore pan-India pharma ingredients business at Transchem Corporation Pharma. What are the key growth drivers for the business, and where do you see the next set of opportunities in India's pharma excipients market?
The next growth story won't be written by whoever has the longest product catalogue, but by whoever serves the customer best. Customised solutions, dependable logistics and consistent service across geographies will be critical differentiators. AI will make customer identification, territory mapping and sales processes smarter, but technology alone cannot build relationships. Markets naturally move through cycles of fragmentation and consolidation. The businesses that endure will be those that deliver consistently, not merely those that acquire the most customers.

As pharma manufacturers increasingly focus on formulation development, product performance and supply-chain reliability, how are customer expectations from excipient suppliers evolving, and what role can distribution partners play in addressing these needs?
Today's customers do not always need another sales pitch. They need someone who knows what they are talking about. Customers are increasingly informed about product grades, alternatives and distribution arrangements. What they value is transparency and expertise. An established manufacturer may need technical troubleshooting, while a growing company may need guidance through a new formulation. A good distributor bridges that gap. The real opportunity is to move from being a supplier of ingredients to a partner in the customer's formulation journey.

Your career has involved building partnerships with global manufacturers and pharma companies. What, in your experience, makes these partnerships sustainable, and how do you balance commercial objectives with long-term customer relationships and ethical business practices?
Ethics isn't a competitive advantage; it's the minimum requirement to stay in business. For me, long-term relationships will always take precedence over short-term commercial gains. Whether dealing with global principals or Indian manufacturers, credibility comes from keeping commitments, communicating transparently and standing by partners when challenges arise. I have always believed that when customers and suppliers trust you, commercial success follows. Revenue is the outcome; relationships are the investment.

You advocate a coaching-led approach to leadership. How has your leadership philosophy evolved over the years, and what does it take to build and retain high-performing commercial teams in an increasingly competitive pharma ingredients market?
Over the years, I've realised that leadership is less about giving instructions and more about understanding what motivates people. With a new generation entering the workforce, I feel this has become even more important. Gen Z, in particular, is often misunderstood. They want to see purpose in their work and know that their contributions matter. I try to help my team understand the business, give them room to bring in fresh ideas and ensure their individual growth aligns with our business goals. For me, a good team is one where people grow with the business, not just work for it.

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INTERVIEW

Beyond capacity: Why manufacturing capability will define the next era of pharma excipients?

Awanindra Kumar Singh, Head of Manufacturing, Sigachi Industries Limited, discusses the evolving role of excipients, India's global competitiveness, engineered excipient technologies, operational excellence and the changing demands of pharmaceutical manufacturing in an exclusive conversation with **Lakshmipriya Nair**



> The next era of manufacturing competitiveness will be defined not by how much capacity companies install, but by how intelligently and reliably they utilise it

Pharma manufacturing is evolving rapidly, with greater expectations around quality, consistency, productivity and regulatory compliance. What does manufacturing excellence mean in this environment?
Manufacturing excellence today goes beyond achieving production targets. It is about consistently delivering products that meet defined quality standards while maintaining process reliability, operational efficiency, safety and regulatory compliance.

In pharma excipient manufacturing, even minor variations in process conditions can influence material characteristics and downstream formulation performance. This makes process control, equipment reliability, documentation and continuous improvement essential.

At Sigachi, we view manufacturing as an integrated system where people, processes, technology and quality work together. Our objective is not simply to manufacture more, but to manufacture consistently, responsibly and efficiently while meeting evolving customer expectations.

What are the key manufacturing challenges and opportunities that you foresee for the pharma excipients industry over the next five years?
The excipients industry is entering a period where functionality, consistency and supply reliability will become increasingly important. As pharma formulations become more sophisticated, manufacturers will be expected to deliver materials that offer predictable performance across different applications and manufacturing environments.

The key challenges will include raw material volatility, increasing regulatory expectations, cost competitiveness and the need to maintain consistent product characteristics at scale. At the same time, demand for functional and multifunctional excipients, co-processed materials and application-specific solutions will create significant opportunities

I believe the next phase of industry growth will favour manufacturers that combine material science, advanced process capabilities, R&D collaboration and dependable manufacturing. The ability to deliver both technical performance and supply assurance will be a defining competitive advantage.

Excipients are often referred to as "inactive" ingredients. How different is manufacturing an excipient from other pharma inputs?
The excipients are not inactive, and these are inert and fully play the critical role in pharma formulations. While they may not provide the therapeutic action, they significantly influence tablet flow, compression, disintegration, stability and drug release.

Manufacturing an excipient therefore requires more than meeting chemical purity specifications. Attributes such as particle size distribution, bulk density, moisture content and flow characteristics must remain consistent from batch to batch because pharma formulators depend on their reproducibility.

At Sigachi, our focus is on manufacturing for functionality, not merely compliance. Our manufacturing and R&D teams work closely to ensure that product characteristics align with customer application requirements. This approach is particularly important as the industry increasingly adopts direct compression, complex formulations and engineered excipient systems.

Pharma formulation development is increasingly moving towards high-performance, multifunctional and coprocessed excipients. How are these changing expectations from excipient manufacturers, and what manufacturing capabilities will differentiate industry leaders?
The industry is moving

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beyond conventional excipients towards engineered materials that offer specific functional advantages, improve processability and support consistent formulation performance. This calls for greater control over manufacturing processes and a deeper understanding of how process parameters influence material attributes.

At Sigachi, our portfolio has evolved beyond conventional MCC to include co-processed excipients, specialty grades and application-oriented solutions. Our DAPO-Bal™ technology reflects this focus on advanced process control and material functionality. Going forward, competitive advantage will depend on the ability to translate formulation requirements into consistent, reproducible manufacturing outcomes and deliver greater value to pharma customers.

India has established itself as a global pharma manufacturing hub, yet the excipients industry faces growing expectations around quality consistency, regulatory readiness and supply reliability. What must Indian excipient manufacturers do differently to become preferred strategic partners for global pharma companies?

India has built considerable strength in pharma manufacturing. The next opportunity is to strengthen its position in high-value pharma inputs, including functional excipients.

To become preferred global partners, Indian excipient manufacturers must compete on more than cost. They need to demonstrate consistent quality, reliable supply, strong documentation, regulatory readiness and the ability to support customers across multiple markets.

Global pharma companies increasingly evaluate suppliers based on their capacity to manage risk, maintain product consistency and support long-term formulation requirements. Manufacturing flexibility and technical responsiveness are therefore becoming as important as production capacity.

At Sigachi, our manufacturing strategy focuses on strengthening process capabilities, expanding specialty-grade manufacturing and improving operational reliability across our facilities. Our international customer engagements also reinforce the importance of understanding market-specific expectations.

I believe India's next competitive advantage will come from moving from being a cost-efficient manufacturing destination to becoming a trusted global partner for quality, technology and dependable supply.

As pharma manufacturers balance capacity expansion with cost competitiveness, how should the industry rethink manufacturing productivity? What role will process optimization, asset utilization, operational flexibility and technology play in driving sustainable growth without compromising quality?

Capacity expansion alone does not guarantee competitiveness. The real measure of manufacturing strength is how effectively an organization converts installed capacity into consistent, quality-compliant and commercially viable output.

Manufacturers must increasingly focus on improving equipment effectiveness, reducing process variability, minimizing unplanned downtime and optimizing resource consumption. Data-driven monitoring, preventive maintenance and cross-functional coordination play an important role in achieving these outcomes.

At Sigachi, we are strengthening manufacturing productivity through process optimization and greater operational flexibility at our Dahej and Jhagadia facilities. Improvements in specialty-grade manufacturing capabilities and production processes are intended to support changing customer requirements while improving asset productivity.

The objective is to achieve higher output without compromising quality, safety or process discipline.

The next era of manufacturing competitiveness will be defined not by how much capacity companies install, but by how intelligently and reliably they utilize it.

With increasing regulatory scrutiny and greater emphasis on supply chain resilience, how can pharma manufacturers move beyond compliance driven operations towards a culture where quality, process safety and operational reliability become long-term competitive advantages?

Compliance sets the minimum standard, while manufacturing excellence requires a proactive commitment to quality, safety and reliability. This is built through robust operating procedures, preventive controls, equipment integrity, workforce training and leadership accountability.

At Sigachi, we continue to strengthen our manufacturing systems through equipment reliability initiatives, Behaviour-Based Safety practices, emergency preparedness, process monitoring and

improved safety infrastructure. Our focus is on identifying risks early and preventing issues before they affect people, products or operations.

Ultimately, quality builds customer confidence, safety protects operational continuity and reliability sustains long-term partnerships. Together, they define manufacturing credibility.

Sustainability is increasingly influencing global pharma procurement and manufacturing decisions. How can manufacturers integrate energy efficiency, water conservation, resource optimization and cleaner technologies into their operations while remaining commercially competitive?

Sustainability and manufacturing competitiveness should not be viewed as competing priorities. In many cases, the same initiatives that reduce environmental impact can also improve operational efficiency and long-term cost competitiveness.

Energy optimization, water conservation, process yield improvement, waste reduction and efficient raw material utilization can deliver measurable operational benefits. The key is to integrate sustainability into manufacturing design and everyday operating decisions rather than treating it as a separate initiative.

At Sigachi, our approach includes improving resource efficiency, strengthening water management practices and evaluating cleaner manufacturing technologies. Our initiatives to optimize energy consumption and reduce dependence on conventional fuels are aligned with our broader sustainability direction.

The industry must increasingly evaluate manufacturing investments not only on production capacity and immediate returns, but also on resource productivity, environmental performance and long-term resilience. Sustainable manufacturing will increasingly be about producing more value with fewer resource. That is both an environmental responsibility and a business imperative.

Looking towards 2030, what fundamental shifts do you foresee in pharma and excipient manufacturing, and how is Sigachi preparing its manufacturing capabilities, technology infrastructure and workforce to remain competitive in an increasingly demanding global market?

By 2030, I expect pharma manufacturing to become significantly more technology-driven, application-oriented and performance-focused.

Three developments will be particularly important: greater adoption of intelligent process controls, increasing demand for functional and engineered materials, and stronger integration of sustainability, quality and supply chain resilience into manufacturing strategies.

For excipient manufacturers, this means moving beyond conventional production capabilities towards more flexible, digitally enabled and technically differentiated operations.

At Sigachi, our priorities are aligned with this direction. We are strengthening manufacturing productivity, expanding our ability to manufacture specialty and co-processed excipients, improving

process reliability and building closer collaboration between manufacturing, R&D and customer-facing teams.

Equally important is developing the next generation of manufacturing talent. Technology delivers its full value only when supported by skilled people, disciplined processes and a culture of continuous improvement.

Our long-term ambition is to build manufacturing capabilities that are safer, smarter, more sustainable and globally competitive, enabling Sigachi to remain a dependable partner to the pharma industry as customer expectations continue to evolve.

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INTERVIEW

How advanced analytics is transforming pharma manufacturing

As India's pharma industry moves towards complex generics, advanced drug-delivery systems and biologics, analytical testing is evolving beyond conventional quality control. In this interview, **Nitin Prabhakar,** MD, Anton Paar India discusses how advanced measurement technologies, aQbD, material characterisation and real-time process monitoring can help pharma manufacturers improve process and strengthen quality systems for its next phase of growth with **Swati Rana**

How are complex generics and advanced formulations changing pharma's analytical testing needs in India?
The shift towards complex generics, novel drug-delivery systems and increasingly sophisticated formulations is changing the role of analytical testing. It is no longer sufficient to establish only the chemical identity or assay of a product. Manufacturers increasingly need to understand its physical and structural behaviour.

Parameters such as particle size and distribution, zeta potential, rheology, viscosity, density, surface characteristics and solid-state structure can directly influence formulation stability, processability, dissolution and, ultimately, product performance.

For Indian pharmaceutical companies competing in highly regulated global markets, the analytical laboratory is therefore moving from being primarily a quality-control function to becoming an important part of formulation understanding, process development and risk reduction.

Where are Indian pharma companies falling short in adopting Analytical Quality by Design (aQbD)?
India has made significant progress in adopting aQbD principles, particularly among large pharmaceutical manufacturers. The opportunity now is to integrate aQbD more deeply into routine development and manufacturing.



> As India's capabilities in biologics and biosimilars expand, analytical characterisation is expected to become an increasingly important component of both research and development (R&D) and quality strategies

A common gap is the transition from collecting analytical data to using that data to understand the relationships between Critical Material Attributes (CMAs), Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs).

For example, understanding how material structure changes during formulation and processing can help establish a more meaningful design space.

Ultimately, aQbD should move analytical science from answering, "Did this batch pass?" to "Do we understand why this process consistently produces the required quality?"
How important is material characterisation in improving formulation performance and batch consistency?

Material characterisation is becoming fundamental to modern formulation science.

Two raw materials may meet the same chemical specifications and still behave differently during processing because their particle size, surface area, porosity, morphology, crystallinity or rheological properties differ.

This becomes particularly important for active pharmaceutical ingredients (APIs), excipients and advanced formulations, where relatively small variations in physical properties can influence mixing, flow, dispersion, dissolution, stability and manufacturability.

By understanding these characteristics during development and monitoring the relevant attributes during production, pharmaceutical companies can identify sources of variability earlier and establish more robust specifications. Better material understanding ultimately leads to better process understanding.

How can advanced measurement technologies improve consistency during manufacturing scale-up?
Consistency during scale-up begins with robust process development. The objective is not simply to reproduce laboratory conditions at a larger scale, but to understand which material and process parameters actually influence product quality.

Advanced measurement technologies help establish this understanding during process development by linking CMAs and CPPs with CQAs. Measurements involving rheology, viscosity, particle size and distribution, density and material

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characterisation can reveal how a formulation responds to changes in shear, mixing, temperature, concentration or raw-material variability.

This allows development teams to define a stronger process window before moving to commercial manufacturing. When material behaviour and process sensitivity are understood early, scale-up becomes more predictable, deviations can be reduced, and batch-to-batch consistency improves.

Ultimately, advanced measurement should support a shift from “scaling up a recipe” to “scaling up a well-understood process.”

Is India ready to move from end-product testing to real-time process monitoring?
India is certainly moving in that direction, although the transition will be gradual.

End-product testing will remain essential, but the larger opportunity is to complement it with at-line, in-line and offline process measurements. Instead of discovering a deviation after production is completed, manufacturers can identify changes while the process is running.

Density, concentration, viscosity and other process-relevant parameters can increasingly be measured closer to the manufacturing process. This creates the foundation for Process Analytical Technology (PAT) and, eventually, more automated process control.

For Indian pharmaceutical companies, the business case is compelling: earlier detection of deviations can reduce rework, improve batch consistency and strengthen process understanding.

How is revised Schedule M influencing investments in analytical instruments and quality-control systems?
Revised Schedule M is accelerating a broader shift from compliance centred primarily on documentation towards compliance supported by robust systems, validated processes, quality risk management and reliable scientific data.

The revised framework places clear emphasis on the Pharmaceutical Quality System, Good Manufacturing Practices (GMP) and Quality Risk Management. Its implementation is also increasing the focus on modern quality systems and reliable data across pharmaceutical manufacturing.

This is encouraging companies to look beyond simply adding laboratory capacity. Investments increasingly need to address instrument qualification, reproducibility, electronic data management, traceability, data integrity and validated analytical workflows.

This modernisation is also receiving policy support. The government's technology-upgradation scheme specifically supports pharmaceutical units upgrading towards revised Schedule M and WHO-GMP standards.

How can mid-sized pharma companies modernise their laboratories while managing costs?
For mid-sized pharmaceutical companies, laboratory modernisation should focus on automation, data integrity and efficiency rather than simply adding more instruments.

Automating routine analytical workflows can reduce manual intervention, minimise transcription errors, improve reproducibility and allow skilled laboratory personnel to focus on higher-value scientific activities. Equally important is ensuring that analytical data is secure, traceable and generated through compliant workflows, particularly as regulatory expectations around data integrity continue to increase.

Companies should therefore evaluate technology based on total cost of ownership and the level of automation and digital integration it provides, rather than acquisition cost alone. Instruments that simplify workflows, automate measurements and calculations, support user management and maintain reliable audit trails can improve both productivity and compliance.

A phased approach, beginning with high-throughput, repetitive or compliance-critical workflows, allows mid-sized laboratories to strengthen data integrity and operational efficiency while keeping modernisation financially sustainable.

How can integrating laboratory and manufacturing data improve quality and reduce deviations?
One of the industry's biggest opportunities is connecting analytical results with what is actually happening during manufacturing.

Traditionally, laboratory data and process data have often existed in separate systems. When evaluated together, they can help companies identify correlations between raw-material properties, process conditions and final product quality.

For example, a change in raw-material particle characteristics may correlate with a change in rheology during processing and subsequently with final product performance.

Creating this analytical chain makes root-cause investigations faster and, more importantly, allows manufacturers to identify trends before they become deviations. The future of pharmaceutical quality will increasingly depend on connected, contextualised and trustworthy data rather than isolated measurements.

What new analytical challenges are emerging as India expands its biologics and biosimilars capabilities?
Biologics introduce a different level of analytical complexity because they are sensitive, structurally complex systems in which aggregation, particle formation and formulation stability can significantly affect performance.

This increases the importance of particle and nanoparticle characterisation, dynamic light scattering, zeta potential, rheology and complementary structural characterisation techniques.

Another challenge is that biologics development requires understanding changes over time rather than relying on a single measurement. Stability, aggregation behaviour and interactions within the formulation need to be monitored throughout development and storage.

As India's capabilities in biologics and biosimilars expand, analytical characterisation is expected to become an increasingly important component of both research and development (R&D) and quality strategies.

Which pharmaceutical segments will drive demand for advanced analytical technologies in India over the next three to five years?

We see several areas with strong potential.

Complex generics and advanced drug-delivery systems will require deeper particle, surface and formulation characterisation. Biologics and biosimilars will increase demand for particle, stability and formulation analysis. API and formulation manufacturing will continue investing in technologies that support process understanding, quality control and regulatory compliance.

We also expect growing analytical requirements around nanoparticle-based delivery systems, lyophilised formulations, injectable products and other high-value formulations, where relatively small changes in material properties can have significant consequences.

At the same time, regulatory modernisation is raising the analytical baseline across the broader pharmaceutical manufacturing ecosystem. India's regulatory framework is increasingly emphasising stronger GMP practices, risk-based oversight, traceability and reliable scientific data.

What is the biggest gap in India's adoption of advanced analytical technologies, and how can the industry address it?
The biggest gap is perhaps not access to technology, but the ability to translate measurement capabilities into meaningful process and material understanding.

India has world-class pharmaceutical scientists, manufacturing infrastructure and increasingly sophisticated laboratories. The next stage is to connect these strengths more effectively.

An advanced instrument creates maximum value when scientists understand which parameter to measure, why it matters to the formulation or process, and how that information should influence a manufacturing decision.

This requires closer collaboration between formulation scientists, analytical teams, manufacturing and quality functions, and technology providers.

At Anton Paar, we see our role extending beyond supplying instrumentation. It is about combining measurement technology with application expertise so that customers can convert accurate analytical data into meaningful scientific and manufacturing decisions.

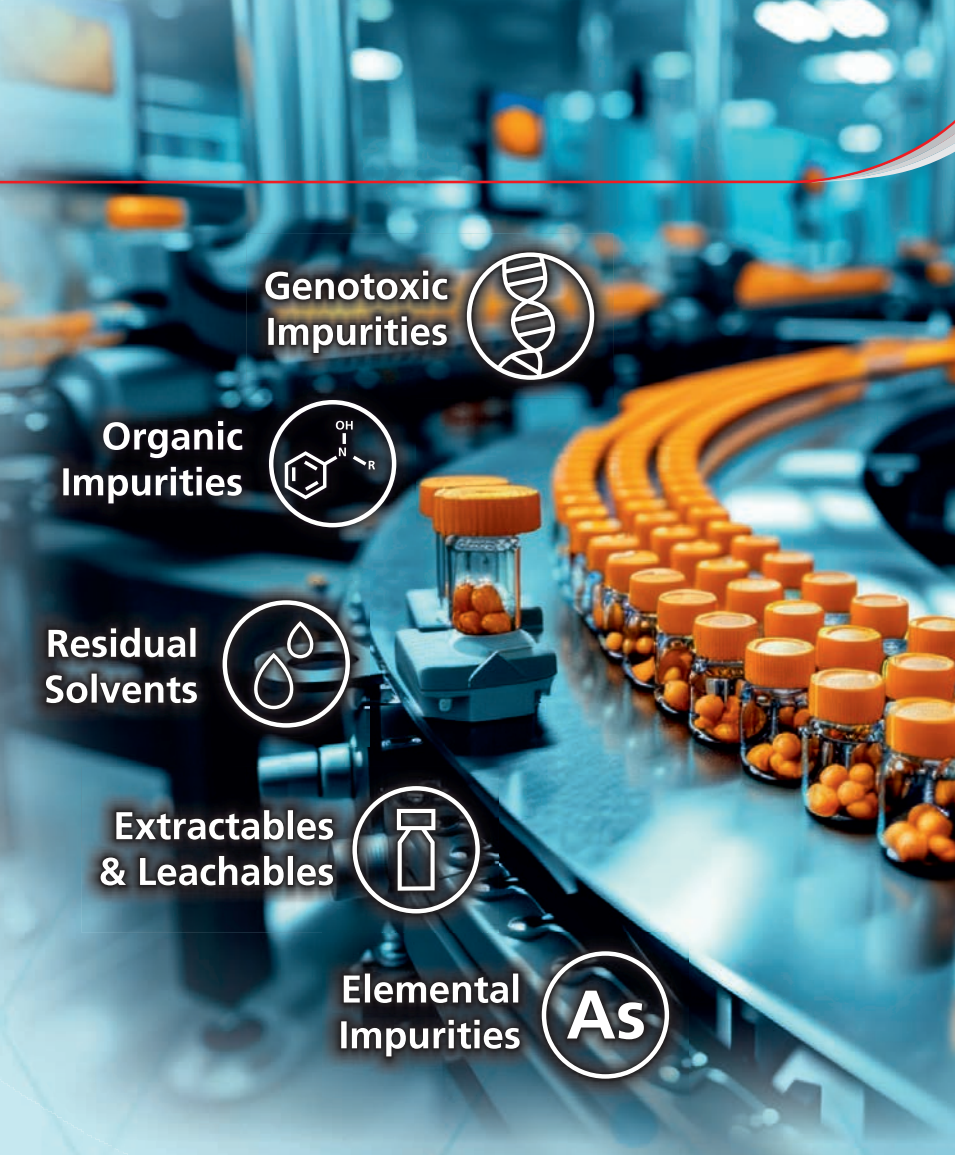
For India's pharmaceutical industry, the transition from testing products to understanding materials and processes will be one of the most important steps towards the next level of quality, innovation and global competitiveness.

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INTERVIEW

India is at the centre of Newtronic's growth strategy

Jignesh Mehta, Director, Newtronic Lifecare Equipment Pvt Ltd, discusses his company's global growth ambitions, its strategic alliance with Memmert and Aralab, upcoming Gujarat facility and plans to strengthen its portfolio of pharma and laboratory solutions, in an interview with **Express Pharma**

What are you most excited to show at CPhI & P-MEC this year, and what problem does it solve for your customers?
At CPhI & P-MEC 2026, we are excited to showcase Newtronic's expanding portfolio of pharmaceutical stability testing and controlled-environment solutions, supported by our growing international collaborations.

An important part of our journey is the strategic alliance between Newtronic, Memmert and Aralab. By bringing together complementary engineering capabilities, technological expertise and market knowledge, we aim to offer customers a broader range of solutions and access to international best practices.

Our portfolio includes stability chambers, humidity chambers, photostability chambers, walk-in stability chambers, deep freezers, environmental chambers and customised laboratory solutions. Recently added large cold rooms and clean room products like Autoclave, Biosafety Cabinets and Laminar Flow.

Our objective is to help pharmaceutical and biotechnology companies address increasingly demanding requirements for regulatory compliance, environmental control, data integrity and operational reliability.

What's the biggest change you're seeing in pharma right now? How is it shaping your plans?
The pharmaceutical landscape is undergoing a profound transformation driven by an increasing demand for dependable environmental control systems, strict alignment with international regulatory compliance, and cost-effective operational excellence. As global standards evolve, pharmaceutical manufacturers are prioritizing tailored solutions and trusted strategic partnerships to navigate complex regulatory environments and ensure data integrity. Concurrently, India is solidifying its position as a premier global hub for advanced manufacturing and technological innovation, leveraging strong engineering capabilities and international collaborations to deliver world-class products to the global market.

At Newtronic, this macro shift is directly shaping our core strategic priorities. We are heavily investing in next-generation technology development, systematic process improvement, and comprehensive after-sales support designed specifically for complete customer delight. By focusing on continuous innovation, stringent quality controls, and expanded service capabilities, we strive to retain customer trust at every single level. Our goal is to empower pharmaceutical companies worldwide by providing world-class products and reliable services at accessible, highly affordable prices.



> Our next phase of growth will be driven by international expansion, product diversification, technological collaboration and increased manufacturing capabilities

Where will your next phase of growth come from? What will it take to get there?
Our next phase of growth will be driven by international expansion, product diversification, technological collaboration and increased manufacturing capabilities. We will be inaugurating our new production facility in Gujarat. Spread in 8.5 acres with world class production facilities and lean manufacturing, we will be manufacturing world class products with speed, accuracy and reliability.

A significant element of this strategy is our alliance with Memmert and Aralab. We see tremendous potential in combining the strengths of three organisations with complementary capabilities and geographical reach.

Memmert brings its German engineering heritage and expertise in temperature-control technology, while Aralab contributes its European experience in environmental testing and specialised climatic solutions. Newtronic brings strong Indian manufacturing capabilities, pharmaceutical industry understanding, an established customer base and an extensive service network.

Together, this combination creates opportunities to expand product offerings, exchange technological expertise, strengthen international market access and develop solutions for evolving customer requirements.

Our ambition is to create a globally competitive platform that combines the best of European technological expertise with India's manufacturing capabilities and growth potential.

How does India fit into your

growth story?
India is at the centre of Newtronic's growth strategy. It is our manufacturing base, engineering hub and the foundation of our international ambitions.

Through our alliance with Memmert and Aralab, we also see an opportunity to strengthen India's position as a global manufacturing and technology destination.

We believe the future of the industry will increasingly involve international collaboration, where engineering knowledge, manufacturing capabilities and market expertise are brought together across geographical boundaries.

Our vision is to leverage this collaboration to create world-class products and solutions from India, serve international markets and establish Newtronic as a globally recognised Indian engineering brand.

Five years from now, what will the leaders in your space be doing differently?
Five years from now, we believe the laboratory equipment industry will look significantly different. The leaders will not simply be those who manufacture reliable equipment, but those who successfully combine engineering excellence, digital intelligence, sustainability and global collaboration.

We see four major developments shaping the industry.

First, smart and connected equipment will become increasingly important. IoT-enabled monitoring, remote diagnostics, predictive maintenance, advanced data analytics and AI-assisted systems will transform how laboratory equipment is operated and maintained. Customers will expect greater visibility, traceability and control over their equipment.

Second, sustainability will become a competitive differentiator. Energy-efficient refrigeration systems, low-GWP refrigerants, better insulation technologies and intelligent energy management will become essential considerations in equipment design and manufacturing.

Third, global collaboration will accelerate innovation. No single manufacturer will necessarily have all the technologies, capabilities and market access required to serve every customer segment. Strategic alliances combining European engineering expertise with Indian manufacturing capabilities and international market reach will create new opportunities. Our collaboration between Newtronic, Memmert and Aralab reflects this philosophy.

Finally, customer expectations will move beyond equipment ownership towards lifecycle partnerships. Customers will look for manufacturers who can provide application expertise, installation, validation support, preventive maintenance, refurbishment and dependable service throughout the equipment's operating life.

At Newtronic, we believe the next five years will be about moving from being equipment manufacturers to becoming technology-driven solution providers and long-term partners to the pharmaceutical and scientific industries.

Our belief is that the future leaders will be those who combine the best of engineering, technology and customer trust.

Who would you love to meet at CPhI & P-MEC, and what would a great partnership look like?
We would particularly like to connect with pharmaceutical manufacturers, CDMOs, biotechnology companies, vaccine manufacturers, laboratory infrastructure providers, international distributors and technology partners.

Our alliance with Memmert and Aralab also reflects our belief in the importance of strategic international collaborations.

We are interested in developing relationships with organisations that share our vision of innovation, engineering excellence and long-term customer commitment.

A great partnership is not simply about selling products. It is about combining complementary strengths, sharing knowledge, developing new opportunities and creating sustainable value for customers and partners.

We are open to international distribution, OEM manufacturing, technology exchange, joint product development and strategic collaborations.

What's one thing you'd like visitors to remember about your company after CPhI & P-MEC?
We would like visitors to remember Newtronic as more than just a manufacturer of pharmaceutical and laboratory equipment. We want them to recognise us as a trusted engineering partner committed to reliability, innovation and long-term customer relationships.

Our philosophy is simple: we don't just manufacture equipment; we build confidence that lasts for decades.

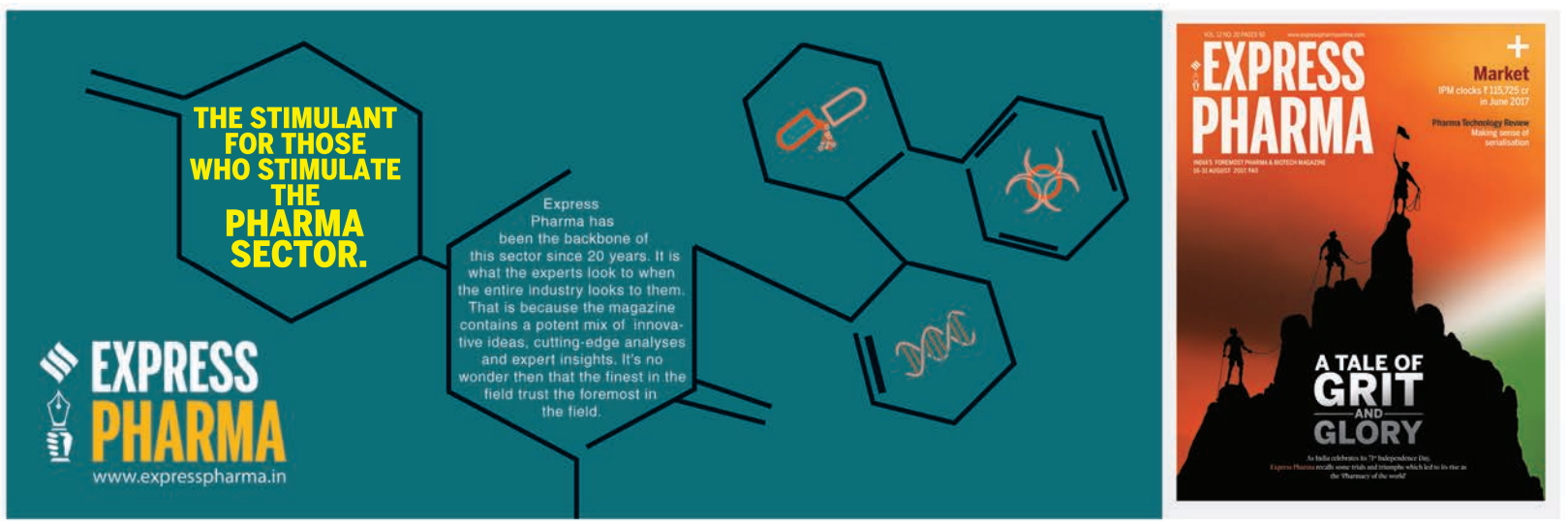
We have customers whose Newtronic stability chambers and environmental testing equipment have been operating reliably for more than 14–15 years. In some facilities, newly installed Newtronic equipment operates alongside machines supplied by us more than a decade ago. This is a reflection of our engineering philosophy and commitment to product longevity.

With more than 6,000 machines under annual maintenance contracts and a nationwide network of over 150 field service engineers, we understand that customer support is just as important as the equipment itself.

Our growing international collaboration with Memmert and Aralab further strengthens our vision of combining Indian manufacturing capabilities with European engineering expertise to serve customers globally.

Ultimately, we want visitors to remember one message: Newtronic is an Indian engineering company with a global vision, a strong commitment to quality and the ambition to become a trusted global name in pharmaceutical and laboratory equipment.

Newtronic is The Name You Can Trust



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Building pharma technology that evolves with your business

AmpleLogic's approach to unified GxP applications brings together industry-ready software, low-code flexibility and AI-powered customisation to help pharmaceutical companies innovate with confidence

What happens when a pharmaceutical company's processes evolve faster than the software supporting them? It is a challenge many organisations encounter as they expand operations, introduce new products, respond to changing regulatory expectations and pursue digital transformation. Technology implemented to meet today's requirements must also accommodate tomorrow's needs. Yet conventional enterprise software can make that evolution difficult, often requiring extensive customisation, additional applications or lengthy development cycles. For pharmaceutical companies, the question is no longer simply whether a system can digitise a process, but whether the technology can continue adapting as the business grows without compromising compliance, reliability or operational control.



Venkanna Chowdary Manne, CEO, AmpleLogic

Building a more adaptable digital foundation

Pharmaceutical operations depend on closely connected activities across quality, manufacturing, laboratories and regulatory affairs. Although individual applications address specific business requirements, managing these functions through disconnected systems can lead to duplicated effort, fragmented information and greater maintenance complexity. A unified GxP platform offers an alternative by bringing multiple applications into a common technology environment, enabling more consistent workflows, improved information accessibility and better coordination across departments. At AmpleLogic, this philosophy guides the development of our unified AI-powered low-code/no-code platform, which supports industry-specific applications across critical pharmaceutical functions while providing a foundation for future expansion.

However, a unified platform alone is not enough. Pharmaceutical organisations need software that understands the operational realities of their industry while accommodating differences in business processes, organisational structures and internal procedures. Industry-ready applications provide established functionality and preconfigured workflows that can accelerate implementation, but the ability to adapt those applications is equally important. Low-code/no-code technology helps bridge this gap by allowing organisations to configure workflows, forms, business rules and other functional elements without treating every requirement as a major development project. This flexibility becomes particularly valuable as companies expand into new markets, introduce additional product lines or refine their operating models.

In a regulated environment, adaptability must always be balanced with control. Changes to GxP applications require appropriate governance, testing, validation and documentation, regardless of how easily those changes can be configured. The objective is not unrestricted customisation, but controlled flexibility that allows technology to evolve alongside business requirements while maintaining the integrity of regulated processes. When industry-ready functionality and configurable technology operate within a governed environment, organisations can respond more effectively to change without repeatedly rebuilding their digital foundations.

Bringing practical AI into GxP operations

Artificial intelligence introduces another dimension to enterprise technology by making applications more responsive to users and business requirements. Its potential extends beyond analytics and reporting into how organisations configure software, manage information and support operational decisions. At AmpleLogic, natural-language-driven AI customisation capabilities are already part of our approach to simplifying enterprise application configuration. By making technology more accessible to business users, these capabilities can help reduce the effort involved in translating operational requirements into application changes, while preserving the governance needed in regulated environments.

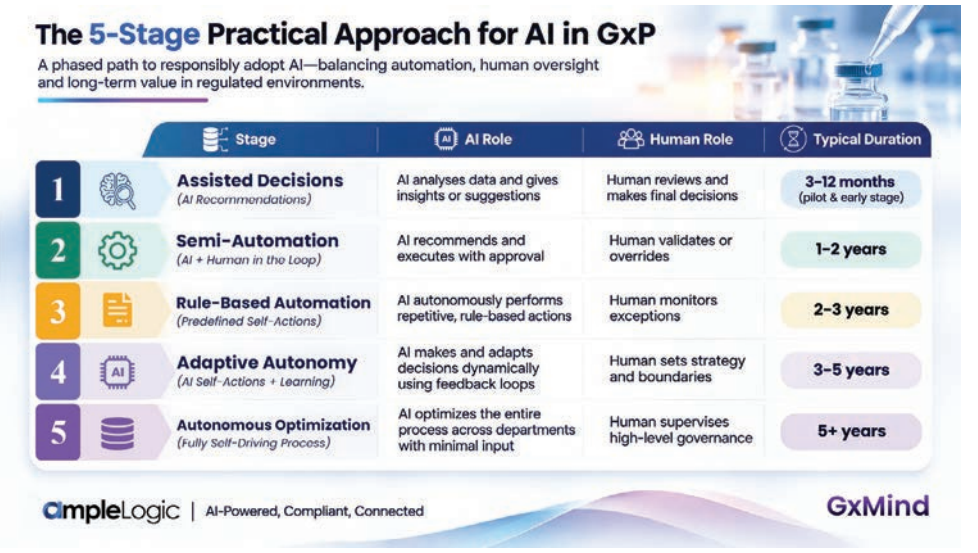


Figure: A phased approach to AI adoption in regulated pharmaceutical operations, illustrating increasing automation alongside appropriate human oversight

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However, introducing AI into pharmaceutical operations requires a measured approach. The objective should not be to automate every activity immediately, but to identify where intelligent capabilities can deliver meaningful improvements while maintaining appropriate human oversight. Organisations need to consider data quality, process criticality, regulatory impact and the controls required for each use case. A phased approach provides a practical way to build confidence and maturity, beginning with AI-assisted decisions before progressing toward greater levels of automation where justified.

AmpleLogic's five-stage practical approach to AI adoption in GxP environments illustrates this progression, moving from assisted decision-making and semi-automation through rule-based automation and adaptive autonomy toward autonomous optimisation. Rather than prescribing a fixed timeline, the framework encourages organisations to evaluate their readiness and introduce capabilities according to business value, technical maturity and regulatory risk. Human involvement remains essential, although the nature and extent of oversight may evolve as systems become more capable and processes demonstrate the reliability needed for greater autonomy.

Supporting business growth without technology constraints

As pharmaceutical organisations grow, their digital requirements rarely remain static. A company may initially focus on quality management or document control and subsequently extend its technology environment into laboratory operations, manufacturing execution, product quality review or regulatory management. A unified platform allows these capabilities to develop within a broader technology architecture rather than creating another collection of isolated applications. This approach can simplify long-term system management while supporting greater consistency and information sharing across business functions.

Deployment flexibility also plays an important role in long-term technology decisions. Pharmaceutical companies differ in their infrastructure strategies, security requirements, operating environments and internal IT capabilities. Supporting appropriate hosting and deployment models allows organisations to align technology investments with their operational priorities rather than forcing business requirements to conform to a rigid software architecture. Combined with configurable applications and an extensible platform, this flexibility helps organisations make technology decisions that remain relevant as their businesses evolve.

Ultimately, the future of pharmaceutical enterprise technology will depend on how effectively industry-specific functionality, low-code flexibility, connected applications and practical AI can operate together within a controlled environment. For technology providers, this requires looking beyond individual features and understanding how pharmaceutical businesses change over time.

For pharmaceutical organisations, it means investing in digital foundations that support current operational and regulatory requirements while remaining adaptable to future opportunities.

At AmpleLogic, we believe the real value of enterprise technology lies in how easily it can evolve with the business, without compromising the reliability and control that pharmaceutical operations demand.

INTERVIEW

We are shaping Arihant into a scientifically driven organisation

Jinesh Shah, MD, Arihant Innochem, discusses the company's growth journey, its expansion across the lifesciences sector and how its pharma and nutra application lab will shape its future focus in science, innovation and partnerships with **Express Pharma**

How has Arihant Innochem evolved since it was first founded?
Arihant Innochem was founded three decades back with a dream, a dream to build something enduring and meaningful. While staying true to our founding values, we have worked to grow the business with the changing times and transform Arihant into a scientifically driven organization in the specialty ingredient space. Today we represent global manufactures and are present in all the Lifesciences verticals as a leading distributor in India and neighbouring countries.

Which industries and segments does Arihant Innochem currently serve?
We are firmly established in Pharmaceuticals as well as Personal and Home care sectors. We are steadily expanding into Nutraceuticals, Injectables, and Biopharma which are the sectors of the future. Through our diverse portfolio of excipients and value-added ingredients, we serve across the Lifesciences space.



What makes the launch of Arihant Innochem Research and Innovation lab a defining moment in the growth story of Arihant Innochem?
The launch of our Pharma & Nutra application lab marks a major milestone built on vision, perseverance, and strong partnerships. It represents a key step forward in our growth story as a leader in Lifesciences sector.

You already had an application lab for personal care in Mumbai. How was your experience and how did the first application lab in Mumbai impact the business?
Setting up our personal and home care application lab in Mumbai a few years ago completely transformed how we engage with customers. By developing prototypes and proof of concepts, we built stronger relationships and demonstrated the true potential of our ingredients.

Why did you decide to open a pharma and nutra application lab now?
With excipients taking centre stage globally, the timing was right to invest in dedicated pharma and nutra capabilities. This facility is much more than just infrastructure—it is a symbol of innovation, collaboration, and value creation.

What does this new lab offer to your partners and customers?
Backed by a highly qualified scientific team, this is essentially a lab for our principals and customers. It serves as a collaborative space for our partners to expand, innovate, and explore new horizons together.

What role have your Principal partners played in Arihant's success?
Whether they have been with us since day one or joined hands with us more recently, our Principal partners are vital to our growth. Each one embodies trust, quality, and commitment—the three pillars on which Arihant stands tall. Our transparent association with our principals is the strength of our business.

What comes next for Arihant Innochem following this launch?
This lab is the beginning of a new chapter in our growth story. It reaffirms our commitment to science, partnership, and shaping the future of specialty ingredients. This will help us bring concepts to reality and shape our technical vision for the future.

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AI and Automation Redefine Pharma Manufacturing

Industry leaders from Amneal Pharmaceuticals, Mankind Pharma, Piramal Pharma Solutions and OneSource discuss predictive maintenance, digital integration, process control and the role of human expertise in pharmaceutical manufacturing

Connecting automation, digitalisation and analytics to predict pharma manufacturing risks

Anurag Chauhan, Deputy General Manager - Digitalisation, Automation, Analytics, Amneal Pharmaceuticals

In my experience leading digitalisation, automation and analytics initiatives across pharmaceutical manufacturing sites, the real opportunity is not just to automate machines or create more dashboards, but to connect the entire manufacturing ecosystem so that we can identify risks much earlier and support faster, more informed decisions.

The starting point is connectivity. Equipment and process-control systems such as PLC, SCADA, DCS, BMS and utility systems need to be integrated with higher-level platforms such as MES, LIMS, e-logbooks, historians and enterprise data platforms. Once this data is connected and contextualised, manufacturers can move from simply monitoring what is happening to understanding what may happen next.

We have seen this in our own projects. In predictive maintenance, continuous monitoring of vibration, temperature and other equipment parameters helps identify abnormal patterns before they result in failure or unplanned downtime. Similarly, initiatives such as centralised SCADA/L2 integration, MES, digital logbooks and asset lifecycle management create the data foundation needed for advanced analytics.

The next step is to combine process and quality data. Projects such as Golden Batch Analytics and advanced yield analytics can compare historical batch performance, process parameters and quality outcomes to identify operating windows and early signs of process drift. AI-based use cases can further support faster review and exception-based decision-making.



> The real opportunity is not just to automate machines or create more dashboards, but to connect the entire manufacturing ecosystem so that we can identify risks much earlier and support faster, more informed decisions

For greenfield projects, we are now designing this integration from the beginning—connecting equipment, control systems, MES, data platforms, analytics and Operation Control Tower as one architecture. For brownfield plants, the approach is more pragmatic: connect critical assets first, demonstrate value, and then scale.

At the same time, regulatory compliance, validation, cybersecurity and data integrity must be built into the design—not added later. Equally important is preparing Operations, Engineering, Quality and IT teams to trust and act on the insights.

The goal is simple: move from monitoring production to predicting deviations, anticipating failures and enabling timely, controlled intervention.

Mankind Pharma standardises automation across 32 manufacturing facilities

Abhay Kumar Srivastava, Senior President – Operations, Mankind Pharma

As pharmaceutical companies expand across multiple manufacturing facilities, the challenge is not simply deploying more automation, but ensuring that automation delivers consistent quality, regulatory compliance and operational excellence across diverse manufacturing environments. While dosage forms, equipment configurations and process complexities may differ from site to site, the underlying automation philosophy and governance framework should remain common. A practical approach is to standardise automation at the enterprise level while allowing process-specific flexibility at individual plants.

At Mankind Pharma, this approach is supported by a network of 32 manufacturing facilities and the continued advancement of digital systems across manufacturing and quality. This year, we brought our Laboratory Information Management System (LIMS) live, while Document Management Systems (DMS), Annual Product Quality Review (APQR) tools, electronic logbooks, Environmental Monitoring Systems (EMS) and electronic batch manufacturing record (eBMR) platforms continued to advance across our network. Digital planning, warehouse management and integrated sample management systems are also helping bring greater consistency to planning and execution across plants and depots.



Technology alone, however, is not enough. Strong quality systems and continuous process improvement are equally important. Our Quality by Excellence (QbX) framework, supported by Lean, Kaizen and Six Sigma methodologies, has seen more than 400 projects identified across sites. These efforts reinforce process discipline and support improvements in manufacturing performance.

Ultimately, the future of pharmaceutical automation lies in creating smart, connected and autonomous manufacturing ecosystems where machines, systems and people work seamlessly together. By standardising core automation platforms while retaining flexibility for product- and process-specific needs, organisations can improve quality, productivity, compliance, resilience and customer responsiveness—ensuring that every manufacturing site consistently delivers safe, high-quality medicines to patients worldwide.

The future of pharmaceutical automation lies in creating smart, connected and autonomous manufacturing ecosystems where machines, systems and people work seamlessly together



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AI and connected digital systems to shape the future of pharma operations

Surinder Gulati, Executive Vice President - Manufacturing, Piramal Pharma Solutions

Looking ahead, the most significant impact on Indian pharmaceutical operations will come from the convergence of automation, artificial intelligence (AI), advanced analytics, and connected digital ecosystems. While automation has traditionally focused on improving efficiency on manufacturing lines, the next wave of transformation will extend across the pharmaceutical value chain, from R&D and technology transfer to manufacturing, quality, supply chain, and customer engagement.

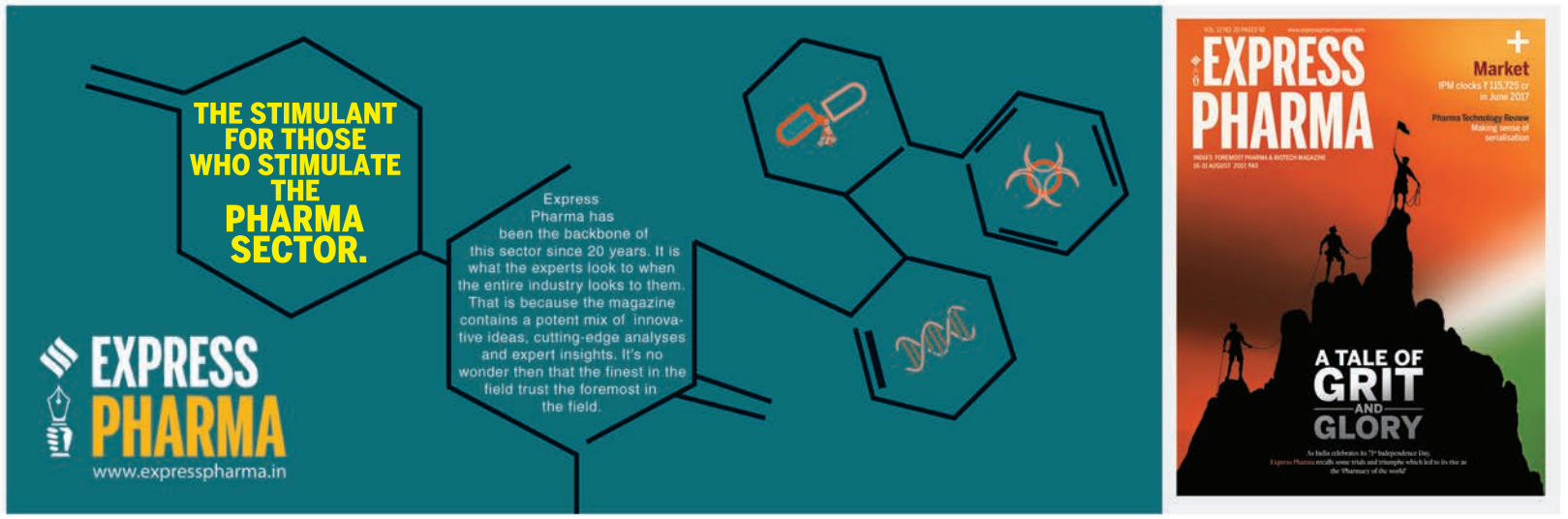
Globally, the industry is progressing toward Pharma 4.0, where AI, digital twins, robotics, industrial IoT, and real-time data platforms enable faster, more informed decision-making. Pharmaceutical companies are increasingly leveraging these technologies to optimise processes, improve yields, predict equipment failures, accelerate investigations, strengthen quality performance, and move from reactive to predictive operations.

At Piramal Pharma, we believe the greatest opportunity lies not simply in automating tasks, but in augmenting decision-making across the enterprise. Emerging capabilities such as AI-assisted deviation investigations, predictive quality management, intelligent manufacturing optimisation, digital twins, and autonomous planning and scheduling have the potential to significantly enhance compliance, right-first-time performance, and operational agility. AI-enabled scientific workflows, including route scouting, reaction yield prediction, process optimisation, and automated technical documentation, can further accelerate innovation and improve productivity.



> The future of automation in pharma will be less about replacing human effort and more about amplifying human expertise

Our ongoing AI transformation journey reinforces that the highest value will come not from isolated pilots, but from scaling these capabilities across laboratories, manufacturing facilities, quality systems, supply chains, and commercial operations through an integrated digital ecosystem. We also see significant potential in AI-enabled supply chain resilience, where AI can anticipate disruptions and enable earlier, more effective interventions. In parallel, agentic AI can help orchestrate complex CDMO programs by monitoring dependencies across customer projects, manufacturing, quality, procurement, and supply chains, identifying bottlenecks early and helping information, decisions, and materials move seamlessly across the value chain.



Automation and human expertise to drive India's biologics manufacturing

Dr Huzaifa S. Choonia, AVP and Head, Biologics Tech Transfer & MSAT, OneSource

India's recognition as the 'pharmacy of the world' has been established through its manufacturing capabilities, cost competitiveness and ability to supply quality medicines at scale. With the recent changes in regulatory guidelines and geo-political landscape, particularly for biologics and other advanced therapeutics, automation is expected to play a pivotal role in strengthening manufacturing reliability, process consistency and global competitiveness.

Industry 4.0 focuses heavily on digitalisation and automation to ensure better control of CPPs enabling greater batch-to-batch consistency (CQAs), process robustness (performance attributes) and continued process verification.

However, automation alone cannot eliminate inherent biological variability or compensate for inadequate process understanding. Human expertise remains indispensable in interpreting complex process behaviour, investigating atypical trends, assessing unforeseen risks and making scientifically justified quality decisions.

This drives India towards Industry 5.0, with 5 core pillars:

1. Human-Machine collaboration, that introduces collaborative robots ("cobots") to handle repetitive, heavy, or hazardous tasks, while human operators focus on high-level problem-solving, quality oversight, and ethical decision-making.

2. Hyper-Personalised medicine, where production shifts from one-size-fits-all to small-batch, targeted therapies and treatments tailored to a patient's exact genetic profile

3. Environmental sustainability, with green chemistry, renewable energy, and circular manufacturing as core operating principles

4. Resilient, patient-connected supply chains that help organisations adapt quickly to global disruptions, raw material shortages, or shifting clinical demands

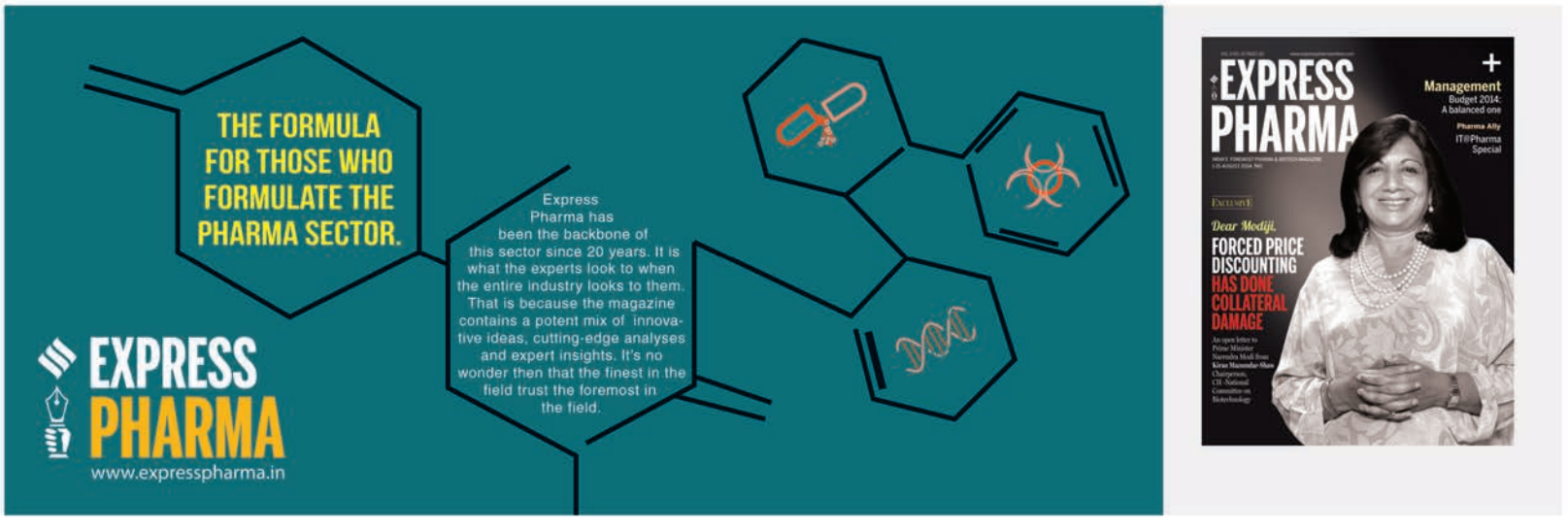
5. Ethical & transparent AI, with guiding principles from agencies like the U.S. FDA and European Medicines Agency for drug discovery, CMC and clinical approaches



> Automation alone cannot eliminate inherent biological variability or compensate for inadequate process understanding

Additionally, for Indian manufacturers, considerations such as capital investment, integration with legacy infrastructure, data integrity, regulatory compliance and workforce readiness are particularly relevant.

Finally, India's competitive advantage will increasingly depend not merely on adopting automation, but also on a phased, risk-based implementation strategy, prioritising processes where automation can deliver measurable improvements in quality, efficiency and reliability, is likely to provide more sustainable benefits.



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Pharma cold chain
Is India ready for what's next?

With biologics and temperature-sensitive therapies reshaping logistics requirements, **Swati Rana** speaks to industry experts on the infrastructure, technology and supply-chain capabilities India needs to ensure product integrity.

India's pharma industry is entering a new phase of growth, with increasing capabilities in biologics, biosimilars, vaccines, specialised injectables and other temperature-sensitive medicines. As the country strengthens its position as a global pharma manufacturing hub, the need for reliable, efficient and technology-enabled cold-chain infrastructure is becoming increasingly important. Ensuring product integrity from manufacturing and storage to transportation and last-mile delivery is now a critical part of pharma quality and supply-chain management.

The requirements for pharma cold-chain logistics are becoming more complex. While conventional medicines may require standard temperature-controlled storage, advanced biologics and certain specialised therapies demand ultra-low-temperature conditions, validated packaging and highly controlled transportation environments. Maintaining these conditions throughout a product's journey is challenging, particularly when shipments pass through multiple logistics partners, warehouses, airports, ports and distribution facilities.

India has made considerable progress in developing its cold-chain infrastructure, particularly for products requiring storage between 2°C and 8°C. Major pharma hubs have access to temperature-controlled warehouses, refrigerated transportation and established distribution networks. However, the availability of specialised infrastructure for products requiring temperatures of -60°C to -80°C or even lower remains more limited. Moreover, infrastructure and service capabilities are not equally distributed across all regions, creating challenges for manufacturers operating beyond established pharma centres.



The challenge extends beyond storage capacity

Even when products leave manufacturing facilities under validated temperature conditions, their integrity can be affected during transportation, handling and transfer between logistics partners. Airport cargo terminals, customs clearance procedures, port operations and last-mile delivery can introduce potential points of temperature exposure. Delays in unloading, inadequate temperature-controlled handling areas, power interruptions in refrigerated containers and inefficient coordination between stakeholders can increase the risk of temperature excursions.

For pharma exporters, these operational challenges are further compounded by the stringent documentation and compliance requirements of international markets. Equipment qualification, validated packaging systems, continuous temperature records and documented excursion assessments are increasingly important for demonstrating product integrity. Any gap in documentation or monitoring can result in shipment delays, product quarantine or rejection, adding to costs and affecting customer confidence.

End-to-end visibility and accountability

Traditional temperature monitoring, which often provides information only at specific stages of the shipment, may not be sufficient for increasingly complex pharma products. Manufacturers need greater visibility across the entire supply chain, including the ability to track shipment location, temperature and other relevant environmental conditions in real time. IoT-enabled sensors, GPS-integrated data loggers, automated alerts and cloud-based monitoring platforms can help identify potential disruptions and support timely corrective action. However, technology must be supported by clearly defined responsibilities, standardised operating procedures and coordination among manufacturers, logistics providers and distributors.

Cost is another important consideration. Temperature-controlled logistics involves higher transportation, packaging, warehousing and monitoring expenses than conventional supply chains. The selection of active or passive packaging, use of phase-change materials, improved payload utilisation, strategic route planning and the adoption of suitable ocean reefer transportation can contribute to greater efficiency. At the same time, investments in validated infrastructure, backup systems and specialised transportation remain essential to minimise the financial impact of product losses and temperature excursions. The changing requirements are also creating investment opportunities across pharma-grade warehousing, cold-chain packaging, specialised transportation and digital monitoring. Emerging technologies such as artificial intelligence, predictive analytics, digital twins and advanced traceability systems could further strengthen supply-chain planning and risk management. Equally important will be investments in trained personnel and standardised handling practices, particularly at critical transfer points and during last-mile delivery.

As the industry expands into increasingly complex medicines and export markets, the ability to maintain uninterrupted temperature integrity across the entire supply chain will become a key measure of competitiveness and reliability.

To understand how well India's pharma cold chain is equipped to meet these evolving demands, read the perspectives of industry experts below in the interviews with Swati Rana.

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India's pharma cold chain: Strengthening supply-chain reliability

Deeppak Khurana, Vice President SCM, SCL Lifesciences



How well equipped is India's cold-chain infrastructure to handle increasingly complex pharma, including products that require ultra-low-temperature storage and transport?
In my view, India's pharma cold chain has advanced considerably over the past decade, particularly for products stored at 2°C to 8°C. Major logistics providers, airports and pharma hubs are now reasonably well equipped. This provides a strong foundation, but readiness for increasingly complex medicines remains uneven. Capabilities for ultra-low-temperature products, advanced biologics, cell and gene therapies, and highly sensitive specialty medicines are still developing. The distinction is between having capacity at key locations and maintaining consistent conditions throughout a product's journey. Storage, transport and handovers must work together reliably; strength in one part of the network does not resolve gaps elsewhere. Capacity remains concentrated in a few major cities, while service consistency across the wider network remains a challenge. Supporting the next generation of pharma therefore requires more than additional infrastructure. Greater standardisation and broader geographic coverage are equally important. The priority is to build on existing progress while making reliable cold-chain services available beyond the principal pharma hubs.

How serious are the operational and financial risks from product losses, shipment delays and temperature excursions? Where is improvement most urgent?
Product losses, shipment delays and temperature excursions are among the pharma supply chain's most serious operational and financial risks. A single temperature excursion can compromise product quality, raise regulatory concerns and cause substantial losses. Delays can also restrict patient access and undermine customer trust. These risks should therefore be considered together rather than treated as isolated logistics problems. Despite stronger compliance and monitoring, gaps persist in last-mile delivery, handovers between logistics partners and real-time shipment visibility. These are the areas where improvement is most urgent: a shipment needs consistent oversight across its entire journey, not only while it remains with one provider. Priorities include end-to-end monitoring, consistent adherence to procedures, predictive risk management and workforce training. Monitoring and procedures need to reinforce each other so that visibility supports a coordinated response to potential disruption. Closer coordination among manufacturers, logistics providers and distributors is equally important. A shared focus on product integrity and timely delivery can help reduce preventable disruptions while protecting patient access and customer confidence.

What new investment opportunities are emerging in pharma-grade warehousing, cold-chain packaging, digital monitoring and specialised transport?
I see substantial investment potential across pharma-grade warehousing, cold-chain packaging, digital monitoring and specialised transport. The strongest opportunity lies in connecting these capabilities rather than developing them in isolation. pharma-grade warehouses with automated temperature controls, validated storage conditions and scalable capacity will continue to attract investment. Their value is closely linked to how effectively they support the wider distribution network. Demand is also rising for high-performance, reusable packaging that offers longer thermal protection alongside sustainability benefits. Digital monitoring provides another avenue through growing adoption of IoT sensors, real-time tracking, analytics and exception-management platforms. These capabilities complement physical infrastructure by improving shipment visibility and supporting the management of disruptions. Specialised transport, particularly dedicated pharma fleets and validated air and road services, is also poised for strong growth. Together, these opportunities point toward a more integrated cold chain. Combining suitable storage, protective packaging, specialised transport and digital visibility offers the clearest route to a more reliable, compliant and patient-focused supply chain.

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Addressing cold-chain challenges: Improving pharma logistics efficiency

Amit R Goyal, Director, Tempnote

What challenges do Indian pharma exporters face in meeting the cold-chain handling and documentation requirements of international markets?

Indian pharma exporters operate in a high-stakes environment where a single temperature deviation can lead to the destruction of multi-million dollar life-saving batches. Achieving seamless, international-grade cold-chain compliance requires navigating a complex mix of harsh environmental realities, severe terminal bottlenecks, and uncompromising digital documentation standards.



1. Hard ground-level operational & infrastructure challenges

The "Last Pallet" sequential processing vulnerability: When a refrigerated truck carrying sensitive 2–8°C biopharma docks at an airport Cargo Service Center (CSC), hot ambient air instantly rushes into the truck bed. Because pallets must be unloaded sequentially, each pallet undergoes a multi-step manual process: unloading, manual weighing, manual dimensioning, and X-ray scanning. Even a fast team taking a maximum of 40 minutes to unload a 10-pallet truck structurally guarantees that the final pallets sit trapped in an escalating heat zone for nearly an hour, risking critical thermal shock.

- **Redundant terminal workflows:** Exporters frequently lease active air containers (like Envirotainers) on a flat, lump-sum freight cost basis. Despite buying the entire aircraft space as a complete unit, airport terminals still mandate individual pallet weighing and dimensioning. This legacy workflow adds zero commercial value but keeps sensitive biologicals exposed to ambient temperatures for longer periods.
- **The port gate & vessel loading vacuum (Sea Freight):** In ocean freight, cargo is safe while protected by the truck's generator set (genset) up to the port gate. However, port authorities routinely mandate that gensets be switched off immediately upon entry due to noise-pollution regulations. The container is grounded and left without power for a 2 to 10-hour vacuum before being plugged into the port grid. A secondary thermal break occurs during vessel loading, where the container is unplugged from the port grid, craned, and stowed on the ship—a process that routinely takes several hours in peak summer heat.
- **Destinational infrastructure deficits:** Thermal breaks are not unique to origin ports. Several destination airports and warehouses across the US and EU lack the specialised infrastructure required to dock or support active air containers. This forces handlers to open the Envirotainers on ambient docks and hastily transfer loose cargo into refrigerated trucks, exposing the product to unmonitored atmospheric conditions.

Regulatory & documentation disparities

- **The air vs. ocean factory stuffing disparity:** Indian Customs allows empty 20ft and 40ft ocean reefer containers to be brought directly to an exporter's manufacturing unit for secure factory stuffing within a controlled 2–8°C environment. Conversely, Customs prohibits active air units (Envirotainers) from being taken to manufacturing warehouses. Exporters are legally forced to transport sensitive cargo via reefer trucks to the airport cargo terminal, break the shipment open, and stuff the Envirotainer in an ambient environment, introducing an entirely avoidable point of failure.

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● **Rigorous equipment validation (IQ/OQ/PQ):** International regulatory bodies, such as the US FDA and European Medicines Agency (EMA), demand exhaustive Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) documentation for all cold storage units, reefer trucks, and passive packaging. Exporters face heavy compliance documentation costs to validate that their thermal packaging can withstand extreme Indian summer ambient shifts (up to 50°C) during transit delays.

Zero-tolerance deviation logs & data integrity: International markets strictly reject manual or missing temperature sheets. Continuous, tamper-proof IoT data logger records are mandatory. If a temperature excursion occurs during the 2-to-10-hour port grounding or the 40-minute airport scanning window, exporters face immediate cargo rejection unless they can generate immediate, validated scientific documentation proving that the product's efficacy was not degraded by the thermal spike.

● **Portal lag and compliance friction:** Navigating the domestic clearance steps—such as aligning shipping bills, Importer-Exporter Codes (IEC), and temperature-controlled handling declarations on the CDSCO SUGAM Portal—requires absolute precision. Any documentation typo or system sync delay at the customs border leads to immediate cargo staging on open, unconditioned terminal docks.

How do companies balance the high cost of temperature-controlled logistics with the need to maintain product quality, minimise wastage and protect supply-chain reliability?

Balancing the high cost of temperature-controlled logistics with zero-tolerance quality mandates is one of the toughest financial and operational puzzles for pharma companies. Because cold-chain logistics can cost up to 80% more than standard dry shipping, companies cannot simply throw money at the problem.

Instead, they achieve this balance through risk-stratified logistics, data-driven optimisation, and smart asset management.

1. Risk-stratified packaging and transport selection

Companies do not treat all cold-chain shipments equally; they match the cost of the packaging and transport mode to the financial value and environmental risk of the product.

Active vs. passive Cost balancing:

● **Active systems (e.g., Envirotainers, CSafe):** These are leased at premium, flat lump-sum rates but offer near-perfect climate control via built-in refrigeration units. Companies reserve these exclusively for ultra-high-value, highly sensitive biologicals, vaccines, and large-bulk shipments where a single batch rejection would mean millions of dollars in losses.

● **Passive systems (e.g., Phase Change Materials, Polyurethane Shippers):** These rely on advanced insulation and gel packs to maintain temperature without electronics. They have a lower upfront freight cost but require complex structural validation (IQ/OQ/PQ). Companies use these for shorter routes, secondary markets, or stabler cold-chain generics.

● **The sea-freight migration:** To slash shipping costs by up to 70% compared to air freight, companies are increasingly migrating eligible cold-chain products to ocean reefers. However, to maintain supply-chain reliability over long transit times, they implement strict port-to-port risk assessments, using active container tracking to mitigate the 2-to-10-hour port grounding power gaps.

> To transform India from a pharmacy hub into a resilient, zero-failure global cold-chain hub, regulators and industry bodies must shift from being passive inspectors to active infrastructure enablers

2. Shifting from reactive salvage to proactive IoT monitoring

Historically, companies discovered temperature excursions after the cargo arrived at the destination, leading to catastrophic product wastage and total write-offs. Modern cost-balancing relies heavily on real-time visibility.

● **Preventing waste with real-time IoT:** By embedding cellular or Bluetooth IoT data loggers inside individual pallets, supply chain teams monitor real-time temperature, humidity, and location. If a truck doors stays open too long during an airport terminal unload, an automated SMS/email alert is triggered. Ground teams can intervene before the product degrades, turning a potential total loss into a quick corrective action.

● **Utilising stability data to protect integrity:** When an excursion does occur (such as the 40-minute airport scanning bottleneck), companies use advanced Mean Kinetic Temperature (MKT) calculations and pre-documented product stability profiles. If documentation proves that a brief spike within a specific thermal threshold does not denature the protein, the batch is legally and safely saved, preventing millions in unnecessary product destruction.

3. Structural and operational cost optimisations

To offset the inherent high costs of cold chain handling, companies optimise their internal workflows to squeeze out hidden logistics expenses.

[Factory Control Room] --> [Optimised Payload] --> [Strategic Routing]

(Secure 2-8°C Stuffing) (Zero Volumetric Waste) (Bypassing Congested Hubs)

● **Maximising payload volumetric efficiency:** Cold-chain space is expensive. Companies work closely with packaging engineers to design ultra-compact primary and secondary packaging. Minimising empty air space inside a shipper means more medicine can be packed onto a single pallet, directly lowering the per-unit logistics cost.

● **Strategic carrier SLAs and routing:** Pharma companies negotiate strict Service Level Agreements (SLAs) with accredited logistics partners. They intentionally select routes that bypass highly congested, low-infrastructure airports or ports—even if the initial lane cost is slightly higher—because the reduction in transit delays and terminal exposure drastically reduces the overall cost of wastage.

● **Consensus inventory staging:** To maintain reliability without paying for frequent, emergency air-freight shipments, companies use predictive analytics to stage inventory in regional, GDP-compliant hub warehouses near major international markets. This allows them to bulk-ship via lower-cost sea reefers during off-peak seasons while maintaining a reliable, immediate local supply.

What role should regulators and industry bodies play in strengthening cold-chain standards, harmonising practices and improving compliance across logistics partners?

To transform India from a pharmacy hub into a resilient, zero-failure global cold-chain hub, regulators and industry bodies must shift from being passive inspectors to active infrastructure enablers. They hold the unique power to bridge the gap between ground-level operational bottlenecks and international compliance standards.

Here is the strategic framework detailing the exact roles they must play:

1. The role of regulators (CDSCO, CBIC, and Ministry of Civil Aviation)

Regulators must eliminate policy friction and treat cold-chain logistics as an extension of the manufacturing cleanroom.

● **Abolish the air-ocean disparity:** The Central Board of Indirect Taxes and Customs (CBIC) must issue a unified circular allowing active air cargo units (like Envirotainers and CSafe) to be taken directly to manufacturing plants for Factory Stuffing and Customs Sealing, matching the long-standing protocol permitted for ocean reefers.

● **Eliminate redundant terminal workflows:** Regulators, in tandem with the Airport Authority of India (AAI), should officially exempt pharma shipments moving in leased active containers from manual, individual pallet weighing and dimensioning (W&D). Since space is leased on a flat, lump-sum basis, removing this legacy bureaucratic hurdle instantly eliminates unnecessary thermal exposure.

● **Mandate "Pharma Green Channels" at hub ports:** The Ministry of Shipping and port authorities must enforce strict Service Level Agreements (SLAs) at major maritime gateways (like JNPT and Mundra). This includes creating specialised "Pharma Corridors" where reefers are exempted from shutting down their gensets at the gate due to noise regulations, or providing instant-plug-in transit docks to eliminate the hazardous 2-to-10-hour power vacuum.

● **Enforce Harmonised GDP (Good Distribution Practices) Guidelines:** The CDSCO must mandate unified, enforceable GDP guidelines across India. Currently, while manufacturing plants adhere strictly to GMP, the domestic logistics chain remains highly fragmented. Regulators must make GDP certification mandatory for any logistics provider handling export-grade pharma.

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Preparing pharma cold chain for next-gen temperature-sensitive medicines

Naresh Ranade, Vice President Supply Chain, Sharon Bio Medicine



Where are the biggest growth and investment opportunities emerging in India's pharma supply-chain and cold-chain ecosystem?
As the pharma industry increasingly shifts towards complex therapies, including biologics, biosimilars, vaccines and specialised injectable products, significant investment opportunities are emerging across pharma logistics, temperature-controlled warehousing, cold-chain packaging, digital monitoring and specialised transportation.

India's pharma logistics market is projected to grow from US$18.28 billion in 2025 to US$25.35 billion by 2031, while value-added services are projected to grow at a CAGR of 8.38%. This growth reflects the increasing need for specialised, technology-enabled and compliant supply-chain solutions.

Key investment opportunities include:

- **Pharma warehousing:** Opportunities exist in GMP-compliant and validated warehouses, multi-temperature storage zones, humidity-controlled facilities, micronisation, repacking, secondary packaging and distribution services. Regulatory compliance, Good Warehousing Practices (GWP), operational flexibility and product integrity will remain critical differentiators.
- **Cold-chain packaging:** Demand is expected to increase for validated insulated shippers, phase-change materials (PCMs), reusable temperature-controlled containers and packaging solutions designed for long-distance air and road transportation. Reusable packaging can reduce lifecycle costs, provided reverse logistics, cleaning, turnaround time and revalidation are effectively managed.
- **Digital monitoring and visibility:** This represents a scalable, relatively asset-light opportunity that does not necessarily require ownership of warehouses or transport fleets. Key areas include IoT-enabled sensors, GPS-integrated data loggers, cloud-based monitoring platforms, automated temperature-excursion alerts, electronic audit trails and end-to-end shipment visibility.
- **Specialised pharma transportation:** Opportunities extend beyond temperature control to include time-critical delivery, validated refrigerated and multi-temperature transportation, and specialised air and road freight. Clinical-trial materials, biologics, advanced therapies and other temperature-sensitive healthcare products require customised packaging, contingency planning and, where applicable, chain-of-identity documentation. Reliable services connecting Tier 2 and Tier 3 cities and remote healthcare markets also represent an important growth opportunity.

Technology will be a key differentiator. Several emerging technologies offer significant potential for wider adoption across India's pharma supply chain:

- Next-generation thermal packaging and advanced phase-change materials.
- Artificial intelligence (AI) and predictive analytics for demand, route and risk optimisation.
- Digital twins for supply-chain simulation and predictive maintenance.
- RFID, 2D barcodes and digital product traceability.
- Smart refrigerated vehicles, energy-efficient cooling and alternative-energy systems.
- Smart labels and battery-free sensors for continuous condition monitoring.
- Advanced battery systems and real-time refrigeration telemetry.
- Blockchain-enabled traceability and secure data sharing.
- Robotics and autonomous warehouse systems.
- AI-enabled inventory, shelf-life and expiry

optimisation.

In conclusion, the next phase of pharma supply-chain investment in India will be driven by the convergence of specialised infrastructure, advanced packaging, real-time digital visibility and predictive decision-making. The strongest competitive advantage will belong to service providers that can demonstrably deliver product integrity, regulatory compliance, end-to-end traceability and reliable on-time performance—rather than relying solely on ownership of refrigerated warehouses or transportation fleets.

What are the biggest supply-chain risks facing pharma manufacturers today, and how can companies minimise losses while ensuring product quality and timely delivery?

Product losses, shipment delays and temperature excursions represent significant operational and financial risks for India's pharma and generic industry. Their impact extends beyond logistics costs to product quality, regulatory compliance, working capital, customer confidence and profitability.

Product losses arising from damage, expiry, improper storage, rejected consignments or quality failures can materially affect margins, particularly in the generic segment, where price competition is intense. The financial impact includes inventory write-offs, replacement manufacturing, additional freight, quality investigations and potential contractual penalties.

Shipment delays can disrupt domestic medicine availability and compromise export commitments. Delays increase inventory holding costs, reduce remaining product shelf life and may result in stock-outs, expedited freight expenses and loss of customer confidence. These risks are particularly relevant to Indian pharma exporters operating across multiple international markets and complex distribution networks.

Temperature excursions are increasingly important with the growing share of vaccines, biologics, insulin and other temperature-sensitive medicines. Even a temporary deviation may require product quarantine and a documented quality assessment. Depending on the product, stability data and excursion severity, the outcome may range from authorised release to complete batch rejection. Conventional generics also require appropriate temperature and humidity controls in accordance with their labelled storage conditions.

Where improvements are most urgently needed?

- **Infrastructure and handling:** Strengthen pharma-grade warehousing, qualified transport, temperature-controlled packaging and reliable power backup, particularly across secondary distribution centres and Tier 2 and Tier 3 locations.
- **Digital visibility and monitoring:** Expand real-time temperature monitoring, GPS-enabled shipment tracking, automated alerts and predictive analytics to identify deviations, anticipate delays and enable timely intervention.
- **Transit and last-mile control:** Improve coordination across manufacturers, third-party logistics providers, airport handlers, distributors and healthcare facilities. Standardised handover protocols and clearly defined accountability are essential to minimise avoidable losses.
- **Logistics partner performance:** Evaluate service providers on delivery reliability, temperature compliance, incident response and corrective actions—not merely transportation cost. Stronger adherence to Good Distribution Practices is critical.
- **Financial measurement and risk management:** Establish measurable indicators for product write-offs, temperature excursions, on-time delivery, shipment rejection and cost per incident. This will enable companies to quantify avoidable losses and prioritise investments based on measurable returns.
- **Training & awareness:** this is a key element. Training & upgradation of knowledge not only to supervisory level but to the last operational guy including the last handler is a key.

Conclusion

India's pharma industry has established a strong global position in generic medicines. However, maintaining this competitiveness requires supply-chain reliability to evolve alongside manufacturing capabilities. The priority should be to shift from reactive problem-solving to a preventive, technology-enabled and quality-driven supply-chain model. Targeted investments in infrastructure, digital monitoring and operational accountability can reduce avoidable losses, protect margins and strengthen the reliability of pharma supplies across domestic and export markets.

Is India's cold-chain infrastructure ready for the next generation of pharma products, particularly biologics, advanced therapies and medicines requiring ultra-low-temperature storage?

India's existing cold-chain infrastructure has developed considerably, supported by its vaccine manufacturing capabilities, pharma exports and established distribution networks. However, its readiness to handle increasingly complex pharma products remains uneven, particularly for advanced biologics, cell and gene therapies, and products requiring ultra-low-temperature storage.

The distinction is important. Conventional pharma cold-chain operations typically operate at 2–8°C, whereas certain advanced therapies require storage at -60°C to -80°C or even lower temperatures. These requirements demand specialised freezers, validated packaging, temperature-controlled transportation, continuous monitoring and stringent contingency planning.

Current capacity and scale

India's public vaccine network demonstrates the scale of its existing capabilities, with approximately 30,000 cold-chain points, over 106,000 ice-lined refrigerators and deep freezers, and 432 walk-in coolers and freezers. The nationwide eVIN platform also enables real-time monitoring of vaccine stocks and storage temperatures. However, this infrastructure is primarily designed for immunisation requirements and should not be equated with commercial pharma-grade ultra-low-temperature capability.

Commercial demand is also expanding. One industry estimate values India's pharma cold-chain logistics market at approximately US$2.5 billion, reflecting growing demand for vaccines, biologics and temperature-sensitive medicines.

The strategic question is whether specialised infrastructure is expanding at the same pace as product complexity.

Key gaps and business implications

The principal gaps are not limited to storage capacity. They include:

- **Ultra-low-temperature capability:** Limited specialised infrastructure for -60°C to -80°C storage, validated shipping systems and dry-ice replenishment.
- **End-to-end integrity:** Temperature excursions can occur during loading, airport transfers, customs clearance, cross-docking and last-mile delivery, even where primary storage is compliant.
- **Digital visibility:** Greater integration is needed between IoT sensors, GPS tracking, automated excursion alerts and quality-management systems, supported by auditable records.
- **Network resilience:** Backup power, equipment redundancy, qualified service providers and contingency routes are essential to minimise product loss and supply disruption.
- **Specialised expertise:** Handling advanced therapies requires validated processes, trained personnel and clear accountability across logistics partners.

Assessment and priorities

In my assessment, India is reasonably equipped for conventional pharma cold-chain requirements, but its readiness for advanced biologics and ultra-low-temperature products remains selective and concentrated rather than comprehensive.

The immediate priority should be to strengthen capabilities across critical pharma corridors and export gateways rather than pursue undifferentiated cold-storage expansion. Investment should focus on validated ultra-low-temperature facilities, specialised packaging, active and passive temperature-control solutions, real-time monitoring and qualified transportation networks.

Companies should also evaluate the total cost of cold-chain failure, including product write-offs, replacement shipments, regulatory exposure and potential damage to customer confidence. Infrastructure decisions must therefore be based on risk-adjusted economics, product volumes and service-level requirements.

India has a strong foundation, but the next stage requires a shift from conventional cold storage to integrated, technology-enabled pharma cold-chain management. The competitive advantage will increasingly lie not in storage capacity alone, but in the ability to demonstrate uninterrupted temperature integrity, traceability and reliability from manufacturing site to final destination.

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QbD and PAT: Bridging promise and practice

As pharma manufacturing becomes more complex, Quality by Design (QbD) and Process Analytical Technology (PAT) are gaining importance. The challenge now is to move beyond adoption on paper and translate scientific understanding into better manufacturing outcomes, finds **Lakshmipriya Nair**

For decades, pharma quality control has largely depended on testing finished products. A batch would be manufactured, samples would be collected and tested, and the results would determine whether it met the required specifications. While this approach has played an important role in protecting product quality, it has an inherent limitation. Problems are often identified after the manufacturing process is complete. By then, time, materials and resources may already have been lost.

The industry is now looking at a more proactive approach. Instead of relying primarily on end-product testing, manufacturers are increasingly expected to understand their processes, identify potential sources of variation and build quality into every stage of production.

The fundamental shift

From testing quality to building quality

- **Traditional approach:** Test the finished product to identify defects.
- **QbD approach:** Understand the process and build quality into product development.
- **PAT approach:** Monitor processes in real time to identify and control variations.

This is where Quality by Design (QbD) and Process Analytical Technology (PAT) become important.

QbD shifts the focus towards understanding how raw materials, process parameters and manufacturing conditions influence the quality of a product. It encourages manufacturers to identify Critical Quality Attributes (CQAs), assess risks and establish appropriate controls to ensure consistent outcomes. The idea is to understand the science behind a manufacturing process rather than simply follow a fixed set of instructions.

PAT complements this approach by providing tools to monitor and understand processes during manufacturing. Technologies such as near-infrared (NIR) spectroscopy, Raman spectroscopy and other analytical tools can help manufacturers track parameters such as moisture levels, blend uniformity and drying endpoints in real time. This allows operators to identify variations early and take corrective action before they affect the final product.

Together, these approaches offer an opportunity to move from detecting quality problems to preventing them.

The business case for better process understanding

The benefits extend beyond product quality. Better process understanding can reduce batch failures, minimise material wastage and improve manufacturing efficiency. Real-time monitoring can help identify deviations earlier, reduce unnecessary processing time and support more informed decisions on the shop floor.

For manufacturers, the larger opportunity lies in making production more predictable. Fewer deviations, improved yields, reduced rework and better utilisation of equipment can all contribute to lower operating costs.

Why does adoption matter now?

The industry is under pressure to strengthen quality systems, meet increasingly demanding global regulatory expectations and compete in markets where consistency and reliability are critical.

India has built a strong position as a global supplier of affordable medicines. Sustaining and expanding this position will require manufacturers to demonstrate not just production capacity, but also process capability, quality consistency and reliable supply.

Regulatory developments have reinforced this need. The US FDA's PAT framework, introduced in 2004, encouraged manufacturers to adopt science-based approaches to process understanding and control. International guidelines such as ICH Q8 on Pharmaceutical Development, Q9 on Quality Risk Management and Q10 on Pharmaceutical Quality Systems provide a broader foundation for this shift.

For Indian companies, adopting these principles is not merely about meeting regulatory expectations. It is also about building manufacturing systems that can compete on quality, efficiency and reliability.

The gap between potential and practice

Despite the promise, implementation remains uneven. Adopting QbD and PAT is not simply about installing analytical instruments or generating more process data. It requires a deeper understanding of manufacturing science, reliable measurement systems, validated analytical models and effective integration with production and quality systems.

Legacy equipment, fragmented data systems, investment requirements and gaps in technical expertise can slow implementation. There are also practical questions around the representativeness of samples, instrument calibration, model performance and the reliability of measurements under changing process conditions.

Another challenge is demonstrating business value. Faster measurements do not automatically translate into cost savings. Manufacturers need to establish whether these technologies are actually improving yields, reducing deviations, shortening production cycles or lowering the cost per acceptable batch.

This calls for a more focused approach. Companies need to identify processes where QbD and PAT can deliver the greatest value, select suitable technologies and establish clear measures of success. Equally important is the involvement of production, quality, engineering, regulatory and analytical teams. Successful implementation requires these functions to work together.

The next phase of pharma manufacturing will depend on how effectively companies translate these principles into everyday operations. The objective is not technology adoption for its own sake. It is to build processes that are predictable, measurable and capable of delivering consistent quality.

Ultimately, quality cannot be tested into a product at the end of a production line. It has to be built into the process from the beginning.

But how can manufacturers realise the full potential of QbD and PAT? What operational benefits can these approaches deliver, and what is holding back their wider adoption?

To explore these questions, *Express Pharma* reached out to some experts for their perspectives on the subject. **Ranjit Barshikar,** CEO, QbD International and United Nations Advisor, examines how QbD and PAT can improve manufacturing efficiency, product quality and patient safety. **Venugopal V, Dr Sateesh Babu D and Dr BM Rao** of QDOT Associates, examine the challenges of translating PAT capabilities into practical, sustainable manufacturing outcomes.

The business case

What can manufacturers gain?

- Fewer batch failures and rejections
- Reduced material wastage
- Better process consistency
- Shorter manufacturing cycles
- Improved productivity and equipment utilisation
- Faster batch release, where RTRT is justified
- Stronger quality assurance and patient safety

The implementation challenge

Why is adoption still uneven?

- Legacy manufacturing infrastructure
- High initial investment
- Gaps in technical expertise
- Fragmented data systems
- Instrument calibration and model validation
- Difficulty demonstrating measurable business returns

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QbD / PAT benefits in pharma operations

Ranjit Barshikar, CEO, QbD International and United Nations Advisor, examines how QbD and PAT can improve pharma manufacturing through better process control, operational efficiency and consistent product quality

In pharma Industry, product quality has always been very important for patient safety. Traditionally, Quality relied on end product testing of batches. Since last more than a decade industry is adopting Quality by Design (QbD) and Process Analytical Technology (PAT) to monitor, control, and optimise processes in real time.

QbD/PAT benefits in key business operations

Enhanced product quality and patient safety

● **Predictive consistency:** Processes are designed to absorb variations in raw materials without compromising final product quality. QbD defines Critical Quality Attributes (CQA) & Critical Material Attributes (CMAs) having potential to impact product quality, for e.g. particle size or moisture content. Variation in particle size, beyond Design Space, can affect hardness and dissolution parameters. Hence pre-defined Design Space allows to subtly adjust machine settings to maintain consistency. *(Fig. 1)*

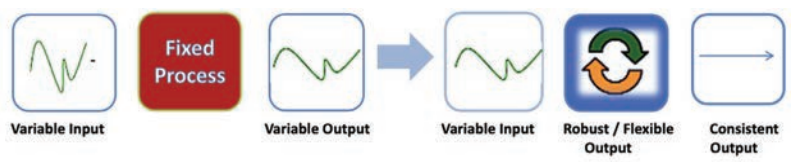


Fig. 1: Input materials variability is mitigated for consistency in manufacturing.

Operational efficiency & cost reduction

● **Reduced costs:** By shifting from end-product laboratory testing to Real-Time Release Testing (RTRT), can release batches faster than traditional testing methods. It supports faster release of batches. Real-time monitoring helps to timely identify substandard batches before release, protecting patients and brand reputation.

● **Optimised scaling:** Moving a process from pilot scale to commercial manufacturing becomes highly predictable, drastically reducing tech-transfer timelines.

Regulatory flexibility

● **Post-approval flexibility:** Operating within an approved Design Space allows manufacturers to make process adjustments without filing time-consuming regulatory amendments.

● **First-time-right submissions:** Regulatory bodies (like the FDA and EMA) look highly favourably upon QbD-backed dossiers, which frequently leads to fewer information requests and faster approval cycles.

Continuous improvement

● **Data-driven automation:** Continuous data feeds from PAT sensors lay the foundation for advanced process control, artificial intelligence, and digital twins.

● **Easier equipment upgrades:** Changes to manufacturing equipment or moving production to a new facility are streamlined because the critical parameter windows are already quantified.

Opportunity in knowledge enhancements

QbD provides an opportunity to demonstrate a higher degree of understanding of material attributes, manufacturing processes, and their controls. This scientific understanding facilitates establishment of an expanded design space.

In these situations, opportunities exist to develop more flexible regulatory approaches, for example, to facilitate:

● Risk-based regulatory decisions (reviews and inspections)

● Manufacturing process improvements, within the approved design space

● Reduction of post-approval submissions

● Real-time quality control, leading to a reduction of end-product release testing

PAT tools enable Real-Time Release Testing (RTRT) for faster batch testing and releases: for example....

● **In blend uniformity:** An inline Near-Infrared (NIR) spectrometer on the blender measures active in blend in real-time. The system automatically stops



mixing at the exact time when homogeneity is achieved (preventing over-mixing).

● **Core tablet uniformity:** During tableting, compression force monitoring feeds data into a mathematical model. Because the relationship between compression force, weight, and API content was established in Design Space, system verifies weight & content uniformity for every single tablet, discarding outliers automatically.

Case Study : Tablet capping in fluid bed granulation of immediate-release paracetamol tablet using QbD / PAT:

● **Problem:** During wet granulation & drying stage, operators traditionally used a "fixed-time recipe" (e.g., dry the wet powder mass for exactly 45 minutes). However, air dried powder too fast. Over-drying removed essential "bound moisture" from granules. These over-dried granules couldn't bind together properly, under pressure, during compression, causing tablet surface to split off, causing capping issue.

● **QbD Solution for capping issues:** Scientists used DoE to identify that CMA had tight granule moisture tolerance of 1.8 per cent to 2.2 per cent. If moisture dropped below 1.6 per cent, capping occurred. If it went above 2.4 per cent, the powder clogged the machine. This defined the Design Space for moisture. Hence, Installed an inline NIR probe (PAT) directly inside fluid bed dryer.

● **Result:** Instead of running fixed 45-minute timer, NIR probe monitored tumbling powder every 5 seconds, reading moisture drop mathematically. When Moisture reached to 2.0 per cent at a particular time (flexible time instead of fixed 45 minutes), PAT sent an automated signal to heater, shutting down air intake. Thus tablet capping was reduced to 0 per cent, with overall higher productivity by 18 per cent, by eliminating unnecessary drying time. Several such & varied examples of different issues are solved with QbD. Avoiding tablet capping using QbD and PAT, moves manufacturing troubleshooting toward predictive, science-based control strategy. To systematically eliminate capping, map CMAs and CPPs to manage air entrapment, moisture, and compression mechanics.

Overall QbD/PAT benefits to pharma business are:

● Enhanced quality/Right first time

● Consistency in manufacturing/ Higher process capability

● Scientific and Risk based understanding of process and methods

● Robust product /process development /minimum tejections

● Faster operations/cost savings

● Real time process monitoring

● Continuous manufacturing

● Transparent operations.

● Continual improvement.

● Patient safety and product efficacy are focused.

● Highly confident organisation and satisfied regulators

QbD implementation enhances the product and process quality in the interests of patient centric product development, manufacturing and testing. There is an increased interest in Real Time Real Testing (RTRT), Continuous manufacturing, Analytical methods development and biopharmaceutical approaches to QbD. Finally, organisations are satisfied with business, if customers are happy.

References

1) US FDA guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q8r2-pharmaceutical-development
2) EU guidance: https://www.ema.europa.eu/en/scientific-guidelines/ich-q8-r2-pharmaceutical-development
3) ICH guidance Q8 (R2) – Product development
4) ICH guidance Q9 – Quality Risk Management
5) ICH guidance Q10 – Pharmaceutical Quality Systems

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Real-time quality monitoring: What is holding back adoption?

Achieving consistent product quality and regulatory compliance calls for more than the adoption of QbD and PAT. Reliable measurements, integrated process control and science-based regulatory strategies are essential to translating these concepts into manufacturing practice, highlight **Venugopal V**, **Dr Sateesh Babu D** and **Dr BM Rao** of QDOT Associates

More than two decades after the US FDA introduced its Process Analytical Technology (PAT) framework in 2004, pharmaceutical manufacturing has advanced in analytical measurement, process understanding and automation. Digital technologies, data analytics and artificial intelligence (AI) offer further opportunities to accelerate this transformation.

Yet an adoption paradox persists: while targeted PAT applications have consistently demonstrated tangible operational and quality benefits, their broader integration into comprehensive manufacturing control strategies remains limited.

The challenge is no longer the generation of process data, but the transformation of reliable measurements into informed decisions, robust process control, consistent product quality, and sustained business value.

True PAT success depends on converting analytical insights into actionable intelligence that drives measurable improvements in manufacturing performance, efficiency, and lifecycle outcomes.



Venugopal V



Dr Sateesh Babu D



Dr BM Rao

Proven applications, yet untapped potential

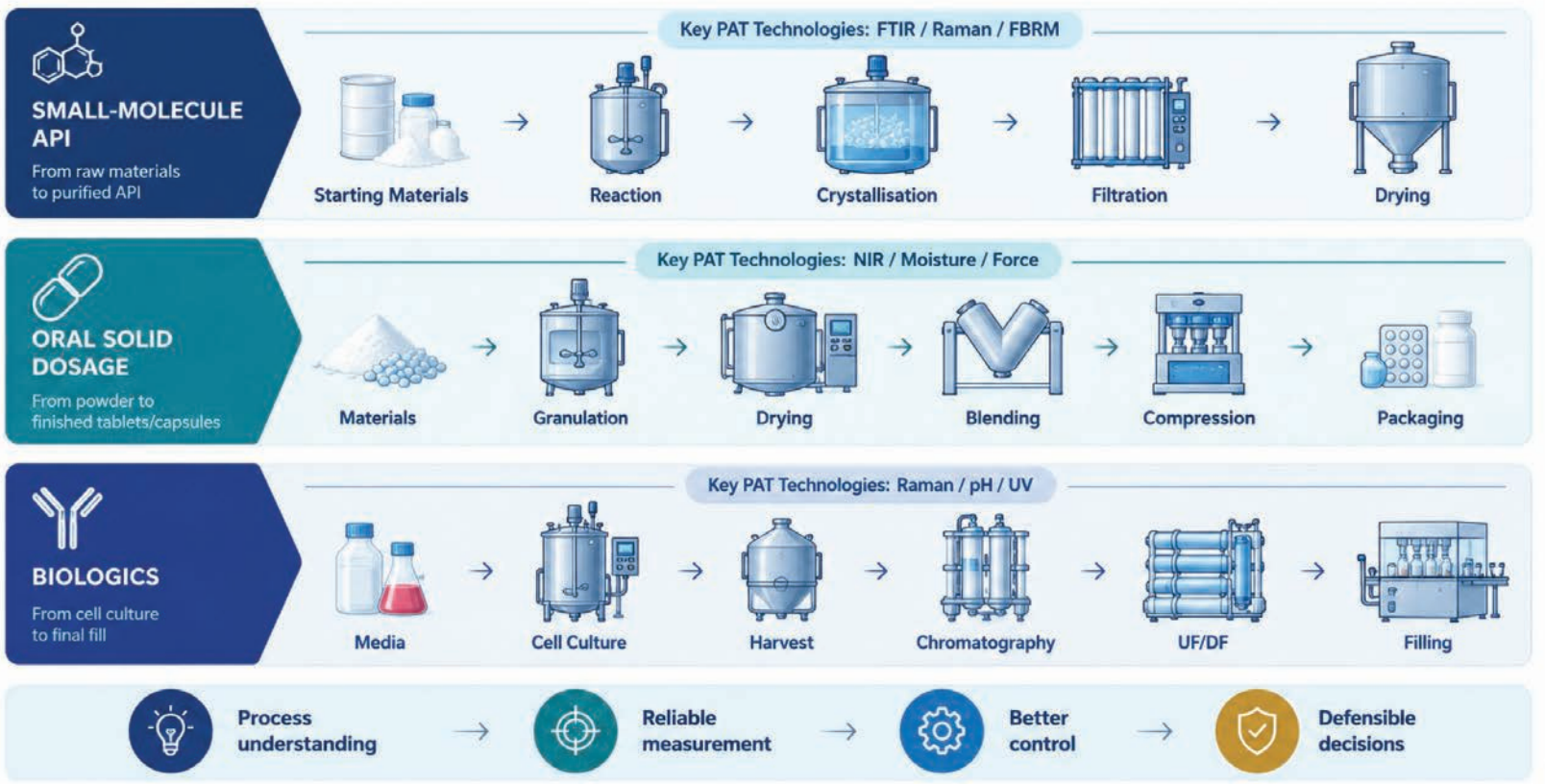
PAT technologies are increasingly deployed across pharmaceutical manufacturing, with applications tailored to specific processes and objectives. NIR, Raman, and FTIR spectroscopy support raw-material verification, reaction monitoring, moisture analysis, and drying-endpoint determination, while particle-monitoring tools enhance crystallisation control.

In oral solid dosage manufacturing, advanced analytics improve granulation and blend uniformity, whereas in biologics, Raman spectroscopy, metabolite monitoring, and chromatography strengthen process understanding. However, analytical capability alone does not ensure value. To improve quality, productivity, and reduce waste, PAT measurements must be scientifically validated, representative of process conditions, and effectively integrated into manufacturing decisions and control strategies.

Why is value realisation uneven?

Implementation challenges extend beyond technology investment, encompassing sampling representativeness, calibration robustness, model drift, legacy infrastructure, fragmented data environments, and organisational readiness. These factors collectively influence PAT performance and sustainability.





Demonstrating business value is equally critical. Faster measurements alone do not guarantee cost savings; benefits should be evidenced through improvements in yield, cycle time, deviation reduction, resource utilisation, and cost per acceptable batch.

Successful implementation begins with a clearly defined process objective, supported by appropriate analytical methods, reliable reference measurements, and effective integration with manufacturing and quality systems.

From monitoring to integrated control and RTRT

Real-time monitoring enables timely detection of process variability and supports informed interventions. Integrated process control further enhances performance through justified feedback or feedforward actions, automated endpoint determination, and predefined process adjustments. RTRT is a distinct application requiring a scientifically justified control strategy to support product-release decisions. For example, an NIR-based moisture prediction does not inherently replace Karl Fischer or loss-on-drying testing; suitability and validation must be demonstrated. Nevertheless, significant operational benefits can be achieved through robust monitoring and integrated process control without implementing RTRT.

The challenge is no longer the generation of process data, but the transformation of reliable measurements into informed decisions, robust process control, consistent product quality, and sustained business value. True PAT success depends on converting analytical insights into actionable intelligence that drives measurable improvements in manufacturing performance, efficiency, and lifecycle outcomes

Scaling through science, systems and regulatory governance

A pragmatic implementation pathway involves identifying high-value process problems, selecting suitable measurements, demonstrating analytical performance and integrating results into controlled decisions. Instrument qualification, model validation, reliable data interfaces, data integrity controls and lifecycle monitoring must support the intended use.

Regulatory assessment should begin early. Depending on the proposed change, authorised product conditions and jurisdiction, implementation may require internal change control, regulatory notification or prior approval. RTRT requires additional release-specific scientific justification and an appropriate regulatory pathway.

From technology capability to sustainable manufacturing value

The industry's opportunity lies not in installing more sensors, but in transforming reliable process intelligence into improvements in quality, productivity, resource efficiency and supply resilience.

Ultimately, PAT maturity should be measured not by the volume of data generated, but by the reliability of decisions, robustness of processes and sustainability of manufacturing outcomes.

Conclusion

The future of PAT lies in linking reliable measurements, scientific understanding, and integrated process control to tangible manufacturing outcomes. RTRT may represent a further step where scientific, regulatory, and business justifications are compelling.

The broader objective is to build data-driven manufacturing systems in which robust evidence consistently supports product quality, process performance, compliance, and confident release decisions throughout the product lifecycle.

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An integrated approach to pharma anti-counterfeiting

Dr Subhashis Chakraborty, Priyanka Salunkhe and **Ganesh Adasul** from ACG Capsules; **Dr Sheikh Akbar Ali** and **Jyoti Chavan** from ACG Packaging Materials; and **Nikit Sharma** from ACG Inspection; examine how product authentication, packaging security, inspection and digital technologies can help prevent medicine counterfeiting and enable product verification

The pharma counterfeiting challenge

Pharmaceutical counterfeiting remains one of the industry's most persistent challenges. Despite advances in manufacturing controls, packaging security and supply chain traceability, counterfeit medicines continue to pose a serious threat to patient safety, cost of healthcare and confidence in healthcare.

The scale of the problem is considerable. The World Health Organization (WHO) estimates that at least one in ten medical products in low- and middle-income countries is substandard or counterfeit, with approximately $30.5 billion spent annually on these products.

The commercial incentives for counterfeiters are significant. Medicines can command high prices and attract consistent demand, while counterfeiters can exploit established brands with substandard or fake molecules.

Meanwhile, increasingly complex global supply chains and the growth of digital sales channels create further opportunities for falsified and counterfeit products to enter circulation. Improvements in printing, packaging and digital technologies can also make counterfeit medicines more convincing and harder to identify through visual inspection alone.

The challenge is not simply to introduce stronger security features, but to ensure that the different measures used to protect medicines work together - seamlessly.

It can be argued that no single technology can provide complete assurance of authenticity throughout a medicine's journey from manufacture to patient. Instead, effective protection depends on multiple, complementary layers of defence, supported by cooperation across the pharmaceutical supply chain.



> No single technology can provide complete assurance of authenticity throughout a medicine's journey from manufacture to patient. Instead, effective protection depends on multiple, complementary layers of defence, supported by cooperation across the pharmaceutical supply chain

Authenticate the medicine, not just its packaging

Much of the discussion around pharmaceutical counterfeiting focuses on packaging security, serialisation and traceability. These are essential safeguards, but they represent only part of the picture. An important distinction is the difference between authenticating the packaging and authenticating the medicine itself.

Packaging may carry security features, unique identifiers and digital records, but there is no way the medicine can be authenticated once the product is separated from its original pack.

For some dosage forms, including capsules, manufacturers can introduce identifiable characteristics directly into the medicine. Distinctive colour combinations, dimensions and printed markings can provide additional authentication points. More sophisticated on dose anti-counterfeiting approaches, such as high-definition printing, circumferential capsule markings, laser-engraved identifiers and tracer-based authentication technologies embedded within capsule materials, can significantly increase product security and make counterfeit products far more difficult to replicate convincingly. And these features remain with the medicine even when its outer packaging is removed.

Altogether, the objective is to establish several opportunities to recognise and verify genuine products, rather than relying on one feature to provide assurance.

Packaging: Protects medicine and the brand

Packaging provides another critical layer of protection. Beyond preserving product quality and stability, it can incorporate visible and covert authentication features designed to make imitation and tampering more difficult.

These may include distinctive printing, holographic effects, specialist inks, UV-visible markings and identifiers that require magnification or other verification methods.

The purpose is not simply to make packaging visually distinctive. Each additional security measure should increase the complexity, cost and technical capability required to reproduce it – deterring the counterfeiters.

However, even sophisticated packaging can be vulnerable if physical security features are not connected to reliable product identification systems. A pack may carry a barcode, serial number, batch information and expiry date, but these identifiers are only useful when they are correctly applied and verified.

There is also a fundamental limitation to relying on printed codes alone, because a code can potentially be copied from a genuine product and reproduced on a falsified pack.

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This is why the relationship between physical and digital identity is becoming increasingly important. Combining unique identifiers with physical authentication features that can be independently checked offers a stronger approach than relying on either measure in isolation.

Connecting inspection, serialisation and traceability

Inspection technologies provide a critical link between the physical medicine, its packaging and its digital identity.

During manufacturing, automated systems can verify printed information, inspect two-dimensional Data Matrix codes, check labels and confirm that serialised data corresponds with approved production records. They can also identify unreadable codes, incorrect batch information, printing defects and inconsistencies between packaging and its assigned identity.

If a product leaves the manufacturing environment carrying incorrect or inconsistent identification data, its movement through the supply chain becomes harder to verify.

Serialisation assigns unique identifiers to individual packs, while aggregation establishes relationships between those packs and larger packaging units, such as cases and pallets. Together, these capabilities can create a connected record linking physical packaging, unique identifiers and manufacturing information. The opportunity is to extend this verification beyond the production line.

However, verification must be designed carefully. A valid serial number does not necessarily establish that the physical pack carrying it is genuine, particularly where identifiers have been copied.

Connecting digital records with independently verifiable physical features therefore remains essential, and in practice that connection is made at the point of scanning. The serialised identity is usually carried in a QR code on the pack, and scanning it opens the brand's own verification page rather than returning a simple pass or fail. The security of that destination matters as much as the code itself.



ACG

Make it better.

The page then asks for a photograph of a second, physical feature on the same pack: either a variable security print, generated individually for each pack and applied inline during the production order, or a microprinted artefact fixed within the approved artwork. The code establishes which pack it claims to be; the photograph establishes whether the pack carries the feature produced for that code. Because no specialist equipment is required, a distributor, pharmacist or patient can make that check with an ordinary smartphone camera.

Could AI strengthen pharmaceutical authentication?

Artificial intelligence offers another potential layer of protection, particularly in identifying patterns and anomalies across large volumes of manufacturing and supply chain data.

Traditional inspection systems typically operate against defined acceptance criteria, and these remain essential for consistent, validated checks.

AI could complement these controls by analysing data from inspection, authentication, serialisation and traceability systems to identify unusual patterns that warrant further investigation. For example, a pack may carry a valid, readable identifier but display physical characteristics inconsistent with the genuine product.

Image-analysis AI technologies can already compare a variable security feature against the reference held for that pack. Where the pattern is dynamic, the models work as a pair: one encodes, generating a pattern unique to each pack and embedding the pack's data within it, while the other decodes, reading that pattern back from an ordinary photograph and reconstructing the data for comparison. Because the design is produced by an AI/ML model rather than held as a fixed master, there is no artwork or plate for a counterfeiter to obtain.

At a wider level, repeated use of the same serialised identifier, unusual concentrations of failed verification attempts or unexpected patterns in particular locations could provide early warning of possible falsification or diversion. Such information could help manufacturers and supply chain partners investigate emerging threats before they become more widespread.

Nevertheless, AI introduces its own challenges. This is because AI-generated alerts must be interpreted carefully, particularly where the available evidence is incomplete. Reliable analysis depends on representative data, appropriate validation, cybersecurity and clear processes for investigating results.

The technology should support human decision-making rather than replace established verification controls.

Equally, counterfeiters can exploit AI themselves - using increasingly accessible technologies to reproduce branding, create convincing packaging and generate fraudulent digital content. The industry must therefore consider how its authentication methods will remain effective as the capabilities available to falsifiers evolve.

The challenge of integration

Although many of the technologies needed for stronger pharmaceutical authentication already exist, integrating them across the global supply chain remains difficult, yet vital.

Manufacturers, packaging suppliers, distributors and healthcare organisations often operate different systems, with varying data standards and levels of digital maturity. Connecting these securely requires investment, technical compatibility and agreement about how information should be shared and protected.

Regulatory differences between markets add further complexity, while smaller organisations may face challenges in adopting advanced authentication and traceability technologies.

Organisations may be reluctant to discuss vulnerabilities because of concerns about public confidence or brand reputation. Yet limited information sharing can make it harder to recognise emerging threats and coordinate effective responses.

Stronger protection therefore depends on more than technology. It requires common approaches to verification and greater collaboration between manufacturers, suppliers, regulators, distributors and law enforcement.

Patients also have a role, particularly through purchasing medicines from authorised sources and reporting suspicious products. However, public education should encourage informed vigilance without creating unnecessary alarm or transferring responsibility for authentication onto patients.

Moving towards connected protection

Pharmaceutical counterfeiting will continue to evolve, and the industry's response must evolve alongside it.

The priority should not be to identify one definitive anti-counterfeiting technology, but to connect complementary safeguards across the product lifecycle.

Authentication at dosage-form level, physical packaging security, inspection, serialisation and traceability each address different vulnerabilities. Their collective value increases when the information and verification capabilities associated with them can work together.

AI may eventually strengthen this approach further by identifying anomalies and emerging patterns across connected systems.

Ultimately, the goal is to make falsification progressively more difficult to achieve and easier to detect. Achieving this will require the pharmaceutical industry to move beyond isolated interventions towards a more coordinated, collaborative approach to product protection.

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Building confidence in combination product development through pre-verified syringe–device configurations

Chiara Carraro, EMEA TEC DDS Testing Analyst, and **Enrico Barichello,** Product Manager Syringe Platform, Stevanato Group, explain how pre-verified autoinjector and prefilled syringe configurations can help pharmaceutical companies make faster, evidence-based decisions when developing combination products for complex injectable therapies

The pre-filled syringe: A performance-critical component

As more injectable therapies move towards self-administration, pharmaceutical companies are under increasing pressure to ensure that drug formulations, primary containers and delivery devices work reliably together from development through commercial launch. The challenge is particularly acute for biologics and other complex injectable products, where high concentrations, high viscosities, large dose volumes, and sensitivity to container interactions can all influence device performance. In this context, the prefilled syringe is a performance-critical component of the delivery system.



These pressures are changing the way companies think about container and device selection. A decision made late, or based on limited compatibility evidence, can lead to avoidable risks: unexpected injection times during stability studies, additional verification work, delays to device integration or even the need to revisit the container choice. Conversely, early access to data on proven syringe-device configurations can give development teams a clearer understanding of expected behaviour and help mitigate technical and functional risks associated with combination product development.

From compatibility testing to development de-risking

Compatibility testing is often discussed as a confirmation step, but its strategic value is much broader. When performed early and systematically, it can help reduce uncertainty around the interaction between the components of a combination product.

Stevanato Group's approach is to generate data around pre-verified configurations. Rather than asking customers to start from an entirely blank sheet, these data packages provide an evidence base for selecting and implementing a suitable configuration. This can be particularly valuable when teams need to understand formulation behaviour over time, meet shelf-life expectations and maintain a positive patient experience, all within a compressed development timeline.

If consistent device behaviour is observed, teams can gain confidence in performance trends earlier rather than waiting until the end of shelf life. In this way, lower variability in initial tests may help optimise development activities and support faster decision-making.

AIDAPTUS® and Stevanato Group prefilled syringes: compatible by design

Aidaptus® is a two-step, single-use autoinjector platform with a highly adaptable device architecture. Developed through an integrated collaboration model between Owen Mumford and Stevanato Group, combining device, syringe, manufacturing, and supply-chain expertise, the platform is designed to accommodate both 1 mL and 2.25 mL prefilled syringes within the same form factor. Additionally, its plunger rod technology automatically adjusts to the fill volume, supporting flexible filling without changing device parts. The platform is available with low- and high-drive spring options, which can make it suitable for a range of viscosities, and enables configuration choices for different formulation and delivery requirements.

Within Stevanato Group's syringe portfolio, Nexa® and Alba® offer different performance profiles for demanding injectable applications. Nexa® glass syringes, featuring an optimized silicone level, are designed for biologics and offer tight dimensional tolerances, high cosmetic quality, consistent functionality and compatibility with multiple drug delivery devices.



Figure 1: Aidaptus® autoinjector platform



Figure 2: 2.25mL Nexa® and Alba® syringes

Alba® syringes are intended for next-generation biologics and formulations sensitive to silicone oil. Their internally cross-linked silicone coating is designed to deliver near-zero levels of silicone oil–related subvisible particles and reduce silicone migration along the barrel, supporting consistent gliding performance over time. Unlike other comparable prefillable syringes available on the market, Alba® syringes do not require dedicated or ad hoc plungers, enabling the use of ISO-standard, commercially available plungers and providing customers greater flexibility in plunger selection.

The value of combining Aidaptus® with Stevanato Group prefilled syringes is not limited to component compatibility. It fits into a wider integrated offering: primary containers, delivery systems, final assembly knowledge and analytical testing can be coordinated within a single ecosystem. For customers, this reduces the number of interfaces to manage and helps align container, device and testing decisions.

Study design: Evaluating delivery performance over real-time ageing

Stevanato Group conducted a stability study to assess the injection-time performance of 2.25 mL Nexa® and Alba® syringes when assembled with the Aidaptus® autoinjector sub-assemblies incorporating a low-drive spring.

The syringes were prefilled with a 1 cP biotech placebo solution and stored under real-time ageing conditions of 25°C and 60% relative humidity. The study evaluated performance at zero, three, six and twelve months. Thirty samples per syringe category were used for each time point.

Delivery time was measured using a high-speed camera: after activation of the autoinjector, the camera recorded the interval from needle deployment to the end of liquid delivery. This provided a



Figure 3: Injection-time testing using a high-speed camera

gauge of how the syringe and autoinjector performed together after ageing.

Why representative placebo models matter

For compatibility testing to be meaningful, the test model must reflect the stresses that a real formulation may place on the syringe and device system. Water for injection can be useful for some early evaluations, but it does not necessarily challenge the container closure system in the same way as a biologic formulation. Excipients and surfactants, such as polysorbate 80, can interact with siliconised surfaces and may influence glideability, break-loose force and injection time.

In the study described above, Stevanato Group used a representative biotech placebo rather than water for injection. The aim was to create a more demanding and realistic model for observing delivery performance over time. This approach also illustrates a wider service capability: Stevanato Group's Technology Excellence Centres can develop ad hoc placebo models and test configurations that mimic customer formulation behaviour, helping customers obtain predictive data before committing to later-stage verification activities.

Why injection time matters

Injection time is a practical and patient-relevant indicator of combination product performance. In a spring-driven autoinjector, the available driving force is fixed, as determined by the device configuration. This means that, if the frictional behaviour of the syringe changes over time, because of formulation-container interactions, silicone redistribution or changes in break-loose and glide force, the time required to deliver the dose may also change.

From a patient perspective, excessively long or variable injection times may affect confidence, comfort and the likelihood that the full dose is delivered as intended. ISO 11608-1, Needle-based injection systems for medical use, stresses that, "the time or speed employed to deliver a discrete volume would be based upon tolerability or convenience".

From a development perspective, a consistent injection-time profile can give teams confidence that the selected syringe-device configuration is behaving predictably over ageing. This is why delivery-time testing, alongside other functional and physical assessments, can play an important role in de-risking combination product development.

Study results: Consistent delivery times

Both Nexa® and Alba® syringe configurations worked effectively with the Aidaptus® autoinjector under the study conditions. Both categories maintained successful delivery performance across all aging conditions tested [See Figure 4]. Differences in injection-time behaviour reflected the distinct design and platform characteristics of the two syringe technologies, providing customers with options depending on formulation and drug requirements. Under the conditions evaluated, Alba® exhibited lower variability in injection time over aging.

In addition to injection-time performance, the compatibility assessment considered other functional parameters relevant to user handling and dose delivery. Cap removal force testing [See Figure 5] demonstrated that no additional effort was required to remove the cap. Measured forces were consistently low and well below the 30 N acceptance threshold [See Figure 6]. The relatively low cap-removal force is primarily attributed to the elasticity of the elastomer needle shield and the shape of the syringe cone, which together facilitate cap removal while maintaining adequate closure integrity.

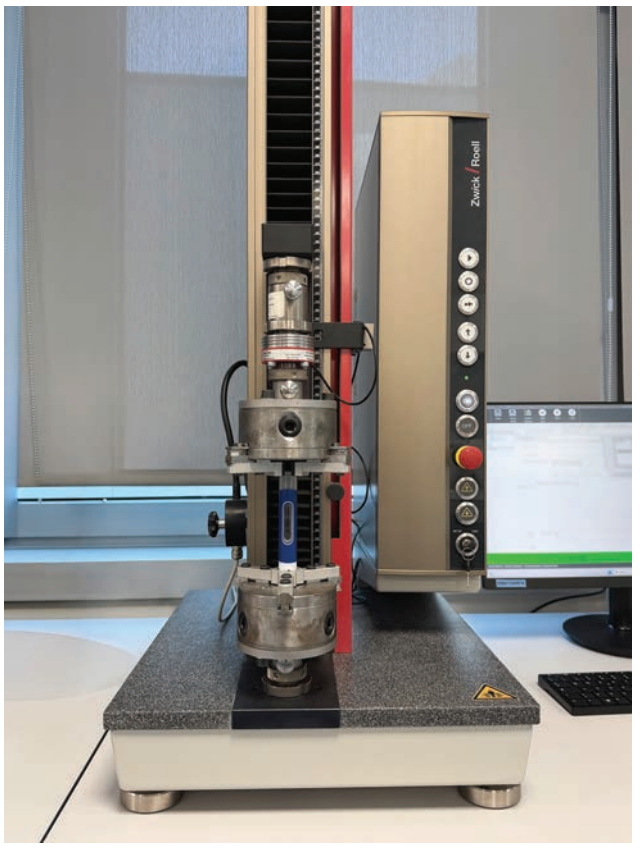


Figure 5: Cap removal force testing

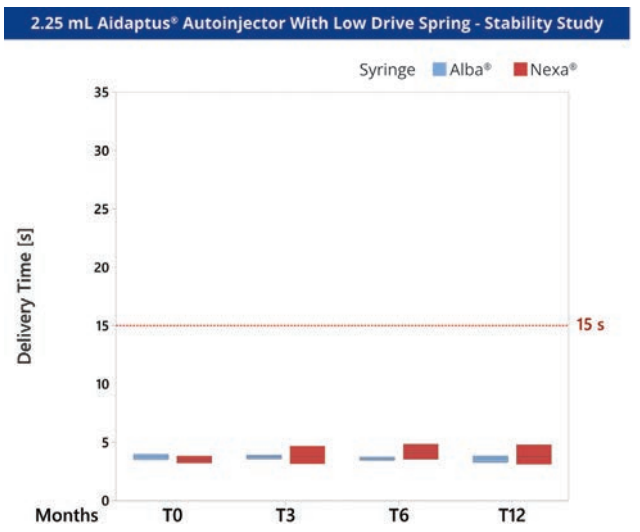


Figure 4: The stability study assessed and compared how injection time changed after three, six and twelve months with prefilled Nexa® and Alba® syringes assembled in the Aidaptus® autoinjector. Historically, the pharmaceutical and drug delivery industries have considered fifteen seconds as the widely accepted limit on user delivery time. Both Alba® and Nexa® fall well below this limit.

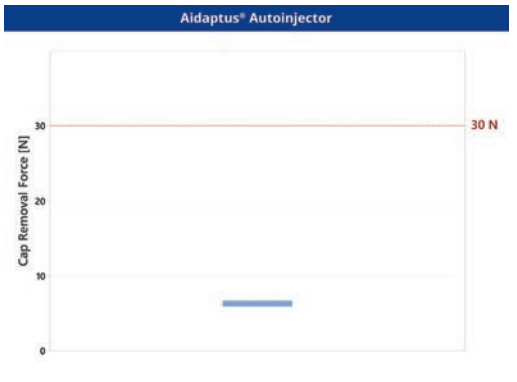


Figure 6: Cap removal force for Aidaptus® autoinjector. No additional effort was required to remove the cap from the syringe, illustrated by the highly consistent results.

Dose accuracy testing demonstrated that the combination of Aidaptus® and either prefilled syringe configuration consistently delivered the intended target dose of 2.1 mL [See Figure 7]. Measured delivered volumes for the high- and low-spring variants were essentially equivalent, indicating reliable dose delivery performance. These results confirm that the Aidaptus® platform can accurately deliver the intended dose irrespective of the spring configuration.

Turning early evidence into development advantage

With the attention of pharmaceutical teams pulled in multiple directions during the development of a drug device combination product, the study described in this article demonstrates how a device partner can ease some of this burden. Easier decision-making at the device selection stage gives pharmaceutical teams greater scope to focus resources on their core priorities, whether drug development, manufacturing strategy, clinical supply or commercialisation planning.

As injectable therapies continue to evolve, understanding the interactions between the primary container and delivery device is critical to avoid complications at later, more demanding stages of development. The compatibility study between Aidaptus® and prefilled syringes provides one example of how early data can provide a foundation for more confident selection. Ultimately, the benefit is not simply a compatible syringe and autoinjector combination, but greater confidence in the path to commercial launch.

This article provides a summary of the study findings. For further information on the evaluation and tested configurations, please contact Stevanato Group.

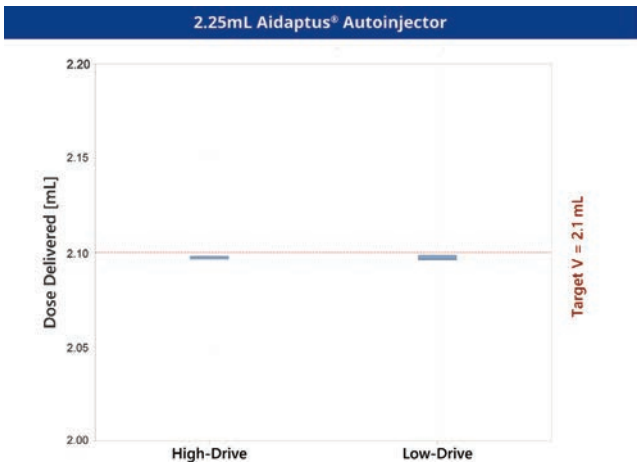


Figure 7: Dose accuracy at high- and low-drive spring configurations. The dose accuracy test established that the combination of Aidaptus® and either prefilled syringe, Alba® or Nexa®, can accurately deliver the intended dose.

About company

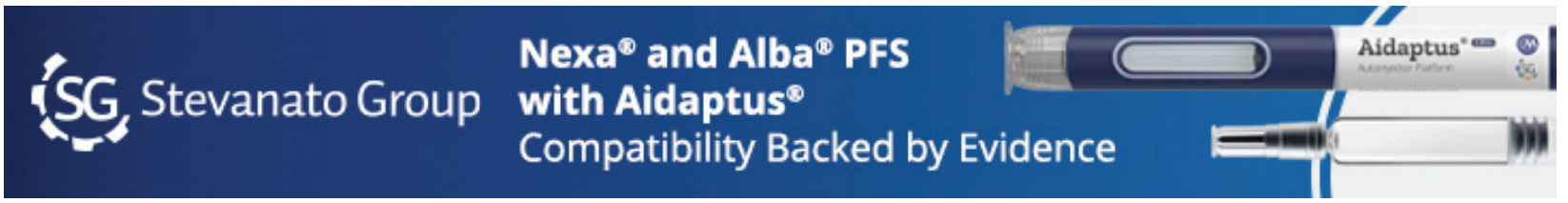
Stevanato Group is a global provider of drug containment, drug delivery and diagnostic solutions to the pharma, biotech and life sciences industries. It delivers an integrated, end-to-end portfolio of products, processes and services across the entire drug lifecycle at each of the development, clinical and commercial stages.

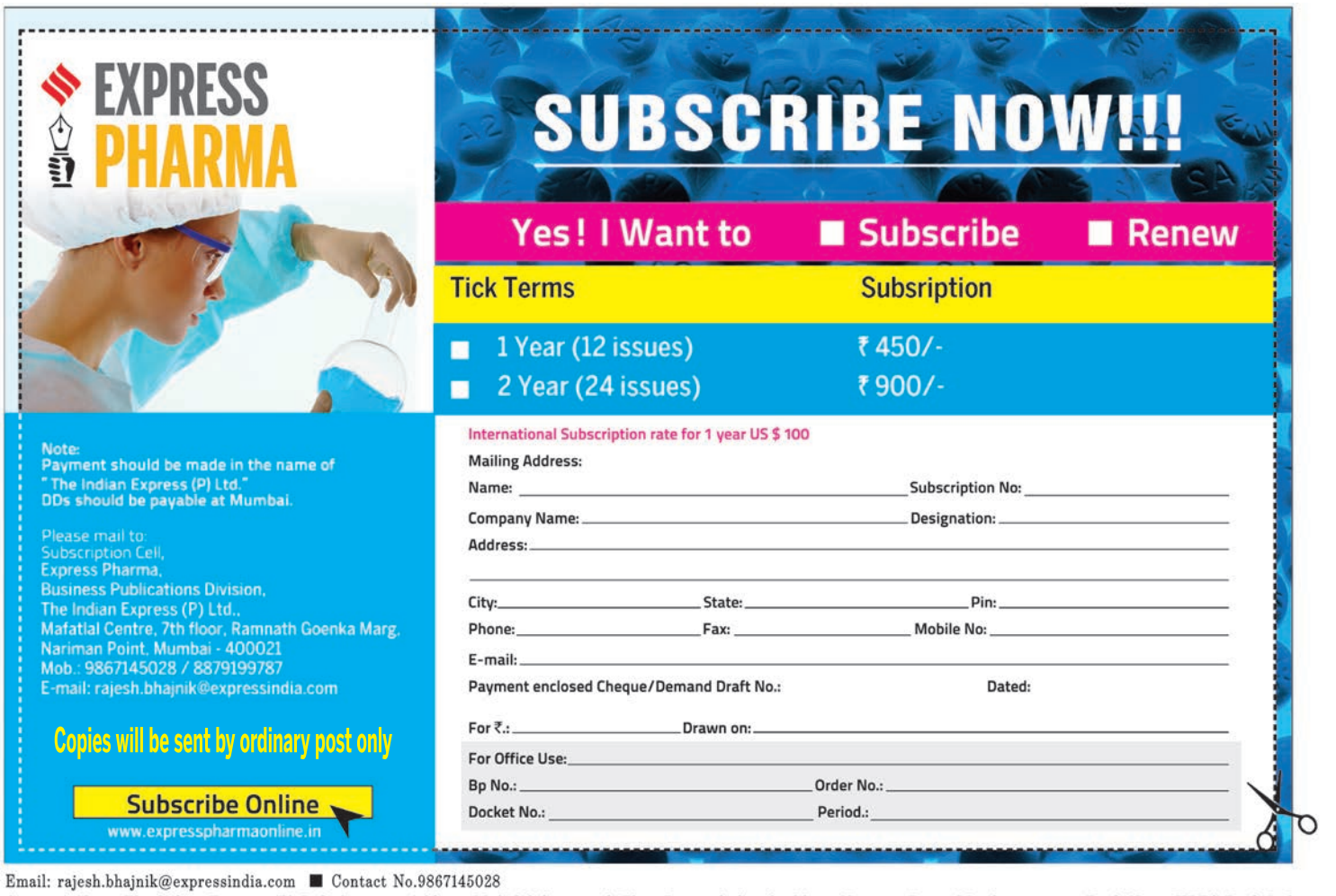
i. See, for instance: The segment of self-administered parenteral products has grown at 15% 5-year CAGR, twice the rate of parenteral products requiring administration by a healthcare professional, often in a hospital setting, and in 2024 represented 60% of parenteral market value. IQVIA, Playing the long game: The promise of ultra long-acting injectables, 18 August 2025

ii. See, for instance: Stephen Dela Ahator, Silvia Franzè, Sybil Obuobi, Giulia Anderluzzi, Gøril Eide Flaten, Nataša Škalko-Basnet, Overcoming barriers to delivery of biologics by novel approaches and advanced delivery systems, Advanced Drug Delivery Reviews, 2026; 34 https://doi.org/10.1016/j.addr.2026.115875

iii. See, for instance: Tingting Wang, Coralie A Richard, Xia Dong, Galen Huaiqiu Shi. Impact of Surfactants on the Functionality of Prefilled Syringes. Journal of Pharmaceutical Sciences. 2020 Nov;109(11):3413-3422. doi: 10.1016/j.xphs.2020.07.033

iv. ISO Online Browsing Platform, ISO 11608-1:2022(en) Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems https://www.iso.org/obp/ui/en/#iso:std:iso:11608:-1:ed-4:v1:en





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Stevanato Group

Romaco PMEC India 2026: Processing, Tableting and Packaging

At PMEC India, the one-stop solutions provider Romaco will present selected technologies for granulation, tableting and primary packaging of pharmaceutical solid dosage forms. From laboratory equipment to high-performance production systems, and from standalone machines to turnkey lines, Romaco offers the right solution for every application

Romaco Noack N 950E blister packaging machine

The N 950E is an ultra-flexible, easy-to-use blister packaging machine with rotary sealing for the high-speed segment. The blisters can be conveyed both longitudinally and crosswise, with the machine achieving a maximum output of 500 blisters a minute. It has a compact design in which the individual stations, such as sealing, coding, perforation and die-cutting, are configured in a way that saves space. Therefore, the N 950E only takes up a very small footprint in the primary packaging cleanroom, enabling space to be used to the max. All machine components are also easy to access, simplifying machine retooling and cleaning. What's more, the use of servo technology ensures fast and reproducible format changes and reliable machine operation with high-quality end products. As a result, the N 950E meets all the requirements for outstanding OEE values, which can easily be read and evaluated on the HMI. The blister packaging machine can handle all sealable films – including sustainable mono-materials of PET, PP, PE and paper – and is equally capable of manufacturing aluminium-aluminium blisters. With its ingenious heating and cooling systems at the forming station and rotary sealing system, the machine can cope with all types of products and packaging materials. Configuration of the product feeding unit is also extremely flexible and takes place either with dedicated feeding, using a brush-box feeder or manually. Furthermore, the N 950E blister packaging machine is compatible with different transfer systems to the downstream cartoners, such as the Romaco Promatic PC 4201 continuous motion cartoner.

The N 950E is equipped with an AI-based vision inspection and pinhole detection system for blister packs. The 3D image analysis checks the tablets for various parameters, including presence, color, shape, breakage, etc. Moreover, this intelligent system inspects the packaging film for defects.



N 950E blister packaging machine

S 710 Prime double-sided rotary press from Romaco Kilian

The high-productivity S 710 Prime double-sided rotary press is suitable for both mono-layer and bi-layer mode. With a maximum output of 1,020,000 tablets per hour, the S 710 Prime is classed as a high-speed press for manufacturing pharmaceutical, food and chemical products – and is ideal for large batches and high volumes. It is an economical tablet press that convinces with excellent value for money and high overall equipment effectiveness (OEE) – the outcome of fast product changes, short cleaning times and long maintenance intervals. For example, durable pressure rollers result in significantly lower costs for maintenance. Owing to the interchangeable die-table, the S 710 Prime is very flexible. The proven fill shoe design and asymmetrical hoppers improve the product flow, so that the technology is similarly perfect for processing powders with poor flow properties. Furthermore, the wear-free brake magnet technology restricts the relative standard deviation during tableting to a minimum ensuring high product quality. The combination of precision-manufactured die-tables with hardly any radial run-out and the Kilian S 710 Prime's magnetic product scrapers moreover enables a systematic reduction in product loss.



S 710 Prime double-sided rotary press

VENTILUS® Lab fluid bed processor by Romaco Innojet

To showcase its broad and varied portfolio of laboratory machines, Romaco will be presenting the VENTILUS® Lab fluid bed processor from Innojet. This exceptionally versatile all-rounder is used for granulating, drying and coating particles of any size from 10 µm to 2 mm. This multipurpose lab unit is intended for batch sizes from 0.7 to 7.0 liters. With its innovative process air distribution system inside the cylindrical product container, the required energy can be used far more efficiently, enabling the VENTILUS® Lab to cut batch processing times by up to 25%. The process air is introduced through the circular ORBITER® booster, ensuring homogeneous flow conditions and gentle intermixing of the batch. In combination with a bottom spray nozzle located in the center, the booster plate forms a unique functional unit enabling much simpler scale-up processes. When it comes to nozzle technology, users can choose between the well-established ROTOJET® and the recently launched FLEXIJET®, which was specifically developed for granulation processes and is both very easy to handle and quick to clean. The patented fluid bed components invented by Dr. h. c. Herbert Hüttlin are behind the remarkably accurate application of the spray liquid, with a precisely defined droplet size. With controlled release formulations, for instance, the modified release profiles are achieved using 10 to 15% less material. This targeted reduction in the amount of spray liquid used also means less power consumption, so that the VENTILUS® Lab substantially reduces CO2 emissions from fluid bed processes. Moreover, the rotating SEPAJET® filter system minimizes general product loss by returning particles retained by the filter to the process rather than discharging them.



VENTILUS® Lab fluid bed processor

On show at PMEC India (IEML, Greater Noida, Delhi) from November 24 to 26, 2026 (Booth 9A32).

Romaco Group

Romaco is a leading international supplier of processing and packaging equipment specializing in engineering technologies for pharmaceutical products. The Group provides individual machines, lines and turnkey solutions for manufacturing, filling and packing powders, granulates, pellets, tablets, capsules, syringes, liquids and medical devices. The company also serves the food and chemical industries.

The Romaco Group has its headquarters in Karlsruhe (Germany) and is part of Truking Technology, a globally operating high-tech enterprise based in Changsha (China). Truking's core competency is handling and filling pharmaceutical liquids.

Romaco operates from six production sites worldwide, with a broad portfolio comprised of seven established product brands. Noack and Siebler (Karlsruhe, Germany) supply blister, heat-sealing and rigid tube filling machines. Macofar (Bologna, Italy) markets technologies for filling sterile and non-sterile powders and liquids. Promatic (also Bologna, Italy) specializes in cartoners, track & trace systems and case packers. Kilian (Cologne, Germany) is a leading manufacturer of tablet presses. Innojet (Steinen, Germany) is in the business of granulating and coating fine solid particles. Tecpharm (Barcelona, Spain) offers tablet coating technologies.

More than 930 highly skilled and committed Romaco employees are dedicated to the development of future product technologies and to the continuous implementation of internal improvement processes. The Romaco Group's multi-brand system solutions are sold worldwide through ten Sales & Service Centers and a dense network of local agent organizations. Over 12,000 installations delivered by Romaco are currently in use in more than 180 different countries.

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Stevanato Group

Seven key decisions for successful API scale-up

John Riley, Director-North America API Technical Support, Piramal Pharma Solutions, discusses seven critical process development decisions that can help mitigate manufacturing risks, ensure commercial readiness and support a seamless transition from laboratory development to large-scale API manufacturing

In an increasingly complex biopharmaceutical landscape, bringing a small-molecule drug candidate from benchtop discovery to full-scale commercial manufacturing requires far more than standard technical execution. As a global contract development and manufacturing organisation (CDMO), Piramal Pharma Solutions, partnering with drug developers across the entire lifecycle, recognises that commercial readiness is rarely only a late-stage event. Instead, it is the cumulative outcome of early, deliberate choices and strategic vision. By taking an integrated approach through our global CDMO services, Piramal's development teams can navigate essential trade-offs, identify and solve technical hurdles early, and establish a resilient manufacturing framework from initial API synthesis to finished formulation.

While a process may perform admirably in a laboratory environment, translating that same chemistry into a robust, economical, and compliant commercial-scale operation presents a complex set of challenges. When small-molecule API processes fail during scale-up, the root cause can almost always be traced back to early trade-offs. By examining seven critical process development decisions through the lens of these common pitfalls, innovators can build commercial resilience into the process from the start.



1. Route selection: Academic elegance vs industrial feasibility

The trade-off: High-yielding, highly elegant synthetic routes developed on the bench often rely on expensive reagents and catalysts, highly energetic or energy inefficient operations, or costly chromatographic purifications. A route utilising safer, lower-cost/readily available starting materials and purification via crystallisation is often far more scalable.

What goes wrong: Selecting a route based solely on overall laboratory yield can lead to unintended safety hazards, supply chain bottlenecks for niche starting materials, or prohibitive raw material costs and purification techniques at commercial volumes.

The commercial reality: Route selection must evaluate raw material security, process safety, economics, and unit-operation simplicity alongside chemistry yields.

2. Critical Process Parameters (CPPs): Rigid envelopes vs manufacturing flexibility

The trade-off: Defining a process design space too narrowly can create an operational bottleneck, while defining it too broadly without sufficient data risks batch failures during routine production.

What goes wrong: Overly rigid parameter limits leave zero margin for minor, natural variations in commercial utility performance (e.g., cooling jacket response times or raw material lot variances), leading to frequent deviations, out-of-specification (OOS) investigations, and the risk of batch rejection.

The Commercial Reality: Adopting a structured Quality by Design (QbD) framework early ensures that process parameters are bounded by true quality risks rather than arbitrary benchtop observations.

3. Scale-up physics: Linear assumptions vs Non-linear realities

The trade-off: Small-scale development prioritises speed of chemical transformation, but volumetric scale-up changes the fundamental physical environment—specifically heat transfer, mass transfer, and mixing dynamics.

What goes wrong: Assuming heat dissipation or mixing profiles will scale linearly from 1-liter flasks to 5,000-liter reactors can lead to uncontrolled exothermic spikes, unpredictable side-reactions, or unexpected polymorphic shifts during crystallisations.

The commercial reality: Process design must account for physical scale-up dynamics early, leveraging scale-down modeling to anticipate reactor geometry and mixing performance.

4. Facility and equipment compatibility: Custom requirements vs standardised assets

The trade-off: Tailoring a process to highly specialised or non-standard equipment may optimise reaction conditions, but it drastically restricts manufacturing site flexibility or requires unplanned capital expenses that impact delivery timelines.

What goes wrong: Designing a route that requires rare vessel metallurgy, extreme temperature/pressure capabilities, or plant modification to ensure safe operations, limits where the product can be made, creating severe capacity bottlenecks.

The commercial reality: Designing chemistry to fit standard, multi-purpose commercial reactor suites ensures flexibility, reduces capital expenditure, and simplifies site-to-site transfers.

5. Analytical controls and impurity fate: Testing out quality vs building in control

The trade-off: Relying on extensive end-product testing to ensure quality vs investing early in understanding impurity formation, fate, and purge pathways.

What goes wrong: Identifying unknown or genotoxic impurities late in development can force expensive re-validation, route modifications, unplanned reworks, or unexpected regulatory delays right before commercial filing.

The commercial reality: Early impurity tracking and identification, followed by thorough fate-and-purge studies combined with suitable in-process controls (IPCs) provide a clear profile of impurity behavior, ensuring seamless regulatory acceptance.

6. cGMP and validation readiness: Speed-to-clinic vs defensible regulatory packages

The trade-off: Cutting corners on documentation, cleaning validation, and analytical method qualification to meet rapid early-phase clinical timelines vs. building a robust validation data package.

What goes wrong: Trying to "retrofit" commercial cGMP rigor into a poorly developed or legacy process late in the game often causes significant timeline slip, as cleaning limits, analytical methods, and safety data must be re-established.

The commercial reality: Establishing phase-appropriate cGMP alignment and robust cleaning frameworks during mid-stage development prevents costly re-work during formal Process Performance Qualification (PPQ).

7. Technology transfer: Isolated hand-offs vs integrated continuity

The trade-off: Treating tech transfer as a sequential "throw-it-over-the-wall" exercise between distinct R&D and manufacturing teams vs. operating

Stevanato Group

an integrated, cross-functional transfer model.

What goes wrong: Unspoken process nuances and tacit knowledge are easily lost during site transfers, leading to first-pass batch failures, delayed commercial launches, and fractured supply chains.

The commercial reality: Tech transfer is a continuous knowledge-management process. Close alignment between development scientists and plant operations ensures a smooth transition and long-term supply resilience.

The Unbroken line: Connecting API properties to final formulation

Ultimately, a small-molecule API does not exist in isolation—it is the functional core of the final drug product. Decisions made during API development directly dictate downstream formulation success.

Parameters such as particle size distribution, crystal form and habit, bulk density, and hygroscopicity—all controlled during API isolation and crystallisation—profoundly affect powder flowability, tablet compressibility, and dissolution rates in commercial formulations. An integrated approach that aligns API process development with final drug product requirements ensures that commercial readiness is achieved not just at the bulk drug level, but all the way to the finished patient dose.



The Piramal differentiator: De-risking decisions through the science collective

Navigating these trade-offs requires more than standard CDMO capacity; it demands multidisciplinary scientific foresight. Piramal Pharma Solutions addresses this through its Science Collective—a core team of senior global leaders encompassing drug substance, drug product, peptides, and bioconjugates. Functioning as a seamless extension of the client's internal CMC team, these specialists apply decades of hands-on experience to evaluate early route feasibility, containment needs, and process economics.

By embedding this cross-functional expertise directly into early development, the Science Collective helps teams evaluate synthetic route trade-offs, model scale-up physics, and align API crystallisation with final formulation performance long before formal tech transfer. The result is an integrated, risk-mitigated pathway that bridges the gap between laboratory benchwork and a scalable, commercial reality.

The ultimate metric: Delivering quality and continuity to the patient

While process optimisation, yield improvements, and tech transfer parameters are measured in kilograms and process logs, the true benchmark of success is measured by the impact on patients. Every decision made to de-risk scale-up, ensure impurity purge, or stabilise physical properties directly translates into product safety, drug efficacy, and supply chain reliability. A commercial manufacturing process built on informed early decisions protects against supply shortages, batch failures, and delays—ensuring life-saving therapies reach the patients who depend on them without interruption. Ultimately, commercial readiness isn't just a technical achievement; it is a commitment to patient centricity.



Stevanato Group

From botanical wealth to global leadership

Sanjaya Mariwala, Executive Chairman & MD, OmniActive Health Technologies, highlights the need for regulatory coordination, research investment and intellectual property protection to help India move from being an ingredient supplier to a global hub for nutraceutical innovation

India has the botanical resources, traditional knowledge, manufacturing facilities and scientific expertise to become a leader in the nutraceuticals field. Yet it remains a small player in a sector increasingly
focused on preventive care and science-based nutrition. The global nutraceutical market stands at $160 billion with 8–10 per cent annual growth, while India's present share of this is around two to three per cent. There may be some difference in market definition behind these numbers, but what they clearly indicate is that India has failed to leverage its inherent strengths in terms of the value that it contributes to the global nutraceutical market. The next stage of development will have to be based on scientific validation, predictable regulation and innovative activity in India.



The challenge is coordination, not the absence of regulation

However, India already has regulations for nutraceuticals through the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016. Yet, there could be some concerns regarding the classification of the product, the list of ingredients used, evidentiary requirements, and various authorities' roles in the industry. Indeed, FSSAI, AYUSH, and CDSCO each follow their own mandate; on the other hand, the industry needs coordination in research, production, and export processes. This causes confusion among companies might struggle to figure out the right path for the approval process beforehand since it would require financial investment in the product development.

Finally, the scientific aspect is another concern. Traditional usage can be a good indicator of where the research should lead; however, it does not guarantee the validity of all health claims. On the other hand, requiring the same evidential standard both for the already known ingredient and a completely new formulation could hinder the research.

Give MoFPI a clear mandate

It is important that the government should make MoFPI the nodal ministry for the nutraceuticals industry. This should be done without the need to merge or dilute the mandates of the regulatory authorities. However, MoFPI should set up a proper process of coordination with FSSAI, AYUSH, CDSCO, and other standards authorities in a time-bound manner.

A single-window process would help in streamlining product classification and evidence requirements, among other processes. The time required for clinical trials should be brought down from six to twelve months to two to three months.

If this is achieved in a proper way then it would be possible to complete 50 per cent more number of approvals every year through clinical trials.

On average there could be five to ten more clinical trials conducted per annum in the nutraceuticals industry. A dedicated route for integrating Ayurveda with modern scientific validation would also help traditional knowledge move towards evidence-backed products.

Make R&D investment commercially worthwhile

Companies are more likely to invest in research when the rules are predictable, the cost of validation is manageable and successful discoveries can generate returns. India should consider increasing the R&D tax incentive from the current 15 per cent to 25 per cent, aligning it with incentives available to the pharma sector, alongside government co-funding of up to 50 per cent for eligible clinical validation studies. These incentives should be linked to independently assessed research plans, measurable milestones and transparent reporting rather than routine expenditure.

This proposal expects such an effort to be able to deliver annual R&D tax benefits worth over Rs 500 crore, along with more than 30 peer reviewed journal publications per year from the nutraceutical industry in India. This is what can be expected; there are no guarantees, and a benchmark must be established, followed by periodic assessment of the program.

Public research organisations need to play a vital role in this program. Funding to CSIR labs, NIN, CSIR-CFTRI, and CSIR-CIMAP may help fund corporate-driven research efforts related to new ingredient development, extraction techniques, bioavailability, formulations, and clinical trials. It is essential for the industry to define the research agenda and fund it, whereas the scientists need to worry about methodology and reporting the research findings. This will ensure that public laboratories get an insight into the industry issues and that companies can leverage the scientific expertise that is beyond their reach.

Protect intellectual property and attract global research

India also needs to improve the commercial case for developing new products from traditional knowledge. The government should consider whether a separate intellectual property regime is necessary for any truly innovative inventions resulting from the study of Ayurveda. The proposal to extend patent protection by an additional 15 years for genuinely innovative Ayurvedic inventions merits serious consideration, subject to India's patent laws and international obligations.This system should be in accordance with Indian patent law and the international treaty; the traditional knowledge itself cannot become an object of monopoly. Also, the process of setting up of research centres and clinics for validation of nutraceuticals and creation of new products should be simplified for foreign companies. The process of obtaining permits, clear regulations for research, the possibility of working with competent scientists and intellectual property protection will help to make India a more attractive place for work.

Move from exports of ingredients to exports of innovation

India could raise its share of the global nutraceutical market to 10–15 per cent by 2030, creating a potential export opportunity of $7–12 billion. These are ambitious industry projections, not assured outcomes. Achieving them will require more than higher production volumes.

India has demonstrated its ability to take home-grown digital solutions to global markets, with UPI emerging as an example. The nutraceutical sector should pursue a similar ambition. Indian companies must develop not only globally competitive products but also the technologies behind them, including specialised extraction, bioavailability enhancement, formulation science and clinical research. These capabilities should be developed as exportable solutions. The objective should be to sell both nutraceutical products and the science and technology used to create them. This can help India move up the value chain, build intellectual property and become a global hub for nutraceutical innovation.

While it is easy for India to boast of the medicinal plants and cost-effective manufacturing capability, its strength lies in bringing its strengths together with science, technology and premium products.

In other words, the criteria for success for India would be research quality, regulatory decision-making, intellectual property created, domestic content and increased high-end exports. With MoFPI driving policy, research organisations collaborating with companies and regulations based on scientific principles, India can evolve from an ingredient supplier to innovator in the area of nutraceuticals.

Stevanato Group

Why workforce management could be pharma and healthcare's next growth lever

Tapan Acharya, Chief Revenue Officer, Keka explains how digital workforce management and HR technology can help India's pharma and healthcare sectors improve productivity, control costs and support scalable growth

India's pharmaceutical industry is expected to grow from a Rs 5.3 lakh crore domestic market in FY26 to Rs 12.47 lakh crore by 2030. India's hospital market, meanwhile, is projected to nearly double by FY32, reaching approximately Rs 16 lakh crore. The capital, demand and policy tailwinds are already visible. The less discussed question is whether organisations can extract the full value of that growth from the workforce they have.

Healthcare is one of the country's largest employers, with 39.4 lakh nursing personnel and more than 13.8 lakh registered allopathic doctors. Yet while healthcare has made significant progress in digitising clinical and patient-facing processes, the digital maturity of the underlying workforce and enterprise operations remains uneven. Recent industry research points to the same gap: Indian hospitals are increasing technology investments, but integration, automation and organisational readiness continue to constrain the value they derive from those investments.

That gap matters because healthcare is fundamentally a people-intensive business. The quality, availability and deployment of its workforce have a direct bearing on patient experience, operational continuity and, ultimately, the reputation and economics of the institution.

Pharma plants cannot run at partial capacity because a shift was poorly staffed. Hospitals cannot defer care because the right people were not available at the right time. Field teams cannot be managed effectively when leadership has limited visibility into where thousands of employees are deployed. Yet workforce management in many large organisations still depends on a patchwork of attendance systems, spreadsheets, manual approvals and disconnected applications.

The cost rarely appears as a single line item on the P&L. That is precisely why it is easy to underestimate.

The cost of workforce friction is hiding in the operating model

Consider a simple calculation.

If 10,000 employees lose just five minutes a day to avoid HR and workforce-administration friction, that is more than 18,000 employee-hours every month, assuming 22 working days. The number rises further when the time spent by managers and HR teams is included.

The same principle applies to workforce visibility.

A shift that is understaffed, overtime that could have been avoided, a field employee whose deployment is unclear, or an attendance discrepancy that takes several people to resolve may individually look immaterial. Across hundreds of locations and thousands of employees, they become a recurring operating cost.

This is particularly relevant when talent itself is becoming more expensive. Deloitte expects pharmaceutical and life sciences companies in India to provide salary increases of close to 10 per cent in 2026, among the highest across sectors. Life sciences also recorded 13.3 per cent average attrition in 2024.

When the cost of people is rising, the next question for leadership should be: how much productivity are we getting from the workforce we are already paying for?

A shift is not an HR event. It is a capacity decision.

For a 24×7 manufacturing facility or hospital, workforce scheduling directly determines available capacity.

The challenge is not merely creating a roster. It is knowing whether the right people are available for the right shift, identifying gaps early, managing overtime and responding when plans change.



A connected workforce system can connect shift planning with attendance and availability, allowing managers to see workforce capacity before a gap becomes an operational problem.

That changes the conversation from "Who was absent?" to "Do we have the capacity we need today?"

For a CXO, that is a fundamentally different question.

The same problem becomes harder when the workforce leaves the premises

Pharma's field workforce creates another blind spot.

India's pharmaceutical industry has built one of the world's largest commercial footprints, supplying roughly 20 per cent of global medicines by volume. Field teams are an important part of that ecosystem, but their work happens across territories rather than inside an office.

For these employees, location-aware attendance, GPS-based check-ins and geo-fencing are not merely attendance features. They create a layer of operational visibility that traditional office-centric systems cannot provide.

The value lies in knowing whether the workforce that is supposed to be deployed in the market is actually deployed and giving managers enough information to act, without creating another reporting burden.

Deloitte's research on biopharma's commercial model points to the productivity opportunity here: sales representatives spend roughly two-thirds of their workday on research, product evaluation, scheduling and administrative activity.

The more administrative friction can be removed, the more of that expensive workforce can remain focused on the work that generates value.

The bigger risk is not inefficiency. It is decisions made without visibility.

A CFO would not make a major capital allocation decision using data that is three weeks old.

Yet workforce decisions are often made using exactly that kind of information.

If attendance, shifts, leave, location and workforce costs sit in different systems, leadership gets reports rather than a live picture. By the time a staffing pattern appears in a monthly review, the opportunity to intervene may already have passed.

This is where modern HR technology has quietly changed the category.

They have moved beyond their traditional role as systems of record. When it brings together workforce scheduling, attendance, location, employee self-service and people data, they can become an operating layer for workforce decisions.

The same principle applies to employee access. A field employee or night-shift worker should not need access to a desktop to interact with HR. Mobile access allows attendance, shifts, leave and routine requests to be managed from wherever work happens. This helps organisations to remove friction at scale, not through another HR initiative, but through better infrastructure.

The next frontier of digital transformation is people

Healthcare and pharma are already investing in digital infrastructure across clinical care, manufacturing, research, patient engagement and data. The next logical step is to bring the same discipline to the workforce that powers those systems.

A modern HRMS can connect shift planning, attendance, geo-fenced and mobile workforce management, employee self-service, payroll and people data into a single operating layer. More advanced platforms can take that foundation further, using analytics and AI to surface patterns and support decisions rather than simply record transactions.

For a healthcare organisation, this can mean better visibility into staffing across facilities and shifts. For pharma, it can mean greater control over workforce deployment across plants, offices and field territories. For both, it creates the possibility of making workforce decisions with the same level of data and precision applied to other parts of the business.

The strategic opportunity is therefore much larger than replacing spreadsheets or automating HR processes.

As these industries invest billions in capacity, infrastructure and growth, the workforce itself cannot remain the least visible part of the operating model. Organisations that combine digital infrastructure with workforce intelligence will be better positioned to deploy talent, control operating costs, protect productivity and scale without proportionately increasing administrative complexity.

For pharma and healthcare, the next phase of digital transformation will increasingly be about bringing the workforce into the same connected, data-driven operating model that is already transforming the rest of the business. The companies that get this right will have a clearer view of their capacity, sharper control over costs and, ultimately, greater room to grow.

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From analytical development to regulatory CMC strategy

Anil Dudam, Regulatory Affairs CMC Expert, explains why integrating regulatory CMC strategy early into analytical and product development is critical to building a coherent quality dossier, strengthening regulatory submissions and managing product lifecycle changes, particularly for Indian pharma companies targeting the US market

For pharma companies developing products for the U.S. market, Chemistry, Manufacturing, and Controls (CMC) should begin well before a regulatory dossier is assembled. The quality section of an application is ultimately the regulatory expression of decisions already made during formulation, analytical development, process development, manufacturing, stability, packaging, and control-strategy development.

This is particularly relevant for Indian pharma organisations supporting U.S.-focused programs. Technical activities may be distributed among API manufacturers, formulation groups, analytical laboratories, manufacturing sites, contract organisations, quality functions, and regulatory teams. Each function may generate technically sound information, yet the submission still has to explain one coherent story: what matters to product quality, how it is controlled, why the proposed controls are appropriate, and how that state of control will be maintained as the product evolves.

An analytical scientist may initially ask whether an attribute can be measured accurately and reliably. Regulatory CMC adds a second set of questions. Why does the attribute matter? What does the development history tell us about it? Where is it controlled? What evidence supports the proposed acceptance criterion? Could manufacturing or stability change the risk? Those questions are easier to answer when regulatory thinking develops alongside the science rather than after the reports are finalised.



Analytical development should be linked to regulatory purpose

Analytical procedures provide much of the evidence used to understand and control a drug substance or drug product. Identity, assay, purity, degradation products, dissolution or drug release, and other product-specific attributes all depend on analytical capability. FDA guidance on analytical procedures and method validation places these procedures within the broader demonstration of identity, strength, quality, purity, and potency. [1]

For development teams, the practical point is that a technically successful method is not the end of the discussion. Its intended regulatory purpose should remain visible throughout development.

Consider a degradation-product method. Specificity, accuracy, precision, range, sensitivity, and other appropriate validation characteristics matter. But the CMC discussion also needs to establish which degradation products are relevant, how they arise, whether they change during stability, which ones require individual control, and whether the method remains suitable for the proposed shelf life and specification.

A useful cross-functional review therefore asks more than whether the validation report passed. It asks whether the analytical procedure generates the evidence needed to support the proposed control. This distinction becomes important when methods are transferred, revised, or applied to later-phase or commercial material, because the regulatory rationale should remain connected to the evolving product knowledge.

Specifications should be justified, not merely populated

Specifications are often where analytical data, process understanding, stability behavior, and regulatory justification meet. ICH Q6A describes a specification as a list of tests, references to analytical procedures, and appropriate acceptance criteria, while also making clear that specifications are only one part of the overall control strategy. [2]

For a U.S.-focused program, teams should be able to trace why each meaningful test is present and why its acceptance criterion is appropriate. Historical batch results are important, but they are not the only consideration. Development experience, process capability, analytical capability, stability data, safety or qualification considerations, and the relationship of an attribute to product performance may all contribute to the justification.

Before finalising a specification, an analytical, quality, development, and regulatory team can ask four practical questions: What risk is this test controlling? What data support the proposed limit? Is the analytical procedure suitable at the level where the control is being applied? Is the rationale described consistently across development reports, specifications, stability documents, and the regulatory dossier?

This review can identify problems that are otherwise discovered during late-stage authoring. A limit may be scientifically reasonable but poorly justified in the dossier. A development report may use terminology that no longer matches the final specification. Stability data may support a different understanding than the narrative used elsewhere. These are documentation issues on the surface, but they often reveal that the underlying scientific rationale has not been managed as a single body of knowledge.

Impurity control is a cross-functional CMC problem

Impurity control illustrates why analytical development and regulatory strategy cannot be separated. ICH Q3A and Q3B provide frameworks for evaluating impurities in new drug substances and new drug products, including the consideration of reporting, identification, and qualification as applicable. [3,4]

When a new or increasing impurity is observed, the analytical question is only the starting point. The development team also needs to understand its origin. Is it process-related or degradation-related? At what step is it formed? Can the process purge or control it? Does it increase on stability? Is a reference standard available or needed? Does the existing specification adequately address the risk? Could the observation affect other batches, sites, suppliers, or storage conditions?

The regulatory team should not first encounter these questions while drafting the impurity section of the submission. A more effective approach is to maintain a clear impurity narrative during development:

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origin, analytical detection and quantitation, fate or purge where relevant, stability behavior, qualification considerations, and final control.

For Indian companies supporting U.S. programs through multiple development and manufacturing partners, this becomes especially important. An impurity may be characterised by one laboratory, investigated by another group, and controlled in a specification maintained elsewhere. Unless the rationale travels with the data, technically correct individual reports can still produce an incomplete regulatory story.

Stability should explain product behavior over time

Stability programs do more than generate results at scheduled time points. They provide evidence about how product quality changes over time and support storage conditions, retest periods, or shelf life. ICH Q1A(R2) provides the established framework for stability testing of new drug substances and products. [5]

For CMC teams, stability is most useful when it is interpreted together with formulation knowledge, manufacturing history, degradation pathways, analytical capability, and the container-closure system. A change in degradation products, dissolution, moisture, assay, physical appearance, or another relevant attribute should be evaluated in that wider context.

A practical review should therefore ask whether observed trends are scientifically understood rather than simply whether each time point meets specification. If a degradation product shows a gradual increase, for example, the discussion may need to connect the analytical method, degradation pathway, packaging protection, manufacturing variability, and proposed shelf-life limit.

This integrated view also matters when changes occur during development. A revised process, new manufacturing site, modified packaging component, or analytical-method change may alter what stability evidence is needed. Regulatory CMC can help identify those implications before a submission timeline makes additional data generation difficult.

Manufacturing changes expose weak links in the CMC story

Products and processes evolve. Suppliers change, equipment is replaced, processes are scaled, manufacturing sites are added, analytical procedures are improved, and container-closure components may change. ICH Q12 provides a framework for more predictable and efficient management of postapproval CMC changes and emphasises lifecycle management of pharma products. [6]

The useful regulatory question is not simply whether a change occurred. It is what product or process knowledge the change touches and what evidence is needed to demonstrate continued control.

Consider a change in the source of a critical material. The assessment may need to extend beyond supplier qualification. Teams may need to consider material attributes, process performance, impurity profiles, analytical controls, finished-product quality, stability, and the regulatory commitments associated with the material. The appropriate evidence will depend on the nature of the material, the process, prior knowledge, and the risk introduced by the change.

This is where a well-connected CMC strategy becomes valuable. When teams understand why controls were established, they can evaluate changes against the underlying scientific rationale rather than relying only on document-by-document impact assessments.

What Indian companies targeting the U.S. market can do differently

The opportunity for Indian pharma organisations is not to create another layer of CMC documentation. It is to make existing development knowledge easier to trace, challenge, and maintain.

First, involve regulatory CMC earlier in development. Regulatory professionals can help identify where a scientific decision will later require a clear justification in the submission. Early involvement is particularly useful for specifications, impurity strategies, stability plans, manufacturing changes, and comparability questions.

Second, create traceability for important controls. For a significant quality concern, the team should be able to move logically from the risk or product attribute to the development evidence, analytical procedure, manufacturing or material control, specification where applicable, and regulatory justification. A simple working map can reveal missing rationale before the dossier is assembled.

Third, establish a cross-functional review at meaningful development transitions. Before PPQ or registration batches, before finalising commercial specifications, and before major submission milestones, analytical, manufacturing, quality, development, and regulatory representatives should challenge whether the control strategy still reflects current knowledge.

Fourth, manage changes as changes to product knowledge, not only changes to documents. When a source, process, method, site, or component changes, the assessment should identify which scientific assumptions and controls may be affected. The resulting updates can then be propagated consistently across reports and regulatory sections.

Finally, distinguish the authoritative rationale from supporting information. If the reason for a control is described differently in development reports, risk assessments, validation documents, and regulatory summaries, teams should establish which rationale represents the current scientific position and ensure that downstream documents remain aligned.

The quality dossier is moving toward connected knowledge

The draft ICH M4Q(R2), which modernises the quality component of the Common Technical Document, provides a useful forward-looking context for this discussion. The draft is intended to improve the efficiency of registration and lifecycle management and to facilitate developments such as digitalisation, knowledge management, and emerging technologies. Because it remains draft guidance, its concepts should not be presented as current implementation requirements. [7]

Its direction, however, reinforces a challenge CMC organisations already face: quality information is most useful when the relationships among development knowledge, risks, controls, evidence, and lifecycle decisions are clear.

This is more than a dossier-format issue. If the rationale for a control is fragmented across pharma-development reports, manufacturing descriptions, specifications, analytical-validation reports, stability studies, and regulatory summaries, a later change can expose inconsistencies that were not obvious when each document was written separately.

Companies can prepare for a more knowledge-oriented regulatory environment now by strengthening traceability, improving cross-functional ownership of scientific rationales, and treating Module 3 as the communication of an integrated control strategy rather than a collection of independently authored sections.

From strong science to a defensible regulatory strategy

Indian pharma organisations already contribute extensive analytical, development, manufacturing, and quality expertise to products intended for global markets. The regulatory challenge is to ensure that this technical work remains connected as a product advances from development to registration and commercial lifecycle management.

Analytical procedures generate evidence. Development studies build understanding. Specifications define selected controls. Stability studies describe product behavior over time. Manufacturing controls manage process and material variability. Regulatory CMC connects these elements and explains why the resulting strategy provides appropriate assurance of product quality.

The practical test is whether a team can explain, for an important quality concern, what is being controlled, why the control is necessary, what evidence supports it, and what would need to be reconsidered if the product or process changes.

When those answers are available before dossier authoring begins, regulatory writing becomes the expression of established product knowledge rather than an exercise in reconstructing the scientific rationale at the end of development. For Indian companies developing products for the U.S. market, that shift can make CMC strategy more coherent, more resilient to change, and better prepared for lifecycle management.

References

U.S. Food and Drug Administration. Analytical Procedures and Methods Validation for Drugs and Biologics. Guidance for Industry.

International Council for Harmonisation (ICH). Q6A: Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.

ICH. Q3A(R2): Impurities in New Drug Substances.

ICH. Q3B(R2): Impurities in New Drug Products.

ICH. Q1A(R2): Stability Testing of New Drug Substances and Products.

ICH. Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.

ICH. M4Q(R2): The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality. Draft guidance - verify current status before submission.

ICH. Q8(R2): Pharmaceutical Development.

ICH. Q9(R1): Quality Risk Management.

ICH. Q10: Pharmaceutical Quality System.

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From manufacturing scale to supply-chain resilience: India's API opportunity

Hari Kiran Chereddi, Founder, Managing Director and CEO, HRV Pharma, highlights the need to strengthen India's API supply chains through diversified sourcing, commercially viable domestic manufacturing and regulatory readiness, and explains why supply resilience depends on having qualified alternatives in place before disruptions occur

In January 2014, I watched our family's API plant in Bibinagar burn for almost 24 hours. No one was hurt, but one dropped spanner during a methanol unloading had stopped our entire production, and every customer who depended on that single site was exposed at once. That experience taught me something the industry is still learning: the strength of a pharmaceutical supply chain is not measured by how much it produces on a good day, but by how many qualified alternatives it has on a bad one. India has built considerable strength in formulations and generic medicines. The next step is to ensure that the foundations supporting this strength are equally resilient.

An API supply chain rarely attracts attention when everything works. The concern becomes visible when a key starting material is delayed, an input becomes suddenly expensive, or a disruption at one manufacturing location affects production across several countries.

Resilience begins with understanding dependence

India's dependence on imported pharmaceutical ingredients is well documented. According to the Department of Pharmaceuticals, India imported APIs, bulk drugs and drug intermediates worth approximately $4.35 billion in FY2024–25, with China accounting for around 73.7 per cent of these imports. This concentration creates an important vulnerability, particularly when individual ingredients have limited alternative sources.

The answer, however, is not to assume that every imported ingredient must immediately be manufactured domestically. Some ingredients can be produced competitively in India today. Others may require years of investment, process development and customer qualification before domestic production becomes commercially viable.

The more useful starting point is to identify where dependence creates the greatest risk. Which inputs have only one or two qualified suppliers? Which products are essential to large volumes of medicines? Where would a disruption have the greatest effect on availability? These questions should guide decisions on domestic manufacturing, alternative sourcing and capacity development.

Resilience is not achieved by replacing one dependency with another. It comes from understanding vulnerabilities and building practical alternatives before they become urgent.

Domestic capacity must become commercial capability

India has taken steps to strengthen domestic production of critical pharmaceutical ingredients through initiatives such as the Production Linked Incentive scheme for bulk drugs and the development of bulk drug parks. By December 2025, the PLI scheme had supported approximately 56,800 metric tonnes of annual manufacturing capacity across 28 critical products. But creating capacity is only the beginning. Manufacturing must also be commercially viable, consistently meet quality standards and remain competitive on cost. Policy support can enable this transition, but sustained competitiveness will ultimately depend on execution.

There is also a faster lever that policy discussions often miss. Much of India's existing API capacity is under-used, not because the chemistry is lacking, but because the plant



lacks the regulatory filings, documentation or market access needed to supply regulated markets. Making existing capacity usable can deliver resilience sooner than building new plants. This is the model we have built at HRV Pharma: we own the Drug Master Files and regulatory dossiers, while a network of more than 50 FDA and EU-GMP certified partner sites does the manufacturing. A product qualified across two or three of those sites is a genuine alternative, not a name in a database.

Quality is the foundation of global competitiveness

Resilience and quality are often discussed separately. In pharmaceutical manufacturing, they are inseparable.

An alternative supplier is useful only when its product meets the required specifications and its manufacturing processes are sufficiently understood and controlled. Qualifying another source involves technical evaluation, analytical comparability, process understanding and, where necessary, regulatory submissions or approvals. These activities take time and cannot be postponed until an existing supplier fails.

This makes regulatory readiness an important part of supply-chain planning. Manufacturers must maintain accurate documentation, robust change-control systems, effective deviation investigations and reliable data-integrity practices. Quality cannot be treated as a final checkpoint after a production decision has already been made. The same principle applies when manufacturing is distributed across multiple partners. A network adds resilience only when every site is technically qualified, operates within clearly defined quality requirements, and responsibilities for documentation, process changes and regulatory commitments are unambiguous. Done well, this is what turns spare capacity into dependable supply.

The industry should therefore measure supply resilience by the availability of qualified, usable alternatives, rather than by the number of suppliers listed in a database.

Global trade is changing the cost of dependence

Pharmaceutical supply chains are being reshaped by trade policies, geopolitical uncertainty and the growing emphasis on domestic manufacturing security. Governments increasingly view access to medicines and critical ingredients as a strategic priority rather than a purely commercial matter.

India's pharmaceutical exports, worth over $31 billion in FY26, reflect the country's growing role in global medicine supply. However, sustaining this position will require stronger domestic API capabilities alongside reliable international partnerships. The objective is not simply to reduce import dependence, but to build a pharmaceutical ecosystem that can maintain reliable supply even when global trade conditions change.

Technology can make supply chains more predictable

As pharmaceutical supply chains become more interconnected, companies need greater visibility into demand, production, quality and potential disruptions. Digital systems and AI can help identify emerging risks, anticipate shortages and evaluate alternative suppliers, allowing businesses to respond before disruptions affect supply. However, technology is only as effective as the data and processes supporting it. Reliable information, traceable decisions and human oversight remain essential in a regulated industry, where identifying a potential disruption is only the first step; the real test is having the capability to respond without compromising quality or supply continuity.

India's next phase of API growth

India does not need to choose between cost competitiveness and resilience; it must build a pharmaceutical ecosystem where both reinforce each other. Ultimately, API resilience is a shared responsibility: policymakers must enable domestic capabilities, manufacturers must invest strategically, and supply-chain partners must work together to ensure reliable, uninterrupted access to quality medicines.

India has already demonstrated that it can manufacture and supply medicines to the world at scale. The next task is to make the ingredients behind those medicines equally dependable. The measure of API resilience will not be how much India can manufacture when supply chains are working normally, but how reliably it can keep medicines moving when they are not.

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Beyond pharma market growth: The business of reaching India's regional markets

India's pharma growth depends not just on national market expansion, but on how effectively companies serve regional markets. **Dr Kruti Mehta** and **Dr Dhwani Mehta,** MDs, Olcare Laboratories, discuss the importance of local market intelligence, inventory planning, distribution efficiency and affordability in building a sustainable pharma business

India's pharma market is growing, but growth at a national level does not tell the whole story. For a pharma company, the real work begins when it has to translate that opportunity into reliable product availability across different regions, each with its own healthcare infrastructure, prescribing patterns and distribution challenges.

According to the India Brand Equity Foundation (IBEF), India's domestic pharma market was valued at Rs 5.30 lakh crore in FY2026, with a projection of $130 billion by 2030. These figures point to the scale of the opportunity. However, the decisions that determines whether a company can participate in that growth are often made much closer to the market.

A pharma business cannot approach every region in exactly the same way. The concentration of hospitals and specialists, the reach of pharmacy networks, local treatment patterns and patients' ability to afford medicines can vary significantly between markets. Even two cities of comparable size may present very different commercial realities.

This is why market expansion needs to begin with a closer understanding of local demand. Population and growth figures provide a useful starting point, but they do not reveal which therapies are most relevant, where prescriptions are generated or whether the existing distribution network can meet demand consistently. These factors should inform decisions about sales coverage, distributor partnerships and the pace at which a company enters a new market.



Dr Kruti Mehta



Dr Dhwani Mehta

> As India's pharma industry expands, companies will need to look beyond national averages when deciding where and how to grow. Market data can help identify opportunities, but regional understanding must guide the decisions that follow

Inventory planning is another part of the equation. Medicines need to be available when patients and healthcare providers require them, but maintaining availability also ties up working capital. Excess stock can increase the risk of expiry and leave resources underutilised. Too little stock, on the other hand, can lead to stock-outs and affect relationships with pharmacies and distributors.

Managing this balance across several regions requires more than a national sales forecast. Companies need timely information from their sales teams and distribution partners, a clear view of stock movement and replenishment processes that reflect local demand. Digital tools can help improve visibility, but their value depends on the quality of the information being used and how quickly teams act on it.

The economics of distribution also change from one market to another. Delivery frequency, logistics costs, distributor coverage and the scale of demand all influence how a business should operate. A dense urban market may support a different model from a geographically dispersed region. The important consideration is not to impose an identical distribution structure everywhere, but to maintain consistent standards of product quality and availability while adapting execution to local conditions.

Affordability deserves equal attention. Demand for a medicine does not depend only on the prevalence of a condition; it also depends on whether patients can access and continue treatment. Companies need to consider pricing, channel strategy and product availability together. A market may offer attractive growth prospects, but the commercial opportunity has to be understood alongside the realities of healthcare access and purchasing power.

These decisions become difficult when sales, supply chain and distribution operate independently. A sales team may identify a change in local demand, but that insight has limited value if inventory planning cannot respond. Similarly, a distributor network may be in place, but it cannot ensure consistent availability without clear communication and timely replenishment.

For leadership teams, the task is to bring these functions closer together. Market intelligence needs to inform supply planning; stock availability needs to be monitored alongside sales performance; and expansion decisions need to account for the cost and effort required to sustain a presence. This is not simply an operational concern. It affects how efficiently a company uses its resources and how reliably it serves its markets.

There is also a difference between entering a market and building a business there. Opening a new territory or appointing a distributor may establish an initial presence, but long-term performance depends on maintaining product availability, understanding changing demand and building dependable channel relationships. The number of markets entered is therefore only one measure of progress. Consistency of service and the ability to sustain operations matter just as much.

As India's pharma industry expands, companies will need to look beyond national averages when deciding where and how to grow. Market data can help identify opportunities, but regional understanding must guide the decisions that follow.

For us, this is the central challenge of pharma distribution in India: combining the scale of a national market with the judgement needed to serve its many local markets. Growth is not simply about reaching more locations. It is about understanding what each market requires and building a distribution model that can serve it reliably over time.

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The molecule went generic. The margin didn't

Saurabh Agarwal, CEO and Director, HAB Pharmaceuticals and Research, writes on why India's next phase of growth in the GLP-1 market will depend on domestic sterile manufacturing, drug-delivery devices, quality systems and specialised talent

Six months after semaglutide's patent expired, India has proved it can copy a peptide overnight. The harder question is whether it can own the parts of the value chain that actually pay.

On the morning of 21 March 2026, India pulled off something no other large market had managed. Within hours of semaglutide's patent lapsing, a dozen companies had product on pharmacy shelves. China lost the same patent on the same day. Seven months later, it has still not approved a single generic.

We are entitled to enjoy that. We are not entitled to mistake it for strategy.

The first six months tell a less flattering story. By April, generics had taken half of India's semaglutide sales by value and roughly four in every five units. By May, month-on-month value growth had dropped from 50 per cent to 6. The cheapest vial sells for Rs 1,290 a month. Depending on who is counting, India has between 12 and 40 semaglutide players, yet far fewer plants actually make the drug, with several brands quietly sourcing from the same few lines.

That is not yet a peptide industry. It is a distribution industry with a peptide in it.

Follow the money, not the molecule

Look closely at the price ladder and one detail stands out. Where the same company sells the same molecule as both a vial and a pen, the pen costs more than three times as much. Same peptide, same strength. The only difference is the device.

That is the real lesson of India's GLP-1 moment, and we risk missing it while we count launches. Once a peptide goes



generic, value leaves the molecule and moves into three places: the sterile fill-finish line, the delivery device, and the quality system that binds them together.

India is thin on all three. Much of the device supply behind the March launches came from overseas pen makers whose order books reportedly run into 2028. Premium aseptic lines carry lead times of 18 to 36 months. Upstream, global peptide synthesis capacity is running at close to 90 per cent utilisation by some estimates, and a large share of the protected amino acids and intermediates feeding Indian synthesis still comes from China. We have built a very fast launch machine on borrowed inputs.

July was the warning shot

In July, one of India's most respected generic makers paused supply after API batches failed specification during scale-up, and a partner brand recalled pens from the same source. It was handled responsibly. It also showed how concentrated the risk is. When one plant stumbles, several brands go silent at once.

Peptides are not tablets. A truncated sequence or an oxidised residue can sit right beside the main peak on a chromatogram and hide there. Regulators know this. In July, the US FDA revised its draft guidance for 17 generic peptides, from semaglutide and tirzepatide to teriparatide. WHO prequalification now expects no new impurity above 0.5 per cent in synthetic semaglutide. The Indian Pharmacopoeia is working towards its own monograph. The bar is rising everywhere at once, and fastest where Indian manufacturing is thinnest: analytical depth and process control at commercial scale.

Four bets for the next five years

First, count lines, not brands. The crowded semaglutide shelf will consolidate sharply by 2028, and the survivors will not be the companies with the largest field force. They will be the ones that own a validated aseptic line and a device platform they truly understand.

Second, the device is becoming the dossier. The next wave of incretins is harder to deliver, not easier. One late-stage combination pairs two peptides in a dual-chamber pen and awaits a US decision around the year end. A triple agonist has shown about 28 per cent weight loss in Phase 3. India needs domestic pen platforms, cartridge glass and needle capacity, co-developed with sterile manufacturers rather than bought from a catalogue. A targeted incentive for drug-device combination components would do more for this sector today than another bulk-drug scheme.

Third, the regulated-market window is shorter than it looks. Canada approved its first generic semaglutide in April, made by an Indian company. Brazil and South Africa followed in July. China is held up by data protection until around April 2027. The US and Europe open around 2031 and 2032. That leaves roughly five years to build EU-GMP and US-grade sterile capacity, which is exactly how long it takes to design, build, validate and get a facility inspected. Anyone starting in 2028 is already late.

Fourth, respect the pill without panicking about it. The US approved an oral small-molecule GLP-1 in April, which sidesteps sterile manufacturing entirely. Some read that as the end of the injectable story. I don't. India's own data show oral semaglutide losing ground to injectables in August, with injectable tirzepatide holding around 72 per cent of that segment. And incretins make up only about three quarters of global peptide sales. The line that fills a semaglutide cartridge today can fill teriparatide, octreotide or leuprolide tomorrow. The opportunity is a platform, not a product.

Where I am placing my own chips

At HAB, we chose to bet on the unglamorous middle of the chain. Our sterile facility for pens, cartridges, prefilled syringes and lyophilised products is now in commissioning, designed with EU-GMP in mind from the first drawing. It has been neither quick nor cheap. But the last six months have convinced me that the cheapest part of a GLP-1 is the peptide, and the hardest part to copy is everything around it.

Which brings me to the real constraint. Capital is available for this space, and capacity can be ordered. What cannot be ordered is people: engineers who can validate an isolator, analysts who can chase a peptide impurity at 0.1 per cent, and regulatory specialists who can write a drug-device dossier that survives a European inspector. India spent three decades producing world-class tablet people. The next decade needs sterile people, and we are not training them fast enough.

India won the race to the shelf. The next race is to the line. It is a different race, and it may well have different winners.

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Advanced automation for dry powder inhaler packaging

The article highlights how Capmatic's BAMBINO-S and BANDSTAR systems integrate component handling, filling, inspection, labelling and final packaging to support automation in dry powder inhaler manufacturing

Dry powder inhalers (DPIs) have become an important delivery platform for respiratory medicines, offering patients a breath-actuated alternative to other inhalation technologies. But behind the relatively simple user experience is a product that can be demanding to manufacture and package consistently.

Unlike conventional pharmaceutical products, an inhaler combines a drug formulation with a delivery device. The performance of the finished product therefore depends not only on the formulation itself, but also on the device components, assembly process and manufacturing controls. The U.S. Food and Drug Administration recognises this relationship in its guidance on MDI and DPI drug products, highlighting the importance of understanding both product and process throughout the product lifecycle.

For DPI manufacturers, this can translate into a series of precise operations. Powder may need to be accurately filled into blisters, capsules or other dose-containing components before the device is assembled and packaged. Small and lightweight components can be difficult to handle consistently, while their orientation and positioning can be critical to subsequent operations.

This makes automation about considerably more than production speed. Feeding, transfer, assembly, filling, inspection and labelling all need to work together with a high degree of repeatability.



Advanced automated solutions for dry powder inhaler packaging from Capmatic

Handling complex components with precision

Capmatic's BAMBINO-S is designed to address this type of challenge. Building on the company's Bambino Monoblock platform, the compact system combines component feeding, precise transfer, filling, robotics and labelling in a space-optimised configuration.

The system is designed to handle inhalers in different shapes and sizes. Mechanical and vibratory sorting systems organise and feed components into the production process, while a combination of linear and rotary servo-driven movements provides controlled indexing. Robotic pick-and-place technology can be incorporated where additional precision is required.

This is particularly relevant when dealing with small or unstable components. Consistent positioning is essential when filling, assembly, inspection or labeling operations depend on a component arriving at precisely the right location and orientation.

Quality control is integrated into the process rather than left entirely to final inspection. In-line systems can verify component presence and integrity, filling accuracy, torque or pressure and label quality, including coding, presence and skewness.

The BAMBINO-S is also designed around pharmaceutical manufacturing requirements, using pharmaceutical-grade construction and specified FDA-approved materials, with an emphasis on cleanability and product protection.

Protecting the finished product

Once the inhaler has been assembled and inspected, final packaging provides another important layer of product protection and presentation.

Capmatic's BANDSTAR is a compact, modular system designed for tamper-evident neck banding and optional shrink-body labeling. It can be integrated into an automated packaging line or used as a stand-alone unit.

The system provides controlled container indexing through either pneumatic gating or a servo-driven feed screw. Film handling is designed for repeatability, with a self-centering reel holder, motorised unwinder and feeding belts driven by two stepper motors.

Programmable film lengths and recipe-based adjustments allow changes between products without extensive manual intervention.

The BANDSTAR can be configured for speeds of up to 300 bottles per minute and can accommodate components up to 200 mm in diameter.

Automation built around consistency

For DPI manufacturers, the value of an automated packaging system lies not simply in replacing manual operations. It lies in creating a controlled sequence in which components are handled consistently, quality checks are performed at the appropriate stages and finished products move through packaging with minimal unnecessary intervention.

As inhalation therapies continue to develop, manufacturers will need equipment capable of accommodating different device geometries, production requirements and packaging formats without compromising repeatability.

The combination of BAMBINO-S and BANDSTAR provides Capmatic with an approach that connects precision handling and assembly with inspection, labeling and final package protection.

The objective is straightforward: to make complex inhaler packaging more controlled, more consistent and easier to scale, while maintaining the standards expected of modern pharmaceutical manufacturing.

For more information on Capmatic's inhaler and nasal spray packaging lines, please contact Vaxom Packaging Pvt Ltd on +91-22-69010532 or send an email to customer.service@vaxom.in

Reference

[1] U.S. Food and Drug Ad*ministration, "Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products — Quality Considerations," April 2018. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/metered-dose-inhaler-mdi-and-dry-powder-inhaler-dpi-drug-products-quality-considerations*

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Building a digital QMS on a strong quality foundation

Dr Raghavender Gunda, Head-R&D Quality, VJ Biosciences, explains how biopharma companies can establish a robust Pharmaceutical Quality System before implementing digital quality management tools, with a focus on regulatory compliance, risk-based implementation and data integrity

Digital transformation in biopharmaceutical manufacturing delivers sustainable value only when technology is built on well-defined, risk-based quality processes. For a greenfield facility, establishing a robust Pharmaceutical Quality System (PQS) before selecting digital platforms creates an opportunity to embed compliance, data integrity, operational discipline and scalability from the outset.

This article outlines a practical approach to electronic Quality Management System (eQMS) implementation, covering process design, SOP development, gap assessment, risk-based prioritisation, technology selection, risk-based computerised system validation and continuous improvement. It highlights the role of Indian GMP requirements and international guidelines in building a digitally enabled, inspection-ready quality ecosystem. Digitalisation should strengthen an established quality framework, not compensate for poorly designed processes.

Introduction: Quality must precede technology

Digital transformation is increasingly shaping how biopharmaceutical organisations manage quality, compliance and operational performance. Electronic document management, digital training, audit management, deviation management, Corrective and Preventive Action (CAPA) workflows, change control and integrated quality analytics can improve traceability, visibility and decision-making.

However, the effectiveness of these technologies depends on a fundamental question: Have the underlying quality processes been adequately designed, risk-assessed and standardised before they are digitised?

A greenfield biopharmaceutical facility has a distinct advantage: its Pharmaceutical Quality System can be designed intentionally, without necessarily inheriting fragmented legacy applications, inconsistent procedures or undocumented workarounds. This opportunity, however, can be undermined if software procurement and configuration begin before process ownership, regulatory obligations and business requirements are clearly established.

The Pharmaceutical Quality System (PQS) is the overarching organisational system of responsibilities, processes, resources and controls used to manage pharmaceutical quality. An electronic Quality Management System (eQMS) platform supports selected PQS processes; it does not constitute the entire PQS. The PQS spans pharmaceutical development, technology transfer, commercial manufacturing and product discontinuation.



A digital platform can route approvals, trigger alerts, restrict access and maintain electronic records. It cannot, by itself, ensure that an investigation is scientifically justified, a root cause is credible, a risk assessment is proportionate or a corrective action prevents recurrence.

The guiding principle is therefore straightforward:

The following sections describe the implementation steps and their principal controls for establishing a robust, compliant and digitally enabled Pharmaceutical Quality System (PQS) in a greenfield biopharmaceutical facility.

Define the pharmaceutical quality system before selecting software

Establish the facility's operational scope, product lifecycle requirements and applicable regulatory obligations before selecting suitable technology. Depending on the business, the PQS may cover pharmaceutical development, technology transfer, manufacturing, QC, QA, engineering, qualification and validation, warehousing, supply chain and product discontinuation.

Map the required processes, departmental interfaces, decision-making authority, independent QA oversight and records needed to demonstrate compliance. Key outputs should include a defined PQS

1. Define the quality system
Set scope, ownership and applicable requirements.
The eQMS supports the PQS; it is not the entire PQS.

2. Establish controlled processes
Define SOPs, records, decisions and escalation.
Refine workflows under controlled governance.

3. Assess readiness and value
Identify gaps in processes, skills and resources.
Set baseline metrics and measurable benefits.

4. Prioritise by risk
Consider patient safety, product quality and data integrity.
Tailor sequencing to readiness and dependencies.

5. Select and configure
Approve baseline user requirements before final selection.
Assess suppliers and maintain requirements traceability.

6. Validate before GMP use
Validate intended use, workflows and interfaces.
Verify access, audit trails and record lifecycle controls.

7. Train and deploy
Confirm validation, procedures and user readiness.
Define official records, cutover and continuity.

8. Sustain and improve
Review system fitness, quality outcomes and suppliers.
Control changes and verify CAPA effectiveness.

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scope and process inventory, governance and responsibility matrix, process interaction map, preliminary quality risk assessment, regulatory requirements matrix and phased digitisation roadmap. Maintain a GMP computerised-system inventory with defined system boundaries, process owners, system owners and relevant data flows and interfaces.

India's revised Schedule M, notified through G.S.R. 922(E) dated 28 December 2023, provides an important GMP foundation for applicable pharmaceutical manufacturing operations. ICH Q10 offers a complementary lifecycle model for an effective pharmaceutical quality system (PQS), including biotechnology and biological products. Applicability should be determined against the facility's products, activities, intended markets and commitments. The notification date should not be treated as a universal site-compliance date; assess applicable implementation provisions separately. For EU-facing operations, consider Annex 2 for relevant biological products, Annex 1 for sterile manufacture or Part IV for advanced therapy medicinal products, as applicable (see Reference 9).

Establish controlled processes and build operational discipline

Establish the PQS architecture, process ownership, regulatory requirements and critical controls before committing to platform configuration. Refine detailed procedures and digital workflows iteratively under controlled governance and ensure that approved SOPs, controlled forms, record templates and validated functionality are in place before GMP use. As applicable, the foundational PQS should address document and record control, training, deviations, investigations, CAPA, change control, quality risk management, supplier quality, complaints, internal audits, management review, product quality review, recalls, out-of-specification (OOS) investigations, outsourced activities, knowledge management and record retention. These processes need not each correspond to a separate software module.

Each SOP should define process ownership, responsibilities, decision criteria, approvals, timelines, escalation and required records. For deviation management, for example, the procedure should cover reporting, immediate impact assessment, investigation, product-quality assessment, CAPA linkage where justified, review, approval and closure, including criteria for assessing investigation adequacy and CAPA effectiveness.

If these requirements are unclear, digitisation simply transfers a poorly designed process into an electronic workflow. A controlled paper-based process may be appropriate during facility establishment where suitably controlled, but a fixed paper-based phase is not a prerequisite. Procedures can be tested through simulations and pilot workflows. For regulated electronic records, intended use, system validation and electronic-record controls must be planned before implementation. The objective is process maturity, not paper accumulation.

Conduct a structured gap assessment and establish a business case

Assess process readiness and effectiveness before deciding what to digitalise. Review manual data entry, duplicate records, approval delays, overdue actions, record-retrieval challenges and weak quality-trend analysis. Distinguish technology limitations from gaps caused by unclear procedures, insufficient training, inadequate resources or weak ownership.

A digital Learning Management System can improve visibility of training status and escalation, provided curricula, role assignments and authorisation requirements are defined. Similarly, a deviation

Digital QMS Implementation Roadmap

Table: Phased implementation roadmap for establishing a digitally enabled Pharmaceutical Quality System (PQS) in a greenfield biopharmaceutical facility.

Phase	Responsible team(s)	Key deliverables	Approval / exit criteria
1. Define PQS and scope	QA; functional process owners; Regulatory Affairs, as applicable	PQS scope, process inventory and interaction map, governance/RACI, regulatory requirements matrix, preliminary risk assessment	QA and relevant functional leadership approve scope, ownership and applicable requirements
2. Standardize processes	QA; QC; Manufacturing; Engineering; Supply Chain; other process owners	Approved SOPs, forms, record templates, process maps and defined decision/escalation criteria	Process owners and QA approve controlled procedures; roles and records are clear
3. Assess gaps and prioritize	QA; process owners; IT; Validation/CSV; business leadership	Readiness/gap assessment, baseline metrics, risk-ranked use cases, approved baseline User Requirements Specification (URS) and critical compliance quirements, business case and phased roadmap	Documented risk rationale, intended use, ownership, dependencies and measurable success criteria; baseline URS approved before final platform selection
4. Select and configure platform	QA; IT; process owners; Validation/CSV; Procurement, as applicable	Supplier assessment, requirements-fit assessment, configuration/design specifications, data/interface and access-control requirements and updated controlled URS	Requirements are approved and traceable; configuration supports approved processes and data-integrity controls
5. Validate system for intended GMP use	Validation/CSV; IT; QA; process owners; supplier, as applicable	Risk assessment, application-validation and infrastructure-qualification evidence, test protocols/results, traceability, defect records, backup/restore evidence and release package	Required validation approved; open defects have justified GMP-impact assessments, approved controls and resolution plans; defects compromising intended GMP use or required controls prevent release; QA and system owner approve release
6. Pilot, train and deploy under approved controls	QA; IT; process owners; Training; site leadership	Controlled pilot results, trained/authorized users, approved SOPs, support/escalation plan, business-continuity arrangements and cutover/reconciliation plan	Readiness review confirms validation, training, access, procedures, support and official-record arrangements before GMP use
7. Monitor and improve	QA; system owner; IT; process owners; management	KPI reviews, periodic system reviews, audit-trail review records, CAPA/change records and improvement actions	Scheduled governance review confirms ongoing fitness for intended use and tracks actions to closure

Abbreviations: PQS – Pharmaceutical Quality System; QA – Quality Assurance; QC – Quality Control; RACI – Responsible, Accountable, Consulted and Informed; URS – User Requirements Specification; CSV – Computerized System Validation; CAPA – Corrective and Preventive Action; KPI – Key Performance Indicator; IT – Information Technology.

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module can improve tracking but cannot replace sound investigation methods or credible root-cause analysis.

Build the business case using baseline indicators such as SOP approval cycle time, overdue training, deviation closure time, CAPA aging and effectiveness, change-control turnaround, repeat audit observations and record-retrieval effort. Interpret metrics carefully: faster closure is not an improvement if investigation quality or CAPA effectiveness declines. Investment should be justified by measurable gains in compliance, control, resource utilisation and management visibility, not assumed savings alone.

Prioritise digitalisation using quality risk and business value

Use a phased approach based on patient and product risk, regulatory obligations, process criticality, dependencies and expected benefit. Document management and training may be early priorities where processes are mature; deviation management, CAPA, change control, audit management and quality analytics may follow. The sequence must reflect facility readiness and manufacturing milestones rather than a universal template.

For each initiative, document the business need and intended use, process owner, user requirements, quality and data-integrity risks, system dependencies, lifecycle costs, acceptance criteria and success measures. ICH Q9(R1) supports science-based, risk-proportionate quality risk management. In eQMS implementation, the depth of assessment and testing should reflect the system's intended use and potential impact on product quality, patient safety, data integrity and compliance. Risk-based prioritisation does not justify omitting applicable regulatory controls.

Implementation roadmap at a glance

The phases below are a practical example, not a universal sequence. Timing and sequencing should be tailored to facility readiness, risk, dependencies and manufacturing milestones.

Risk assessment, application-validation and infrastructure-qualification evidence, test protocols/results, traceability, defect records, backup/restore evidence and release package

Required validation approved; open defects have justified GMP-impact assessments, approved controls and resolution plans; defects compromising intended GMP use or required controls prevent release; QA and system owner approve release

Select and configure technology around the approved process

Evaluate vendors beyond demonstrations and feature lists. Assess functional suitability, configuration, access controls, audit trails, electronic signatures where applicable, reporting, interoperability, cybersecurity, supplier support and maintainability. Approve the baseline URS before final platform selection and use it to assess supplier suitability. The URS should state what the system must do and define testable acceptance criteria traceable through configuration, testing and release. Maintain traceability throughout the lifecycle and control subsequent changes to requirements.

Use realistic GMP scenarios during demonstrations. A CAPA workflow, for example, should support investigation outcomes, root-cause rationale, action assignment, approvals, due-date monitoring, effectiveness verification and escalation in line with approved procedures. Assess whether related records (such as deviations, CAPAs and change controls) can be linked without losing traceability.

For outsourced and cloud services, establish formal agreements defining responsibilities for configuration, updates, access, security, backup, recovery, incident notification, data retention and retrieval. Assess supplier performance throughout operation; supplier assessment alone does not establish ongoing service responsibilities.

Validate the computerised system before GMP use

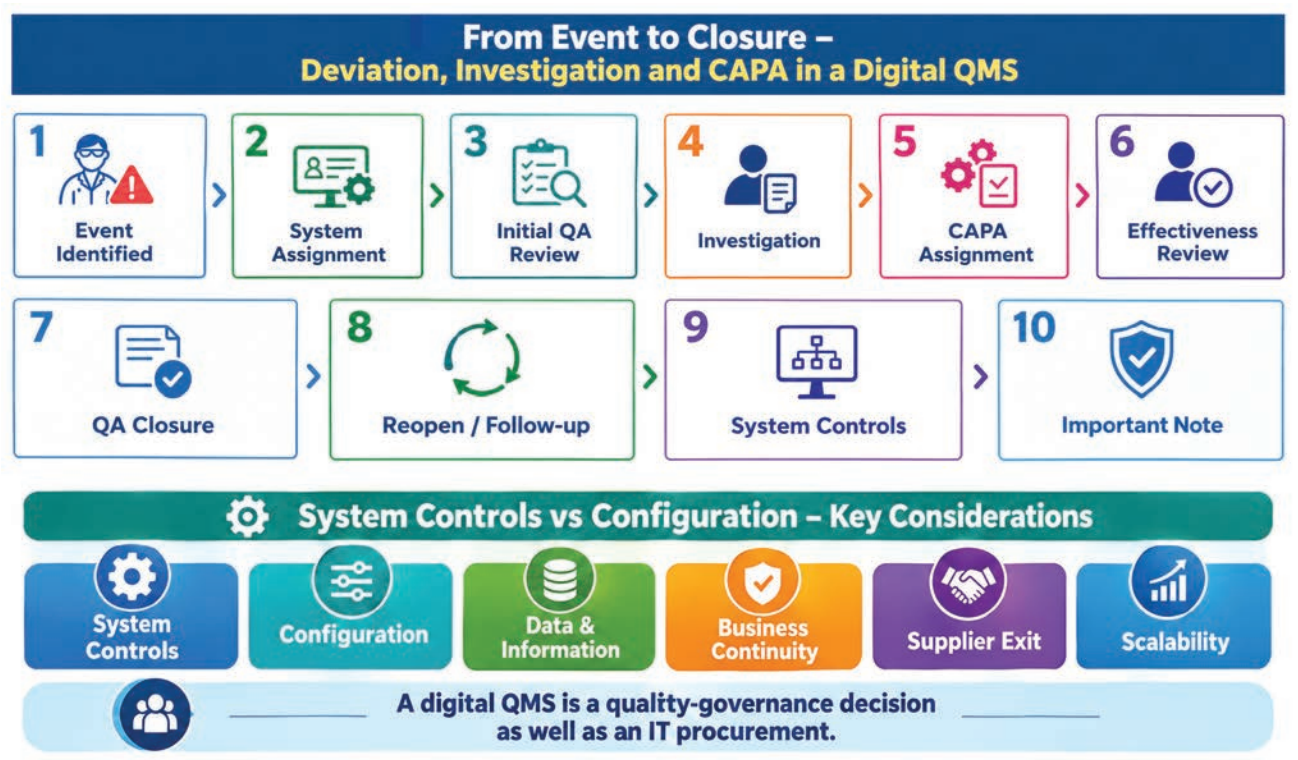
An eQMS platform used for regulated activities must demonstrate fitness for its intended use. A documented, risk-based lifecycle approach should cover requirements, supplier assessment, risk evaluation, configuration, testing, defect management, traceability, release approval and maintenance. Computerised System Validation (CSV) should provide evidence that the configured system and its GMP workflows perform as intended, support applicable GMP requirements and remain in a validated state throughout operation. Validate the application and qualify supporting IT infrastructure using a risk-based approach appropriate to the deployment model. Validation should address relevant interfaces and data transfers, not only the underlying software platform (see References 4 and 6).

Identify applicable pharmaceutical GMP requirements and electronic-record obligations separately. These may include India's revised Schedule M, EU GMP Annex 11 for applicable EU GMP activities and US drug-CGMP predicate rules, including relevant provisions of 21 CFR Parts 210 and 211 such as 21 CFR 211.68. Part 11 applicability depends on relevant predicate-rule requirements and the use of electronic records or signatures; it should not be assumed to apply identically to every application (see References 1, 4, 5 and 7).

FDA's February 2026 Computer Software Assurance guidance addresses software used in medical-device production and quality management systems and supersedes the September 2025 final guidance. It is not the governing guidance for pharmaceutical GMP computerised systems and should not be presented as a replacement for pharmaceutical CSV. Pharmaceutical manufacturers should justify risk-based validation activities against applicable pharmaceutical GMP requirements (see Reference 8).

Controls should address user access and segregation of duties, audit trails, electronic signatures where applicable, data integrity, backup and restoration, disaster recovery, business continuity, migration and interfaces, record retention, archiving and retirement, change management, incidents and periodic review. Testing should be traceable to requirements and proportionate to

Practical example: deviation through an eQMS platform



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risk, including normal-use, negative and failure scenarios. Supplier documentation and testing may support validation where their suitability and applicability have been assessed; they do not replace the manufacturer's responsibility to validate its configured GMP workflows. Platform qualification alone does not establish workflow validation (see Reference 6). Go-live should follow completion and approval of required validation, SOPs, training, access provisioning and operational-readiness checks. Open defects require documented GMP-impact assessment, justified acceptance where appropriate, approved controls and resolution plans. Defects compromising intended GMP use or required controls should prevent release.

Manage records throughout their lifecycle, including associated metadata, audit trails, attachments and electronic signatures. Preserve their relationships and ensure that records remain complete, readable, retrievable and reconstructable through migration, retention, archiving and system retirement (see References 4 and 6).

Distinguish backup and restoration from disaster recovery and business continuity. Establish and test arrangements for continuing critical quality processes during system outages; restoring technology alone does not establish continuity of the supported process.

Audit-trail review should be risk-based, defined in an approved SOP and aligned with the system's intended use and applicable regulatory requirements. Assign review responsibilities in accordance with responsibilities for reviewing the underlying GMP records and applicable quality-unit requirements. Define trained reviewer, process-owner, system-owner, IT and QA responsibilities, including independent oversight, in approved procedures. Reviewers should have appropriate access and should not review their own actions where independent review is required by the approved procedure.

The review frequency should be predefined according to data criticality, process risk, event volume and the applicable record or activity. Review relevant audit trails capturing changes to GMP data as part of the associated record review. Where applicable CGMP requirements specify record-review timing, apply that timing to the associated audit-trail review, including review before approval or release where required. For other audit trails and system logs, define and justify review scope and frequency using data criticality, control mechanisms and potential impact on product quality. The frequency and scope should be justified, approved and reassessed when risks or system use change (see Reference 6).

Each review should be documented with the system/module and records or date range reviewed, reviewer identity and date, review scope, exceptions identified, assessment/conclusion and any linked deviation, investigation, CAPA or change-control number. Unexplained changes, deleted or altered data, inappropriate access, disabled controls, missing entries or other potentially significant anomalies should be promptly escalated to QA and the system owner, with IT/security involvement where appropriate. Potential data-integrity concerns should be assessed and investigated under approved procedures; relevant records and evidence should be preserved, impact on product quality and regulatory commitments assessed and corrective actions tracked to closure. The system should retain review evidence in a traceable, access-controlled manner.

Manage implementation, change and user adoption

Implementation requires coordinated participation from QA, QC, manufacturing, IT, validation, engineering and process owners. A phased rollout or pilot can expose issues with routing, permissions, notifications, reporting and usability. Document and resolve findings through appropriate controls before wider deployment. Use non-production prototypes or pilots to refine processes and configuration before final validation. If pilot activities generate official GMP records or support regulated decisions, apply the required validation, procedures, training and release controls before that use. Assess changes arising from any pilot through change control and perform additional testing where justified.

Training should cover both system operation and GMP responsibilities: timely reporting, accurate documentation, attributable actions, appropriate approvals and reliable record-keeping. Where paper and electronic processes coexist temporarily, define the official record, approval method, reconciliation requirements and exit criteria to prevent ambiguity over authoritative records.

Establish milestones, issue escalation, change control, stakeholder communication and post-go-live support. Treat implementation as an organisational change initiative, not merely a software installation.

Sustain performance through governance and continuous improvement

Go-live is the beginning of the operational lifecycle, not its end. Compare actual performance with baseline measures and the business case, monitoring investigation quality, CAPA effectiveness, overdue actions, recurring deviations, audit findings and user issues. Periodic system reviews should assess access rights, audit-trail controls, incidents, configuration changes, supplier performance, backup recovery, data integrity, record retention, archiving, business continuity and continuing fitness for intended use.

Metrics should promote sound quality decisions rather than superficial closure targets. As maturity grows, integration with Manufacturing Execution Systems (MES), Laboratory Information Management Systems (LIMS) and Enterprise Resource Planning (ERP) systems may improve information flow, provided interfaces and data governance are controlled. Advanced analytics and artificial intelligence may help identify patterns and emerging risks, but require appropriate intended-use assessment, data-quality controls, human oversight and assurance proportionate to their impact on regulated decisions. The goal is a connected, risk-informed quality ecosystem that supports timely, scientifically sound decisions.

Conclusion: Build the quality foundation before the digital layer

For a greenfield biopharmaceutical facility, eQMS implementation should be a strategic quality initiative, not an isolated software project. Define the regulatory and operational scope, establish the PQS, standardise and assess processes, prioritise digitalisation by risk and value, select suitable technology, validate the system for its intended use, train users and monitor performance.

Success should not be measured only by paper eliminated or workflows automated. It should be measured by the ability to maintain control, demonstrate compliance, protect data integrity, identify emerging risks and make reliable quality decisions throughout the product lifecycle.

"When quality is designed before technology is deployed, digitalisation becomes an enabler of compliance, operational excellence and sustainable growth, not a substitute for effective quality management."

References

1. Ministry of Health and Family Welfare, Government of India. G.S.R. 922(E), 28 December 2023: Revised Schedule M: Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products. CDSCO: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadGazette_NotificationsFiles/2023.12.28_DR_Final%20G.S.R.%20922%28E%29_Notification%20of%20Schedule%20M%20of.pdf

2. International Council for Harmonisation (ICH). ICH Q10: Pharmaceutical Quality System. European Medicines Agency: https://www.ema.europa.eu/en/scientific-guidelines/ich-q10-pharmaceutical-quality-system

3. International Council for Harmonisation (ICH). ICH Q9(R1): Quality Risk Management. US Food and Drug Administration: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q9r1-quality-risk-management

4. European Commission. EudraLex, Volume 4, Annex 11: Computerised Systems. January 2011 revision. https://health.ec.europa.eu/system/files/2016-11/annex11_01-2011_en_0.pdf

5. US Food and Drug Administration. Part 11, Electronic Records; Electronic Signatures: Scope and Application: Guidance for Industry. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application

6. U.S. Food and Drug Administration. (2018, December). Data integrity and compliance with drug CGMP: Questions and answers: Guidance for industry. https://www.fda.gov/media/119267/download

7. US Food and Drug Administration. 21 CFR Parts 210 and 211: Current Good Manufacturing Practice for Drugs, including 21 CFR 211.68: Automatic, mechanical and electronic equipment. Electronic Code of Federal Regulations: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-D/section-211.68

8. US Food and Drug Administration. Computer Software Assurance for Production and Quality Management System Software: Guidance for Industry and Food and Drug Administration Staff. February 2026. Medical-device production and quality management system software. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software

9. European Commission. EudraLex, Volume 4: Good Manufacturing Practice guidelines. Current annexes and product-specific guidance: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

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Integration of Sensors, Polymers and Process Analytical Technology in Intelligent Single-Use Fluid Paths

Single-use technology has transformed biopharmaceutical manufacturing through the adoption of pre-assembled, sterilized polymeric tubing, bags, connectors and fluid transfer systems. However, most disposable fluid paths remain passive components, providing limited information about the physical and chemical conditions of the process fluid. The emergence of Bioprocess 4.0 creates an opportunity to transform these assemblies into intelligent process interfaces through integrated sensing and Process Analytical Technology (PAT).

The scientific opportunity extends beyond attaching conventional sensors to disposable assemblies. It involves engineering sensing functionality directly into polymeric structures while preserving extractables and leachables (E&L) compliance, sterilization resistance, mechanical integrity, flexibility and biocompatibility. Printed electronics, optical indicators, fibre-optic systems, capacitive measurement, dielectric spectroscopy and mechanically responsive polymers offer complementary approaches. This article examines their potential, particularly for non-invasive sensing through tubing walls, and proposes a multidisciplinary framework for developing intelligent single-use fluid paths.

Keywords

Single-use technology, Bioprocess 4.0, intelligent tubing, non-invasive sensing, polymer-integrated sensors, PAT, E&L, dielectric spectroscopy.

1. From passive fluid containment to process intelligence

Single-use technology has evolved considerably through advances in polyethylene, polypropylene, ethylene-vinyl acetate, thermoplastic elastomers, silicone and multilayer polymer structures. These materials have enabled flexible fluid management systems that reduce cleaning requirements, simplify changeovers and support modular biopharmaceutical manufacturing.

Yet most polymeric fluid paths remain fundamentally passive. They transport product but do not necessarily communicate what is happening within them. Changes in pressure, temperature, flow, dissolved oxygen or gas entrainment may occur without direct indication from the tubing assembly itself. Monitoring therefore depends on external instruments, dedicated sensor ports and periodic sampling.

The next development opportunity is to make the fluid path an active participant in process monitoring.

This does not require embedding electronics indiscriminately into disposable components. A more practical approach is to engineer the polymeric structure as a sensing interface, separating the sterile fluid boundary from reusable interrogation electronics wherever possible. The result could be a disposable sensing section interrogated externally, combining the contamination control advantages of single-use technology with continuous process visibility.

2. Non-invasive sensing through polymeric tubing walls

The most interesting opportunity lies in measuring process parameters without penetrating the sterile fluid boundary. Polymeric tubing can transmit optical signals, influence electromagnetic fields and transfer mechanical strain, making it a potential substrate for multiple sensing technologies.

Three architectures are relevant:

- **External clamp-on sensing:** Reusable optical, ultrasonic or capacitive instruments interrogate the fluid through the tubing wall.
- **Wall-integrated sensing:** Conductive traces, optical indicators or functional materials are incorporated during extrusion, printing or lamination.
- **Embedded sensing:** Functional elements are positioned between polymer layers, protected from direct fluid exposure but requiring additional interface and integrity qualification.

The appropriate architecture depends on the measurement principle and its associated contamination and performance risks.

Optical and fibre-optic sensing

Optical sensing is among the more mature approaches for chemical monitoring in single-use bioprocessing. Fluorescent or luminescent indicator molecules can be immobilized in sensor spots and interrogated using an external optical reader.

For dissolved oxygen measurement, oxygen-sensitive luminophores undergo fluorescence or luminescence quenching in the presence of molecular oxygen. Changes in emission intensity or lifetime can be correlated with oxygen concentration. Similarly, pH-sensitive indicators provide an optical response to hydrogen-ion activity.

Positioning these indicators behind an optically transparent polymer interface allows measurement without conventional immersed electrodes. However, polymer transparency, autofluorescence, scattering, wall thickness and sterilization-induced optical changes must be controlled.

Fibre-optic sensing offers further possibilities. Fibre Bragg gratings can detect temperature and strain through wavelength shifts, while functionalized fibre tips can support chemical sensing. Multiplexed optical systems could eventually monitor several parameters at different positions along a fluid pathway.

Printed sensors and functional polymer surfaces

Screen printing, inkjet printing and aerosol jet printing can deposit conductive or semiconductive materials onto flexible polymer substrates. Silver inks, carbon-based materials, conductive polymers and nanocomposites can be used to construct electrodes, resistive temperature elements and strain-sensitive structures.

For tubing applications, sensing structures could be printed onto polymer films before lamination or tube formation. Capacitive electrodes could detect fluid presence or gas entrainment, while piezoresistive structures could respond to deformation associated with pressure fluctuations.

The critical issue is the interface between the functional material and polymer. Repeated bending, peristaltic compression, thermal cycling and sterilization may cause cracking, delamination or loss of conductivity. Ink binders, solvents, residual monomers and metallic constituents also introduce potential E&L concerns.

Encapsulating printed structures between compatible polymer layers may reduce exposure, but barrier integrity must be demonstrated under actual operating conditions.

Capacitive sensing and dielectric spectroscopy

Capacitive sensing is particularly attractive because electrodes can be positioned entirely outside the tubing. The electric field passes through the polymer wall and interacts with the fluid. Changes in dielectric properties can indicate fluid presence, gas pockets or changes in fluid composition.

Dielectric spectroscopy extends this principle by measuring electrical response across a range of frequencies. It is already used in bioprocessing to monitor viable biomass through the dielectric properties associated with intact cell membranes.

Applying this technology to flowing fluids through polymeric tubing presents additional challenges, including wall thickness, electrode geometry, fluid conductivity, temperature and electrical interference. Its potential should therefore be explored against specific measurement objectives rather than treated as a universal analytical technique.

3. Physical sensing: pressure, flow and bubble detection

Physical monitoring is equally important because pressure instability, flow interruption and gas entrainment can affect product quality and process performance.

Pressure and strain

Internal pressure produces changes in tubing diameter and wall deformation. These responses can potentially be detected using external strain gauges, fibre Bragg gratings or printed piezoresistive and capacitive elements.

However, estimating pressure from external strain requires careful calibration. Polymer modulus, wall thickness, temperature, viscoelasticity, creep and tubing geometry all influence the relationship. A sensor calibrated on new tubing may drift during prolonged operation as the material undergoes stress relaxation.

Flow and bubble detection

Ultrasonic transit-time measurement offers a compelling non-invasive approach to flow monitoring. Acoustic signals travelling with and against the fluid flow experience different transit times, which can be used to calculate flow velocity and volumetric flow.

Commercial single-use ultrasonic systems are currently available in market that demonstrate the feasibility of combining disposable sensing interfaces with reusable instrumentation. Ultrasonic and optical technologies can also detect air or bubble presence without introducing additional wetted components.

Bubble detection is particularly important because entrained gas can disturb pump performance, filtration, chromatography and sensitive fluid transfers. In cell culture opera-

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tions, gas-liquid interfaces may also contribute to cellular damage.

Combining flow, pressure and bubble measurements could provide a more informative assessment of process disturbances than independent alarms. For example, declining flow accompanied by a pressure change and an acoustic bubble signal could indicate gas ingress, pump malfunction or a developing restriction.

4. Chemical sensing: pH, oxygen, CO2 and temperature

Chemical sensing through tubing walls requires greater attention to selectivity, calibration and material compatibility.

Optical pH indicators can be immobilized behind a transparent polymer interface and interrogated externally. Dissolved oxygen sensors can use oxygen-sensitive luminescent materials, with the sensing chemistry protected by an appropriate polymer barrier.

CO2 measurement is more complex. An indicator responsive to the acid-base equilibrium associated with dissolved carbon dioxide may be used, but pH response alone does not establish selective CO2 measurement. Appropriate sensing chemistry, membrane selectivity and calibration are necessary.

Temperature measurement is comparatively straightforward using printed resistive elements, thermistors or fibre-optic sensors. Nevertheless, the measured tubing-wall temperature may differ from bulk-fluid temperature, particularly during rapid process transitions. Thermal lag and heat transfer characteristics must be quantified.

An important development direction is the creation of multi-parameter sensing zones that combine temperature, pH and dissolved oxygen measurements within a standardized polymeric interface.

5. The polymer engineering challenges

Integrating sensing functionality changes the qualification requirements of a disposable assembly. Every additional material introduces potential sources of chemical or physical contamination.

Conductive inks, metallic nanoparticles, optical dyes, adhesives, encapsulation materials and protective coatings require assessment for extractables and leachables. Particulate generation from brittle coatings, cracking or interfacial delamination must also be investigated.

A comprehensive E&L programme should evaluate the complete assembly, including functional materials, joining interfaces and manufacturing residues, using appropriate chromatographic, mass-spectrometric and elemental analytical techniques.

Sterilization presents another major challenge. Gamma irradiation can cause polymer chain scission, crosslinking and oxidation, potentially altering mechanical strength, optical transmission and electrical properties. A tubing material may retain acceptable tensile strength while its printed sensor loses sensitivity or its adhesive interface deteriorates.

Consequently, qualification must assess the complete integrated assembly following the intended sterilization exposure, including ageing and shelf-life studies.

Mechanical durability is equally important. Single-use tubing experiences bending, torsion, clamping and peristaltic compression. Sensor layers must withstand these stresses without creating weak points, compromising flexibility or affecting burst pressure and connection integrity.

The central principle is that analytical functionality must never compromise the primary function of the disposable component: maintaining a reliable sterile fluid boundary.

6. A multidisciplinary development framework

Development should involve polymer scientists, extrusion specialists, sensor engineers, analytical chemists, sterilization experts, process engineers and regulatory professionals from the earliest design stages. Here I propose a practical framework comprising six interconnected activities:

1. Process definition: Identify the critical parameter, measurement range, accuracy, response time and intended process-control application.

2. Material and architecture selection: Select the polymer substrate, sensing principle, functional materials and encapsulation strategy.

3. Compatibility assessment: Evaluate E&L, particles, biocompatibility, sterilization resistance and mechanical performance.

4. Metrology and calibration: Establish accuracy, repeatability, drift limits, temperature compensation and sensor-to-sensor variability.

5. Manufacturing validation: Qualify extrusion, printing, lamination, joining, sterilization and final assembly.

6. Digital integration: Connect measurements to process control, data acquisition, alarm management and validated PAT models.

A formal failure mode and effects analysis (FMEA) should address sensor failure, false alarms, calibration drift, electrical interference, optical degradation, leakage and loss of communication. Importantly, failure of the sensing function should not compromise the sterile barrier or obstruct fluid flow.

7. Bioprocess 4.0: connecting sensing with process intelligence

The real value of intelligent tubing emerges when its measurements are integrated into the wider manufacturing control architecture.

Consider a downstream purification operation involving transfer between chromatography and filtration. An intelligent tubing section could provide continuous flow, pressure, temperature and bubble information. These measurements could be combined with pump data, filter differential pressure and upstream process parameters.

Soft sensors and predictive models could then identify abnormal process behaviour before it develops into a significant deviation. However, model-derived estimates must be distinguished from direct analytical measurements and independently validated against appropriate reference methods.

Sensor identification, calibration history, sterilization status, manufacturing lot traceability and data integrity must also be incorporated into the digital architecture.

The FDA's Process Analytical Technology framework provides a foundation for linking analytical measurements with process understanding and control. Extending this philosophy to the polymeric fluid path represents a meaningful opportunity for Bioprocess 4.0.

8. Where should the industry focus?

The most practical initial developments are likely to involve ultrasonic flow and bubble detection, optical pH and dissolved oxygen indicators, external temperature measurement and capacitive fluid detection. These approaches offer relatively clear measurement objectives and opportunities to retain reusable instrumentation.

Printed strain sensors, dielectric spectroscopy and multiplexed fibre-optic sensing offer substantial longer-term potential but require further work on material compatibility, manufacturing reproducibility and calibration stability.

There is also a credible alternative to full sensor integration: intelligent connectors and external sensor collars. These can deliver process visibility without introducing additional functional materials into the tubing wall. For applications with particularly stringent E&L requirements, they may prove preferable.

9. Conclusion

The next generation of single-use technology will depend not only on improvements in polymer materials and component design but also on the ability of fluid paths to contribute directly to process understanding.

Optical, fibre-optic, printed, capacitive, ultrasonic and dielectric technologies provide complementary routes towards distributed sensing. Their successful integration, however, depends on demonstrating reliable performance after manufacturing, sterilization, storage and actual process operation.

The most significant opportunity lies in treating polymeric tubing not merely as a passive container but as an engineered functional platform: an optical window, dielectric interface, mechanical transducer or support for analytical functionality.

The objective is not to make every disposable component electronic. It is to engineer intelligent fluid paths in which polymer science, sensing, process compatibility and digital connectivity are designed as one integrated system. This represents a meaningful step towards genuinely connected Bioprocess 4.0 manufacturing.

References

1. Busse, C. (2017). Sensors for disposable bioreactors. Engineering in Life Sciences.

2. Kocincova, A. S., Borisov, S. M., Krause, C., & Wolfbeis, O. S. (2007). Fiber-optic microsensors for simultaneous sensing of oxygen and pH, and of oxygen and temperature. Analytical Chemistry, 79, 8486–8493.

3. Kanoun, O., et al. (2021). Review on conductive polymer/CNTs nanocomposites based flexible and stretchable strain and pressure sensors. Sensors, 21, 341.

4. Randek, J., & Mandenius, C.-F. (2018). On-line soft sensing in upstream bioprocessing. Critical Reviews in Biotechnology, 38, 106–121.

5. Lourenço, N. D., et al. (2012). Bioreactor monitoring with spectroscopy and chemometrics: A review. Analytical and Bioanalytical Chemistry, 404, 1211–1237.

6. Claßen, J., et al. (2017). Spectroscopic sensors for in-line bioprocess monitoring in research and pharmaceutical industrial application. Analytical and Bioanalytical Chemistry, 409, 651–666.

7. Parameswaran, C., & Gupta, D. (2019). Large area flexible pressure/strain sensors and arrays using nanomaterials and printing techniques. Nano Convergence, 6, 28.



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India–New Zealand FTA: Strengthening India's global pharma position

Anurag Kumar, Chairman & Managing Director, Biodeal Pharmaceuticals, highlights how the India–New Zealand FTA can expand market access, strengthen CDMO opportunities and boost India's global pharmaceutical presence

India's pharma industry has earned a strong position in global healthcare through its ability to manufacture quality medicines at scale and supply affordable generics. As global pharma supply chains evolve, the next phase of growth will depend on how effectively Indian manufacturers access new markets, strengthen international partnerships and meet regulatory expectations.

The India–New Zealand Free Trade Agreement (FTA), which came into force on October 20, 2026, offers an opportunity to advance these objectives. While eliminating applicable pharma import duties of up to five per cent provides a commercial benefit, the agreement's greater potential lies in facilitating regulatory processes and improving market access. Realising these opportunities will require an understanding of New Zealand's regulatory framework, medicines procurement system and healthcare requirements.

Understanding New Zealand's pharma market

New Zealand's pharma market has a distinct structure that Indian exporters must understand. Two institutions play particularly important roles: Medsafe, which regulates medicines, and PHARMAC, which determines which medicines receive public funding.

Medsafe evaluates medicines for quality, safety and efficacy before they can be marketed in New Zealand. Manufacturers must meet applicable regulatory requirements and follow the relevant approval process. The FTA's provisions on accepting Good Manufacturing Practice (GMP) inspection reports from comparable regulators can help reduce duplicative assessments, although product-specific approval requirements remain.

PHARMAC determines which medicines are publicly funded within a fixed government budget. Its decisions consider clinical benefits, cost-effectiveness and competing healthcare priorities. Its procurement processes, including competitive tenders, influence which medicines are funded and supplied.

For exporters, regulatory approval alone may not guarantee commercial success. Companies must understand PHARMAC's funding priorities, procurement requirements and competitive landscape. Identifying relevant product categories, evaluating demand and building relationships with appropriate local partners will be essential to establishing a sustainable presence.

Regulatory recognition offers a meaningful advantage

According to India's Ministry of Commerce and Industry, the agreement provides for the acceptance of GMP and Good Clinical Practice (GCP) inspection reports from comparable regulators, including the US Food and Drug Administration (FDA), European Medicines Agency (EMA), UK Medicines and Healthcare products Regulatory Agency (MHRA) and Health Canada. This can reduce duplicative inspections, lower compliance costs and facilitate market entry for eligible products and facilities.

For Indian manufacturers, this reinforces the importance of regulatory preparedness, effective quality controls, robust documentation and consistent manufacturing practices. These capabilities help build confidence among international customers and regulators while supporting compliance with destination-market requirements.

The practical benefits will depend on the applicable provisions and implementation arrangements. Nevertheless, reducing unnecessary duplication can help manufacturers use resources more efficiently and focus on expanding their international reach.



Strengthening India's CDMO capabilities

India's contract development and manufacturing organisations (CDMOs) can play an important role in strengthening the country's participation in global pharma supply chains. By offering formulation development, technology transfer, process optimisation and commercial manufacturing, CDMOs can support pharma companies seeking reliable manufacturing partners.

For Indian CDMOs, the opportunity extends beyond increasing production volumes. It lies in building long-term partnerships through technical expertise, consistent quality and dependable supply. Manufacturers that demonstrate operational reliability and compliance with applicable standards will be better positioned to meet customer expectations and compete internationally.

At Biodeal Pharmaceuticals, our WHO-GMP, PIC/S and Health Canada certifications reflect our focus on quality and compliance. With a presence across more than 80 countries, we have an established international foundation that supports our continued engagement with global markets.

Biodeal Pharma's respiratory capabilities include nasal sprays and dry powder inhaler capsules, with the company continuously innovating in these segments to strengthen its formulation capabilities and respond to evolving healthcare needs.

The FTA provides an opportunity for Indian CDMOs to assess where their capabilities align with New Zealand's requirements and identify potential avenues for collaboration. Such engagement can help strengthen India's contribution to global pharma manufacturing.

Diversification requires a long-term approach

The agreement also highlights the importance of diversifying India's pharma export destinations. A broader geographical presence can help businesses manage exposure to changing commercial conditions, regulatory developments and shifts in demand.

However, market diversification requires careful planning. Companies must evaluate registration requirements, distribution arrangements, logistics, working capital and the resources needed to serve customers consistently. For smaller manufacturers, reliable market intelligence, regulatory guidance and suitable local partnerships can help reduce uncertainty.

Industry associations and government agencies can support exporters by providing clear guidance on tariff provisions, rules of origin, documentation and market-entry requirements. This would help businesses make informed decisions and translate trade opportunities into practical export strategies.

Ultimately, diversification must be supported by manufacturing efficiency, investment in quality systems, skilled talent and technical capabilities. Improved market access can create an advantage, but sustained competitiveness depends on delivering quality medicines reliably and meeting customer expectations.

Building a sustainable foundation for growth

The India–New Zealand FTA should be viewed as part of a broader effort to strengthen India's engagement with international pharma markets. Its long-term value will depend on whether manufacturers use the improved trade environment to build durable partnerships, strengthen regulatory readiness and understand local procurement systems.

Companies must identify opportunities that align with their capabilities, understand the distinction between regulatory approval and public funding, and develop customer relationships based on quality and consistent performance.

India has demonstrated its ability to manufacture and supply medicines for diverse markets. The next stage is to build on this foundation by strengthening technical capabilities, expanding market relationships and maintaining the quality standards that underpin international confidence.

The success of a trade agreement is measured not only by the access it creates but also by the partnerships and capabilities that emerge from it. By combining favourable trade conditions with regulatory preparedness, quality-led manufacturing and a long-term approach to international partnerships, Indian pharma companies can use the India–New Zealand FTA to strengthen their position in global pharma markets and build a sustainable foundation for export growth.

Reference

1. https://www.pib.gov.in/PressReleasePage.aspx?PRID=2255914&lang=1&reg=20
https://static.pib.gov.in/WriteReadData/specificdocs/documents/2026/mar/doc20263218314 01.pdf

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Ecosystem partnerships: The catalyst for pharma's next breakthrough

Subhro Mallik, EVP and Global Head of Life Sciences, Infosys shares insights on how strategic partnerships across R&D, clinical trials, technology and supply chains are reshaping pharma innovation and driving industry growth

Developing a new drug carries an estimated median direct R&D cost of $150 million and a mean cost of $369 million. These numbers reflect how a few outlier programs can balloon well beyond what most companies budget for. Layered on top of that are long R&D timelines, regulatory demands, and manufacturing pressures that primarily define the pharma value chain.

No single organisation can shoulder this burden, which is why modernising clinical development through collaboration can be an effective solution. A McKinsey research shows this collaboration leading to real gains: 15 to 20 percent faster trial start-ups, 15 to 30 per cent shorter trials, and a 10 per cent growth in success rates.

Such numbers are driving pharma companies towards partnerships with others, sharing risk, cost, and capability. There is a definitive move towards open collaboration. Licensing and partnering are now strategic imperatives rather than fallback options. Licensing spend has risen by 37 per cent, driven by strong demand for late-stage, de-risked assets.



Innovate collaboratively via R&D and clinical trials

Partnerships with research organisations, biotech start-ups, and academic institutions are speeding up drug discovery, trial design, and data science capabilities. Collaborative R&D partnerships generated $113.3 billion in aggregate value in the first half of 2026 alone, even as overall dealmaking activity reduced. Deal values are also climbing with a large share of payments going towards removing risks tied to clinical, regulatory, and commercial milestones.

Much of that value traces back to what these partnerships make technologically possible. Working with providers of AI, IoT, cloud, and data platforms gives pharmaceutical companies predictive analytics and manufacturing capabilities difficult to build in-house.

An Infosys Knowledge Institute (IKI) study of ~3,800 business leaders found that life sciences organisations convert AI investment into business value - 28 per cent of AI use cases deliver on all stated objectives, against 19 per cent across industries. Clinical trials and regulatory submissions ranked among the most viable AI use cases studied. The research attributes this advantage to the sector's already well-governed data and tightly structured processes.

That same advantage is what lets AI and ML algorithms interpret vast biological and chemical datasets to help optimise and speed up drug development. It has given rise to a new category of AI-driven Drug Discovery (AIDD) companies, formed to help the industry bring new therapies to market faster.

Build resilience across the supply chain

The pharma supply chain is one of the most demanding to run — temperature-sensitive biologics, tight manufacturing-to-market timelines, multijurisdictional regulatory approvals — all of which leave very little room for error. Pharma companies collaborate and partner with other organisations to improve the resiliency of their supply chains. Partnerships with logistics and regulatory partners, healthcare providers, and suppliers improve supply chain performance and governance. Pharma companies also partner with third-party organizations, such as venture-backed start-ups, to map their value chains and set up risk-monitoring systems.

As a case in point, Hyderabad-based StaTwig has partnered with major Indian vaccine and biologic manufacturers to map and track drug distribution networks. Using an AI- and blockchain-driven platform, it creates an immutable, real-time ledger of pharma shipments.

Share data for effective partnerships

Seamless co-creation involves the integration of diverse data sources with partner systems communicating with each other. Ensuring the privacy and security of this shared data is vital.

Partnerships need to be structured with rigorous intellectual property (IP) accounting to ensure that the deal struck is fair. If not, it could lead to partnerships collapsing. Incentives need to be aligned among all stakeholders, and all partners must agree on regulatory expectations. A single weak link here could jeopardise market access to the drug.

Collaboration is an imperative

Contract Research Organisation (CRO) and Contract Development and Manufacturing Organisation (CDMO) markets were valued at $254.65 billion in 2025 and are projected to reach $594.07 billion by 2035, an 8.84 percent CAGR. This growth presents one of the strongest evidence of pharma's shift to partnership-led models.

The Contract Research, Development and Manufacturing Organisation (CRDMO) sector in India, valued at approximately $3 billion growing at 15 percent CAGR, could reach $25 billion by 2035, as per a BCG-IPSO analysis. In 2025, eleven leading Indian CRDMOs formed the Innovative Pharmaceutical Services Organisation (IPSO) to define the sector and drive its role in global biopharma innovation. This is a clear signal that the industry as a whole is headed toward ecosystem collaboration as the operating standard.

In conclusion

In pharma's next chapter, the most valuable molecule may be trust. It is the one ingredient that no breakthrough can succeed without.

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Revised Schedule M: A pharma MSME challenge

Dr Ashok Omray, Pharma Consultant, examines the challenges pharma MSMEs face in meeting Revised Schedule M requirements, while highlighting the importance of quality systems, sustained investment and global competitiveness. He argues that compliance must become a culture, not just a regulatory obligation

With the current statistics the number of registered MSMEs in 2026 ranges between 7.5 to 9.16 crores (more precise 7.47 - 7.91 crores) and is providing employment to 37 to 40 crores people. This sounds magnanimous when we look at the employment avenue, the number is more than the total population of the US or more than half the population of the European continent. I believe the employment figures are true, I feel this data available on the internet is hypothetical, not verified with the operational enterprises.

The figures are quite staggering for pharma MSMEs, anywhere between 10,000 to 24,000, depending upon how ancillary units are classified.



The cost of entering pharma manufacturing

Across the globe it is becoming difficult day by day to establish drugs and pharma unit completely foolproof and compliant. Primarily the products have to have sustainable quality compliance throughout the assigned shelf life of the product but the quality norms and their adoption is to be tracked to all the necessary and vital aspects and stages. This involves premises, services, raw and packaging material suppliers, working personnel, supply chain, storage, maintaining records of manufacturing, testing, stability, equivalence testing and above all the update and integrity of data and working technical and administrative staff.

Ask anyone associated with pharma operations connected with finished products be it DRUG SUBSTANCES or DRUG PRODUCTS, what's the minimum budget required for a greenfield project even for a simplest API or one million film-coated tablets a day, of a relatively stable drug substances of 300 - 500 mg dose. The possibility of expansion or adding a new manufacturing facility for a large manufacturing house is not at all difficult because of common utilisation of utility and services as well as technical support. For an entrepreneur with the capacity of investing Rs 100 million as well as financial support from RPTUAS (Revamped Pharmaceuticals Technology Upgradation Assistance Scheme) what really can be done with so many formal clearances required before one can dream of compressing the first tablet that is sales worth. The most important and basic requirements for any chemical or pharma industry are power, water, air quality, effluent treatment technical, skilled workforce and adequate logistics support for transportation of goods. Unless the manufacturing units are located in Industrial zones (like MIDC, GIDC etc. or SEZ) all the above are a big expense. Needless to state that the industrial units are not common in urban or residential areas.

These days it is unlikely that one may get a conditional (temporary) manufacturing licence with an assurance of compliance to CGMP requirements or in absolute terms the Revised Schedule M. The compliance is a prerequisite to begin with the manufacturing. The new companies may think of supplementing the earnings (revenue) with the arrangement like loan licence and third party or P to P manufacturing otherwise the manufacturing of own products cannot commence even after six to nine months of starting the unit and having own formulation development, stability testing, analytical development and quality control laboratories fully functional. If the investor and entrepreneurs (not having the background of regulated businesses like drugs and pharma) think the money may start flowing like a fast-food joint or a restaurant then they are living under euphoria.

It's true all the big manufacturing houses of today started as small residential premises but that is the story five to seven decades ago. It never meant that there were no regulations or there was a complete laxity. The products were not complex, the volumes were limited, stability was a concern but stringency was evolving with the advances in the analytical procedures, toxicity and safety studies, impurities and degradation products and the sales network was very limited. Gradually we graduated with the experience of MNCs in 60s and 70s and the net result was a highly scientific approach and regulatory compliance. With the eighties (1980s) India started looking for off shore markets, to start with Africa and CIS and then Europe and Americas.

It is true that many of today's large pharmaceutical manufacturing houses started in small residential premises, but that was five to seven decades ago. The products were less complex, volumes were limited, and regulatory requirements evolved gradually with advances in analytical procedures, toxicity and safety studies, and the understanding of impurities and degradation products. From the 1980s onwards, as India began exploring overseas markets, initially in Africa and the CIS and later in Europe and the Americas, the industry steadily moved towards a more scientific approach to manufacturing and regulatory compliance.

Revised Schedule M and MSMEs

The Revised Schedule M, finalised in 2023 and made available by mid-2024, initially mandated implementation by December 28, 2024. This raises an important question: was the preparedness of drug manufacturers adequately assessed before such an ambitious timeline was set?

I vividly recall being invited as a moderator for a panel discussion at CDRI, Lucknow, in November 2024, where even the present DCGI was also present and presided the event. During the deliberations, both manufacturers and regulators expressed serious concerns regarding the feasibility of implementation. The infrastructure, facilities, quality systems, and technically qualified manpower required under the Revised Schedule M must be viewed in the context of the project cost and the investment capacity of MSMEs. For many small and medium pharma manufacturers, compliance is not merely a regulatory exercise but a substantial financial commitment. Recognising these realities, the implementation deadline was eventually extended to December 2025. Even that extension proved inadequate, and we are now approaching the revised deadline of December 2026. Yet, despite the additional two-year window, uncertainty surrounding complete compliance still persists. One also wonders whether detailed deficiency reports, along with realistic timelines for corrective actions and pre-inspections, were systematically communicated to

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all concerned manufacturers. More importantly, how optimistic can we realistically be that all MSMEs will achieve 100 per cent compliance by the current deadline?

The financial concerns of MSMEs and the immediate impact on their business continuity and revenues cannot simply be brushed aside. A majority of these enterprises are generic manufacturers or contract manufacturing partners for larger pharma companies. Their operational realities deserve careful consideration. At the same time, there can be absolutely no compromise on regulatory compliance, ethical practices, or product quality. These are non-negotiable pillars of pharma manufacturing.

In very simple terms, I would say that if an enterprise cannot invest adequately to fulfil all mandatory regulatory requirements before commencing pharma manufacturing, then perhaps it should not venture into this business at all. There are countless other sectors where profits may be generated with relatively fewer compliance obligations. pharma manufacturing, however, is fundamentally different. It demands patience, sustained investment, scientific discipline, and a long-term commitment to quality rather than an expectation of quick returns or immediate recovery of capital.

It is equally important to recognise that compliance should not be viewed merely as an additional cost. On the contrary, it is a long-term investment that ultimately reduces the cost of poor quality. By adopting scientifically designed manufacturing systems, adhering to well-defined SOPs, employing qualified technical personnel, procuring quality raw materials, and optimising batch sizes, manufacturers can significantly minimise wastage of time and resources. This approach reduces quality failures, batch rejections, reprocessing, repeat testing, vendor-related issues, market complaints, regulatory observations, warning letters, production interruptions, temporary closures, and even license cancellations. Beyond the tangible financial losses, these failures inflict lasting damage on a company's credibility and reputation, disrupt product availability, and erode customer confidence. The broader perspective, therefore, is not merely regulatory compliance for its own sake. It is about building a sustainable manufacturing ecosystem founded on quality, reliability, consistency, and trust—one that earns repeat business, strengthens customer confidence, enhances global competitiveness, and ultimately safeguards public health.

> Documentation is not an administrative burden; it is the factual history of the product and the evidence that quality has been achieved through disciplined manufacturing practices

Building quality into manufacturing systems

If I recollect correctly, the Revised Schedule M places its primary emphasis on the following critical pillars:

- Implementing Quality Risk Management (QRM)
- Ensuring Data Integrity and ALCOA+ Compliance
- Strengthening Supply Chain Management and Vendor Qualification (SCM)
- Upgrading Facility and Equipment Validation (EV)
- Establishing a robust Pharmacovigilance (PV) System

Each of these attributes is mandatory and non-negotiable. Compliance cannot be driven by convenience, individual preferences, or business expediency. Quality cannot be deferred to a later date, nor can consistency, reproducibility, efficacy, and stability be postponed for tomorrow.

The transition towards automation and digitisation is no longer optional. Manual systems inevitably increase the risk of human error and, in some cases, deliberate manipulation of data. Electronic systems with secure audit trails significantly strengthen data reliability, traceability, and integrity. In 2026, there should be no reservations or grievances regarding these expectations because virtually every progressive industry across the world has embraced these very principles as the foundation of modern manufacturing.

It is equally important to appreciate that a robust Quality Management System (QMS) is not merely another regulatory requirement—it is the backbone of pharma manufacturing. A truly effective quality system integrates every critical component of the organisation: the premises and infrastructure, buildings, utilities, machinery and equipment, qualified personnel, continuous training, automation, digitisation, data security, and data integrity. Quality cannot be isolated from manufacturing operations, nor can it be separated from the product that ultimately reaches the patient. It must be embedded into every stage of the product lifecycle. Manual intervention should be reduced to the absolute minimum. While every error may ultimately be human in origin, we often tend to blame the system or the equipment. The real solution lies in designing systems that minimise opportunities for human error. Every critical input, process, and output must therefore be validated to eliminate variability to the greatest possible extent.

This is precisely where Quality by Design (QbD) assumes immense significance. QbD provides a scientific and systematic framework for product and process development, ensuring that quality is built into the product from inception rather than being tested into it later. When the fundamental principles are followed with discipline and without compromise, very little is left to chance.

One standard of quality for every market

Personally, I do not view the implementation of the Revised Schedule M as a challenge as much as I see it as a necessary transition. India has been an active participant in the international pharma trade for well over three decades. During this period, we have earned global recognition as one of the largest and most dependable suppliers of quality medicines, including to countries that proudly consider themselves leaders in pharma innovation. Although India may have comparatively fewer New Drug Applications (NDAs) arising from indigenous discoveries, our manufacturing capabilities have unquestionably established us as the "Pharmacy of the World." Indian pharma companies have continuously upgraded their facilities and systems to comply with stringent international regulatory requirements. Therefore, the principles embodied in the Revised Schedule M are not entirely new to the industry. The real concern lies elsewhere.

For far too long, regulatory leniency, administrative interventions, and the existence of multiple quality expectations for different markets have created an uneven compliance landscape. One standard appears to apply to products destined for highly regulated markets, while another is often tolerated for products intended for the domestic market or for developing and underdeveloped countries. Although pharmacopeial specifications or permissible limits may legitimately differ between regulatory jurisdictions, one undeniable fact remains unchanged: medicines are ultimately consumed by human beings. Whether the patient is an American, an Asian, an African, a European, or an Australian, every individual deserves medicines manufactured under the same uncompromising standards of quality, safety, and efficacy. Unfortunately, there continues to be a perception that absolute compliance with product quality, manufacturing processes, testing, facilities, suppliers, and workforce competence is essential only for exports to highly regulated markets such as North America, Western Europe, Japan, Australia, and South Africa. This mindset deserves serious introspection.

India arguably possesses one of the most comprehensive regulatory frameworks governing pharma manufacturing and quality assurance. On paper, our regulations are robust and comparable with the best in the world. The question, therefore, is not whether we have adequate regulations—it is why we continue to struggle with their consistent implementation. This is a question the industry, regulators, policymakers, and all stakeholders must honestly ask themselves. Equally disappointing is the occasional reluctance, even among some large pharma companies—to consistently implement current Good Manufacturing Practices (cGMP) while manufacturing products for the domestic market or for export to less-regulated countries. Such selective compliance weakens the very foundation of pharma ethics. Quality cannot be destination-specific. Good Manufacturing Practices are not market-dependent obligations but universal responsibilities. The standards that protect one patient must protect every patient, irrespective of geography, economic status, or regulatory jurisdiction. That is the true spirit of the Revised Schedule M, and that is the standard to which the Indian pharma industry must aspire.

Compliance as a continuous process

Sooner or later and certainly no later than December 31, 2026, the Indian pharma companies will have to demonstrate full compliance with the Revised Schedule M.

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This is not merely about satisfying a regulatory mandate; it is the minimum benchmark expected of a nation that aspires to remain the "Pharmacy of the World." Compliance is an opportunity to showcase our scientific capability, our commitment to quality, and, above all, our ability to inspire trust among patients, healthcare professionals, regulators, and global markets.

Yet, experience reminds us that even manufacturing facilities approved by stringent regulatory authorities such as the USFDA, MHRA, and other international agencies continue to receive product complaints and observations ranging from minor deficiencies to major non-compliances during subsequent inspections. This clearly demonstrates that compliance is not a destination but a continuous journey. The management of Indian pharma companies must recognise that quality is not a one-day performance staged for an inspection or regulatory audit. A pharma product cannot be considered "quality assured" merely because it meets the prescribed specifications at the time of analysis and batch release. Quality must be built into the product—it cannot simply be tested into it.

Every manufacturing record, every raw material, every processing condition, every in-process check, every deviation, corrective action, and preventive action must be scientifically monitored, accurately documented, truthfully recorded, and consistently reviewed. Documentation is not an administrative burden; it is the factual history of the product and the evidence that quality has been achieved through disciplined manufacturing practices. More importantly, quality must evolve from being a regulatory obligation into an organisational culture. It should become deeply embedded in the mindset of every individual—from the shop-floor worker to the highest levels of management. Only when quality becomes a shared value rather than a compliance exercise can true excellence be achieved.

India possesses one of its greatest competitive advantages in the form of an exceptionally strong pool of scientific talent, technically qualified professionals, and a highly skilled workforce. The limitation, in my opinion, is not capability but the collective determination to work with unwavering discipline, systematic execution, and uncompromising consistency. Personally, I do not believe that cost is the principal constraint. As a nation, we have demonstrated our capacity for substantial investments and increasingly aspirational lifestyles. India is steadily progressing towards becoming the world's third-largest economy. Investing in quality, therefore, should not be viewed as an expense but as an investment in credibility, sustainability, and long-term global leadership. The philosophy of quality must also extend beyond pharma manufacturers. It must permeate every link of the value chain—including raw material suppliers, packaging vendors, equipment manufacturers, engineering service providers, and all allied stakeholders. A pharma product is only as strong as its weakest component in the supply chain.

From compliance to innovation

With this foundation firmly established and with the global marketplace in clear sight, the Indian pharma industry must now shift its focus towards meaningful innovation. The discovery of entirely new drug molecules has become increasingly difficult, time-consuming, and prohibitively expensive. Moreover, with the rapid emergence of biosimilars, biological products, and biotechnology-driven therapeutics, competition will only intensify. Innovation, therefore, must not be confined solely to discovering new molecules.

There exists enormous scope for innovation in improving the therapeutic performance of well-established, time-tested medicines. By developing smarter drug delivery systems, identifying new therapeutic indications, enhancing bioavailability, targeting drugs more precisely to the affected site, minimising systemic exposure, and reducing dosage requirements, we can significantly improve patient outcomes while reducing the overall burden of medicines on the human body.

Operational excellence and scientific innovation must, therefore, progress hand in hand. With intelligent manufacturing systems, advanced process analytics, automation, digital technologies, Artificial Intelligence (AI), and Machine Learning (ML), the pharma industry can optimise resources, strengthen quality assurance, accelerate product development, and create the capacity to pursue meaningful innovation. These technologies should not merely make manufacturing faster or cheaper; they should enable medicines to become safer, more effective, more accessible, and capable of serving multiple therapeutic purposes.

Planning the transition: The MSME perspective

The fundamental question that needs to be asked is: if pharma manufacturing facilities were already being inspected regularly, issued GMP certificates, and, wherever necessary, served with regulatory observations and warning notices, then what prevented the timely upgradation of infrastructure, technology, quality systems, and workforce capabilities?

Why did both the industry and the regulatory authorities wait for compulsory enforcement before accelerating improvements? Undoubtedly, upgrading facilities, modernising technology, strengthening quality systems, and enhancing technical competencies require significant financial investment. Attempting to achieve all of this within a compressed timeframe can inevitably become expensive and, at times, result in hurried or half-hearted implementation. However, after being granted an additional two years, it is difficult to argue that adequate time was unavailable.

The basic principle of regulatory compliance is straightforward. Every inspection should identify deficiencies, corrective actions should be initiated without delay, and their implementation should subsequently be verified and certified. Continuous improvement is the very essence of Good Manufacturing Practices (GMP). Therefore, the present exercise should not have required manufacturers to begin from scratch. Rather, it should have been the culmination of a process of continual improvements that ought to have been taking place after every inspection.

For MSMEs, however, the practical challenges are undeniable. Major infrastructural modifications, installation of new equipment, process redesign, or facility renovation may require temporary suspension of manufacturing operations. Such interruptions inevitably affect production schedules, revenues, customer commitments, and overall business continuity.

This reality calls for careful planning rather than reactive decision-making. Manufacturers should build adequate inventories in advance, coordinate closely with marketing teams, distributors, and customers, and prepare comprehensive implementation schedules to minimise disruptions. Equally important is the need to remain uncompromising throughout the upgrading process. Shortcuts adopted under commercial pressure, financial constraints, or market demands ultimately defeat the very purpose of modernisation.

Initiatives such as RPTUAS can certainly provide valuable technical guidance and support to MSMEs. However, they cannot substitute for the investments that manufacturers themselves must make. Infrastructure, automation, qualified manpower, validation, digitisation, and quality systems are investments that cannot be outsourced or avoided.

Ultimately, every business must evaluate its investment decisions based on its product portfolio, manufacturing technologies, market positioning, pricing strategy, and the value that customers are willing to recognise and pay for. Regulatory compliance is the indispensable foundation, but sustainable long-term success will depend upon strategic product selection, continuous innovation, operational excellence, and the ability to respond to evolving global market dynamics. These are commercial decisions that every entrepreneur and investor must carefully evaluate.

Compliance as a business enabler

The rapidly expanding opportunities in Contract Development and Manufacturing Organisations (CDMOs) and Contract Development and Research Manufacturing Organisations (CDRMOs) further reinforce this perspective. These business models offer significant growth potential, provided they are supported by world-class manufacturing capabilities and uncompromising quality systems.

Business expansion, however, can only rest upon a strong foundation. A fully cGMP-compliant manufacturing facility is no longer a competitive advantage—it is the basic prerequisite for participating in the global pharma marketplace.

Such facilities not only satisfy regulatory expectations but also inspire confidence among customers, multinational partners, and global pharma companies. They become powerful enablers for outsourcing partnerships, contract manufacturing opportunities, technology collaborations, and sustained business growth. In today's pharma landscape, quality compliance is no longer merely a regulatory obligation; it is a strategic business asset that determines credibility, competitiveness, and long-term success.

Positioning India for the next phase of growth

Looking at the projected growth of the Indian pharma industry—with an anticipated turnover of $120–130 billion by

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2030—one thing is abundantly clear: the opportunities ahead are immense. India has the potential not only to strengthen its position as the Pharmacy of the World but also to emerge as the largest and most trusted supplier of quality medicines globally.

Realising this vision, however, will require far more than increased production capacity. It demands world-class, cGMP-compliant infrastructure, unwavering consistency in product quality, reliable manufacturing volumes, resilient supply chains, and timely deliveries. In this context, the implementation of the Revised Schedule M is not merely a regulatory milestone—it is a strategic enabler that will prepare the Indian pharma industry for sustained participation in global markets.

Well-designed, cGMP-compliant manufacturing facilities can evolve beyond production units to become centres of innovation.

Such facilities provide the ideal ecosystem for research and development aimed at improving the therapeutic performance of established, safe drug molecules, enhancing drug delivery systems, and developing more effective pharma products. They can also emerge as preferred manufacturing destinations for large multinational companies that seek high-quality contract manufacturing without investing heavily in additional infrastructure or production capacity, particularly for high-volume products.

I firmly believe that the Indian pharma industry stands on the threshold of another transformational phase. We have already witnessed the remarkable impact of the Hatch–Waxman Act of 1984, which opened unprecedented opportunities for generic medicines in the US and became a defining milestone in the growth of India's pharma exports. A similar opportunity now lies before us—provided we wholeheartedly align ourselves with globally accepted quality standards and consistently demonstrate our ability to meet them. The future demand for affordable medicines is unlikely to diminish. While biosimilars, biologicals, and advanced biotechnology products will continue to expand their presence, chemically synthesised medicines will remain indispensable because of their affordability, accessibility, established therapeutic value, and widespread availability. At the same time, healthcare needs across developing and underdeveloped nations will continue to grow, while an increasing number of patented medicines will lose exclusivity and enter the generic market. Together, these developments will significantly expand access to quality medicines and create substantial opportunities for capable pharma manufacturers. India is uniquely positioned to respond to this growing global demand. To do so successfully, however, it must earn and retain the confidence of regulators, healthcare providers, and patients across every market it serves.

Let us therefore accept one fundamental truth: regulatory compliance is not a matter of choice—it is an absolute necessity. It represents the first assurance of product quality, patient safety, and manufacturing integrity. The Revised Schedule M is not simply another regulatory requirement; it is a blueprint for building a stronger, more credible, and globally competitive pharma industry.

Its successful implementation will not only elevate the quality standards of Indian pharma manufacturing but will also enhance international confidence, create new business opportunities, strengthen India's position in global supply chains, and pave the way for sustainable long-term growth. Ultimately, investing in quality is not merely an investment in compliance—it is an investment in the future of Indian healthcare, the global pharma industry, and, most importantly, the patients whose lives depend upon the medicines we manufacture.

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CBC India expands Ingredients & Packaging Solutions portfolio for pharma and nutraceutical sectors

Durgesh Sharma, MD, CBC Corporation, highlights how CBC India is bringing together ingredients, formulation expertise and packaging solutions under one platform to support pharma and nutra manufacturers across the product lifecycle

The pharma and nutra industries are entering an era where innovation is no longer limited to discovering new molecules. Today, success depends equally on how effectively a product can be formulated, manufactured, protected, delivered and experienced by the end user.

Behind every successful tablet, capsule, powder, liquid or nutra product is a complex ecosystem of ingredients, formulation technologies, manufacturing expertise and packaging solutions. This is where the right partner can create a real difference.

Recognising the evolving needs of the Indian pharma and nutra industry, CBC India has strengthened its portfolio with a dedicated Ingredients & Packaging Solutions (IPS) business, bringing together quality ingredients, formulation-focused solutions and packaging capabilities under one platform.

IPS represents a significant evolution in CBC India's approach - from being a supplier of individual products to becoming a solutions-oriented partner for customers looking to develop, improve and scale their products.

With access to global technologies, international business networks and local market understanding, CBC India is positioned to connect customers with solutions that address today's formulation and packaging challenges while supporting the opportunities of tomorrow.



Ingredients are the foundation

A formulation is only as strong as the foundation on which it is built. In pharma and nutra manufacturing, excipients and functional ingredients play essential roles beyond simply adding volume or improving appearance. They can influence flowability, compressibility, stability, solubility, release characteristics, bioavailability, taste, texture, manufacturability and overall product performance.

Selecting the right ingredient therefore requires much more than checking a specification sheet. It requires an understanding of the application, formulation objective, manufacturing process and desired product performance.

CBC India's IPS portfolio is built around this understanding. Through its network of global partners and suppliers, CBC India offers access to a broad range of ingredients and formulation solutions designed to support diverse applications across the pharma and nutra sectors.

Supporting diverse formulation requirements

Our solutions can support applications including:

Oral solid dosage: Solutions for tablets, capsules and other solid dosage formulations, with a focus on critical formulation and processing requirements.
Nutraceuticals & health supplements: Functional ingredients and formulation solutions supporting the growing demand for nutritional, wellness and preventive-health products.
Functional excipients: Ingredients that contribute to processing efficiency, stability, performance and desired dosage-form characteristics.
Specialty & advanced formulation needs: Solutions designed to address specific formulation challenges and support the development of differentiated products.
Taste, texture & patient experience: Ingredients that can help improve palatability, mouthfeel and overall user experience, particularly important for consumer-focused pharma and nutra products.
Stability & performance: Solutions supporting formulation robustness, product stability and consistent manufacturing performance.

One of the biggest advantages of CBC India's IPS approach is its focus on application-driven customer engagement. Every formulation is different. A customer may be looking for improved tablet hardness. Another may be facing flow or compression challenges. A nutra manufacturer may be looking to improve taste or mouthfeel. A formulation team may be exploring a new delivery system or seeking an alternative ingredient for a specific application.

The requirement is not simply: "Which product do you have?"

The real question is: "Which solution is right for my application?"

CBC India aims to bridge this gap by combining product knowledge with technical understanding and customer-focused support. Our teams work closely with customers to understand their requirements and identify suitable products and technologies from our portfolio and global partner network.

Right ingredient. Right application. Right support.

This approach enables CBC India to create value at multiple stages - from initial product selection and technical discussions to evaluation, development and commercial implementation.

A pharma or nutra product does not end with formulation. Once a product is developed, its quality and integrity must be protected throughout its journey - from manufacturing and storage to transportation, dispensing and final use.

Packaging plays a critical role in this process. It can protect products from moisture, oxygen, light, contamination and physical damage, while also supporting product stability, shelf life, handling and convenience. For this reason, packaging decisions need to be considered as an integral part of the product-development strategy.

CBC India's Ingredients & Packaging Solutions business extends its solutions approach into this important area, helping customers explore packaging options aligned with their product requirements.

Packaging solutions for a changing industry

The pharma and nutra packag-

ing landscape is evolving rapidly. Manufacturers are looking for solutions that deliver a combination of:

Protection: Safeguarding the product against environmental and physical factors.

Performance: Supporting product integrity throughout its intended shelf life.

Compatibility: Ensuring packaging materials are appropriate for the product and application.

Convenience: Supporting ease of handling, dispensing and use.

Quality & Consistency: Maintaining dependable performance across production and supply chains.

Innovation: Enabling manufacturers to respond to changing product, regulatory and consumer requirements.

Through its packaging solutions portfolio, CBC India seeks to connect customers with technologies and products that support these requirements.

Traditionally, different aspects of the product lifecycle may involve multiple suppliers, multiple communication channels and fragmented sourcing. CBC India's approach is designed to simplify this journey. From ingredient selection and formulation requirements to packaging considerations, customers can engage with one organisation that understands the broader picture.

Ingredients → Formulation → Protection → Delivery

This connected approach can help customers explore opportunities more efficiently and create stronger alignment between formulation and packaging requirements.

It also enables CBC India to have a deeper understanding of the customer's business - moving beyond a transactional supplier relationship towards a long-term strategic partnership.

CBC India is part of the global CBC Group, with a history spanning more than a century and a network extending across international markets. This global foundation provides access to international technologies, products, suppliers and business expertise.

> Traditionally, different aspects of the product lifecycle may involve multiple suppliers, multiple communication channels and fragmented sourcing. CBC India's approach is designed to simplify this journey

At the same time, CBC India brings strong knowledge of the Indian market and a close understanding of the needs of local pharma and nutra manufacturers. Our objective is to identify relevant global solutions and make them accessible to customers in India through a responsive and relationship-driven approach.

In pharma and nutra manufacturing, consistency matters. Customers need confidence not only in the product they purchase today, but also in the reliability of their supply partner over the long term. From dependable sourcing and consistent product quality to responsive communication and timely support, every aspect of the supply relationship plays an important role.

Reliability: At CBC India, reliability goes beyond simply supplying a product. It means building a dependable supply ecosystem that customers can count on. We work closely with established global manufacturers and solution providers to develop a portfolio designed around customer requirements. By building strong supplier relationships, maintaining clear communication and understanding customer needs, we strive to support greater continuity, consistency and confidence across the supply chain.

Our focus is to be a partner customers can rely on—not only when requirements are routine, but also when timelines are demanding, specifications are critical or new challenges emerge. Reliability, for us, means doing what we commit to, responding when it matters and building confidence for the long term.

Quality: Connecting customers with products and solutions from trusted global sources, with a focus on consistency, performance and application requirements.

Knowledge: Understanding applications and helping customers navigate formulation, ingredient and packaging requirements through informed technical and commercial support.

Partnership: Building long-term relationships based on trust, responsiveness and mutual growth by working together with customers and suppliers to create sustainable value.

At CBC India, these principles come together to create more than a product offering. They form the foundation of a relationship built on quality you can trust, reliability you can count on and partnership that grows with you.

At CBC India, we believe that value is created when products are combined with knowledge, accessibility, responsiveness and partnership. That philosophy defines the evolution of our IPS business. We are not simply looking to expand a product catalogue. We are building a platform that enables pharma and nutra companies to discover new possibilities, solve formulation challenges, improve processes and explore innovative approaches to product development.

As the industry moves towards more complex formulations, differentiated dosage forms, better patient experiences and smarter packaging, CBC India is committed to staying close to these evolving requirements.

The next generation of pharma and nutra products will demand more from every component of the value chain. Ingredients will need to deliver greater functionality. Formulations will need to become more efficient and patient centric.

Packaging will need to provide stronger protection, greater convenience and improved performance and businesses will increasingly look for partners capable of bringing these capabilities together.

CBC India's IPS is built for this future. With a growing portfolio, global partnerships, technical understanding and a customer-first approach, CBC India is creating new opportunities to support the industry across the product lifecycle. From the first formulation idea to the final packaged product, we aim to be there connecting customers with the right technologies, the right products and the right possibilities.

The right products are important. the right partner makes the difference

In today's rapidly evolving pharma and nutra landscape, having access to the right ingredients and packaging solutions is only the beginning. What creates lasting value is having the right partner. One who understands your requirements, brings the right expertise to the table and works with you to find solutions that fit your application, quality expectations and business objectives.

At CBC India, our vision for Ingredients & Packaging Solutions is simple: To connect global expertise with Indian opportunities and help our customers turn challenges into possibilities. Our role goes beyond connecting customers with products. We aim to understand the "why" behind every requirement - whether it is a formulation challenge, a need for improved functionality, a search for a specialty ingredient, a packaging requirement or the need for greater supply reliability.

Through our network of established global manufacturers and solution providers, we bring together products, technical knowledge and application-oriented thinking to help customers evaluate possibilities with greater confidence.

Whether you are developing a new formulation, improving an existing product, exploring a specialty ingredient, evaluating packaging options or looking for a dependable long-term supply partner, CBC India is ready to work alongside you.

We believe the strongest solutions emerge when global capabilities meet local understanding. It is about bringing the right products closer to the right applications. It is about understanding market needs, identifying opportunities and creating connections between manufacturers and customers. Because innovation doesn't happen in isolation. It happens when knowledge meets technology, products meet applications, and businesses come together with a shared vision. That is the difference between simply supplying a product and becoming a trusted solution partner.

At CBC India, we believe innovation happens when the right elements come together. By combining Ingredients, Formulation Expertise and Packaging Solutions under one connected ecosystem, we help customers navigate changing market demands. As customer expectations evolve, we remain committed to evolving with them by building new connections, advancing innovative technologies and opening doors to new possibilities across the pharmaceutical, nutra and related industries.

CBC India - Connecting global expertise with local opportunities. Ingredients. Formulation. Packaging. Expertise.

Think Global. Act Local.

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Why digital manufacturing matters for pharma packaging

Rajesh Khosla, CEO, AGI Greenpac emphasises how digital manufacturing, AI-powered inspection and real-time data can improve pharmaceutical packaging quality, traceability and operational efficiency

A pharmaceutical vial is a small, plain object with a demanding job. It has to protect its contents, fit the filling line without fuss, and behave the same way in every batch. A slight variation in wall thickness or neck finish rarely looks serious on the factory floor. It can look very different once it reaches a customer's filling line.

Yet there is a persistent gap in how packaging quality has traditionally been managed. Skilled operators and sampling-based inspection have served the industry well, but they leave blind spots. A sample tells you about the units you tested. It says little about the units produced in between.

Small drifts, not sudden events

Most quality problems in pharma packaging do not arrive as sudden failures. They build slowly. A furnace temperature creeps upward, a mould wears, a raw material behaves slightly differently from the last one. Each change stays inside the limits for a while. Eventually, the process is sitting at the edge of its tolerance and nobody can say exactly when it got there.

Digital manufacturing addresses this directly. Sensors record temperatures, pressures, speeds and dimensions continuously, and when that data feeds a control system, the process can be corrected while it is running. The question moves from "did this sample pass?" to "is the process behaving as it should right now?" That shift is one of the biggest single gains for reliability.

It also changes what a quality team spends its day doing. Instead of reconstructing what went wrong after a rejection, engineers can watch a process approach its limits and step in early. In forming and finishing, where many variables interact, seeing those interactions as they happen is far more useful than reading about them in a report the following morning.

Automation helps too, particularly with repetitive handling and sorting, where fatigue and inconsistency are hardest to avoid. The point is to free experienced people for diagnosis and improvement, not to replace them. A machine can hold a position or a speed steadily for a full shift. A person is better placed to ask why a trend has started.

Inspecting every unit

Automated vision systems can check every container at line speed, rather than relying on a statistical sample. They examine dimensions and surface condition consistently across a long shift, something manual inspection struggles to match. Sampling always carries some residual risk, because a defect that appears only occasionally can go undetected in the units that were never examined. Full inspection narrows that gap considerably.

AI adds another layer. Trained models can learn to tell real defects from harmless variation, reducing both missed defects and false rejections. Each has a cost: a missed defect can reach a customer, while a false rejection throws away good product and the material and energy behind it. But AI in a regulated setting needs proper validation and clear performance criteria. A model nobody can explain or verify creates more risk than it removes. Even a validated model should be reviewed periodically as products, materials and conditions change.



Improving traceability

Pharmaceutical customers want to know where a container came from and under what conditions it was made. Digital systems can tie together raw material lots, process settings, inspection results and finished batches. This satisfies documentation requirements, and it also makes investigations faster. When a question arises, teams can narrow it to a specific line, shift or material lot instead of piecing events together from separate paper records. Corrective action then targets the actual cause rather than everything nearby.

That precision has a practical benefit for customers as well. A narrow, well-documented investigation means less disruption to their own operations, and a clearer answer about what was affected and what was not. Broad, cautious responses are sometimes unavoidable when records are incomplete. Good data reduces the need for them.

None of this works without sound data integrity. Records have to be accurate, complete, secure and attributable, and systems should be built that way from the outset. Retrofitting integrity into a system that was not designed for it is slow, costly and seldom fully effective.

Using data for resilient operations

Collecting data is relatively easy. Making good use of it is harder. Analytics can surface patterns no single operator would spot, such as a setting that consistently precedes a certain defect, or a slow trend that comes before an excursion. Predictive maintenance follows naturally: if a particular equipment condition tends to lead to quality problems, it can be addressed before defects appear. Fewer unplanned stoppages and fewer off-specification units are the usual result, along with better use of materials and energy.

Process optimisation benefits in the same way. When settings are tuned against evidence rather than habit, the gains tend to be modest individually but steady over time. A small reduction in scrap or rework on a high-volume line adds up, and it does so without any change to the product itself.

The harder part is often organisational. Sensors need calibrating, systems need validating, and people need training to read what the data says. Production, quality and maintenance teams also need to work from the same information, rather than three slightly different versions of it. Where those groups disagree about what the numbers mean, even excellent data delivers little.

Legacy equipment is a further constraint. Replacing every line is rarely feasible, and seldom necessary. Adding sensors to existing assets and connecting them is often a sensible place to start, provided the changes are validated and the priorities are clear.

Meeting rising expectations

Regulators and pharmaceutical customers continue to expect more rigour and transparency from packaging suppliers, since the container is an integral part of how a drug is protected. Manufacturers who can show controlled processes, complete records and early detection of problems will be better placed to meet those expectations. They are unlikely to ease, and the ability to demonstrate control, rather than simply claim it, is becoming part of what customers look for when they assess a supplier.

Digital manufacturing is not a project with an end date. The manufacturers that gain the most tend to begin with a specific problem, whether that is variability, inspection coverage or traceability, and build outwards from there. The aim has not changed: containers that perform the same way, batch after batch. Digital tools make that easier to achieve, and easier to prove.

Stevanato Group

The alchemy of talent

Mona Puri, Executive Director – Human Resources, India and APAC, Parexel, explains why organisations need to move beyond recruitment and focus on building capabilities through internal development, external expertise and cross-functional engagement

When organisations identify a "talent gap", the immediate response is often to ask: Who do we need to hire? But that may not be the only question to ask. The more useful question is: What capabilities do we need, and how can we develop or access them?

Capabilities are not created only by hiring people with a particular set of skills. They can be strengthened by developing expertise that already exists within an organisation, creating opportunities for people to work across disciplines, and engaging with expertise beyond its boundaries.

From headcount to capabilities

Clinical research illustrates why this shift matters. Advances in technology, data and AI, alongside increasingly complex clinical development programmes, are changing the capabilities required across the industry. A 2025 industry survey of more than 500 pharmaceutical, biotechnology and CRO leaders and frontline professionals found that adaptability and agility were among the most important skills for the future workforce; significantly, 82 per cent of senior leaders expected cross-functional roles to increase.

In such an environment, workforce planning cannot simply be about filling vacancies.

True, an organisation may need scientific expertise for one challenge, data capabilities for another and therapeutic or operational knowledge for a third. Some capabilities may need to be recruited or acquired; others can be developed internally; simply put, you look in places where the talent is.

The starting point, therefore, should be assessing the capability required, not simply the role that needs to be filled. Before that, one thing to be underscored, even reiterated: capability is not skill. Knowledge or skill is one of four elements that make up capability; the other three are how a person handles complex mental processing, how much they value the work they do, and temperament or behaviour.



Training – or 'upskilling' – is not the same as capacity building. Building capability requires continuous practice, coaching and reinforcement

The genie inside

Looking outside the organisation for filling every capability gap can overlook what already exists within an organisation. Internal engagement can create opportunities for employees to apply their expertise in new contexts, through cross-functional projects, mentoring, knowledge-sharing forums, expert communities or exposure to different areas of the business.

Then, there is the talent stage outside the organisation, visible at industry conclaves. People representing their organisations congregate at conferences, academic lectures or scientific forums. Even they showcase their own expertise, they gain new knowledge and perspectives that enhance their own capabilities. That strengthens their organisation's visibility among the wider professional community.

Over time, this becomes a strong talent pool of demonstrated expertise that is ambassadorial in nature, within the organisation. Other companies have internal hackathons for generating and discovering internal capabilities. The objective is not simply employee development; it is to activate and expand existing capabilities.

Beyond organisational boundaries

The other side of capability building lies outside the organisation. In sectors such as clinical research, organisations cannot realistically have every area of expertise available internally. In R&D driven businesses, the addition of new dimensions like machine learning and artificial intelligence have greatly expanded the boundaries of what companies can do or deliver.

Universities, researchers, clinicians, professional networks and industry specialists can bring knowledge and perspectives that complement existing capabilities. External engagement can take several forms, from academic partnerships, through expert forums, internships, to externships.

Secondments also play a valuable role combining internal and external engagement. When someone spends time working in another organisation, function or environment, they gain exposure to different practices, technologies and perspectives. Importantly, that learning and knowledge can be institutionalised, not remain just with the person.

When they return, the experience is be shared with colleagues, and can possibly be translated into new capabilities across the wider team or system. External engagement can strengthen both individual expertise and organisational capability.

For internal and external engagement to translate into value, organisations need the right platforms and culture to support it. The objective should be to connect expertise with the opportunity to enhance the former. That could be an employee contributing to a cross-functional challenge, or an academic bringing research expertise to an industry problem. It could even be a professional gaining exposure through a secondment. The value of these platforms should ultimately be visible in their outcomes.

Rethinking what we mean by talent

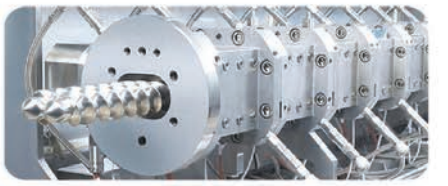
Talent, therefore, cannot be reduced to the people an organisation recruits. Hiring – or recruitment – is just one route to building capability. Internal engagement can develop and activate capabilities that already exist. External engagement can expand access to expertise and perspectives beyond organisational boundaries.

Bringing these approaches together creates a more complete way of thinking about talent - one that is focused not simply on acquiring people, but on building the capabilities an organisation needs to adapt, innovate and deliver. What are the takeaways from all of this?

First, training – or 'upskilling' – is not the same as capacity building. Building capability requires continuous practice, coaching and reinforcement. Second, people need enablers; skills will not scale to capability if workflows, tools and governance prevent people from acting. Last but not least, companies must measure behaviour and business impact rather than activity. As Edward Gibbon, the 18th century historian and author of The Decline and Fall of the Roman Empire said, "Our work is the presentation of our capabilities."

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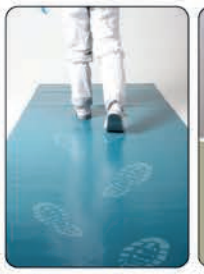
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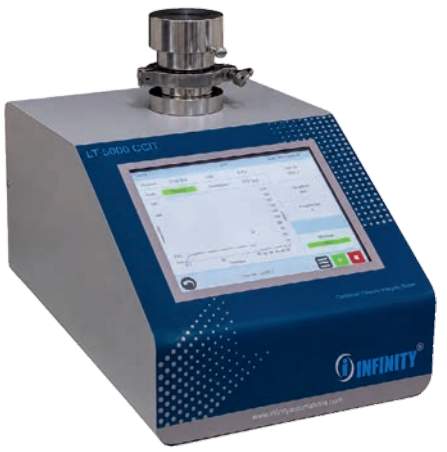
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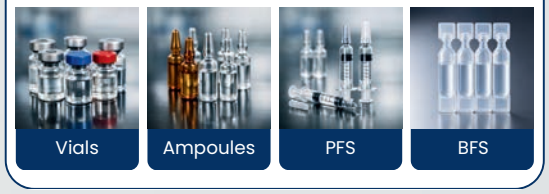
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APPLICATIONS



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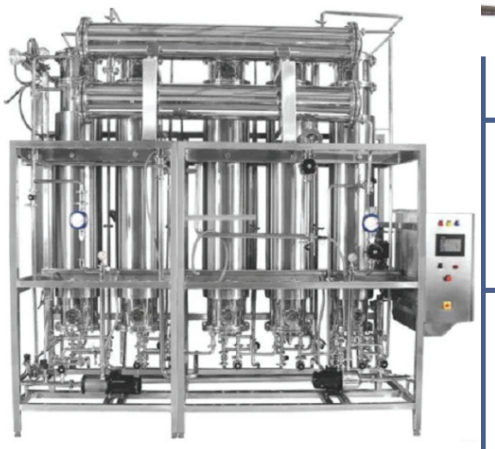
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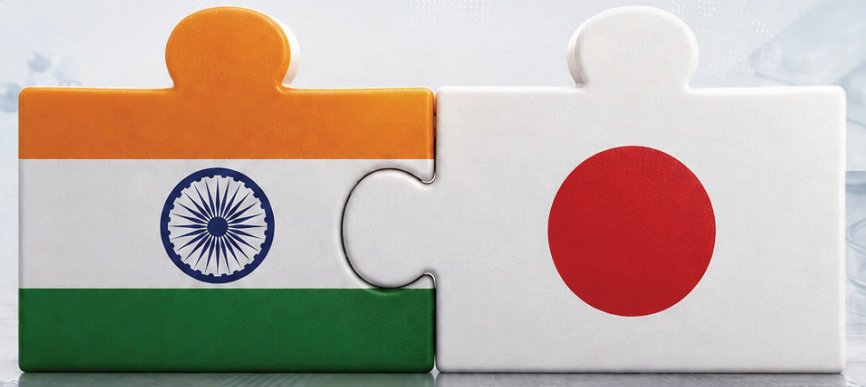
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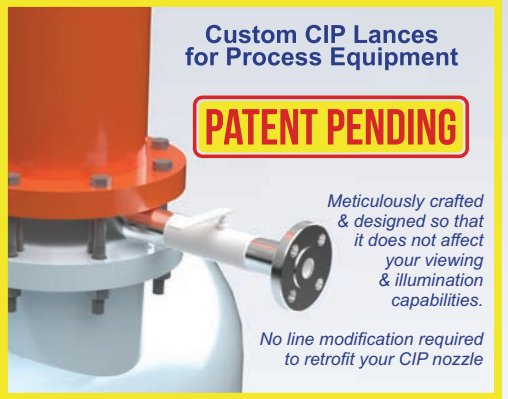
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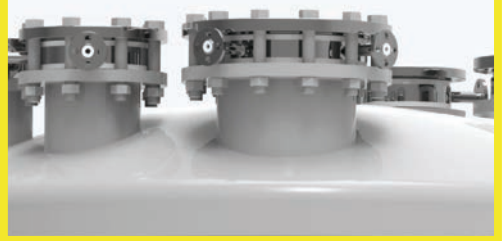


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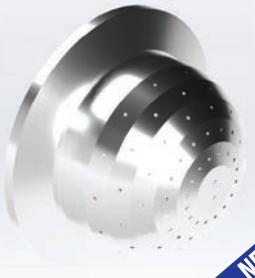


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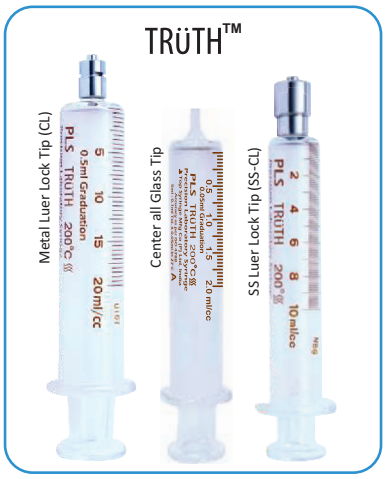
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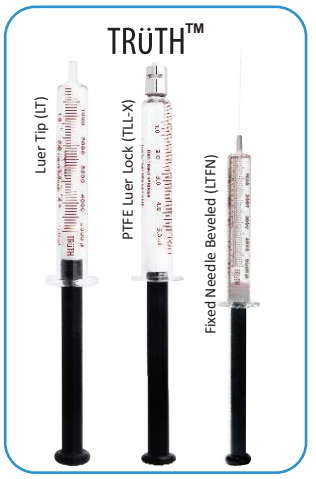
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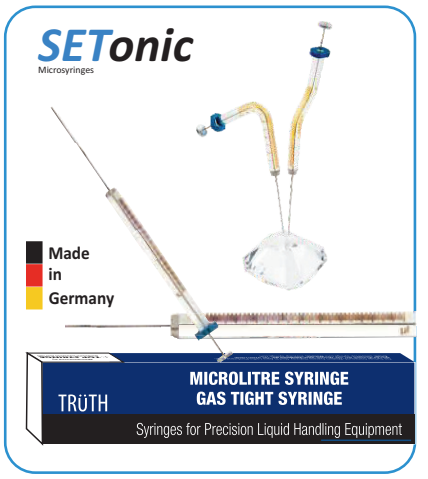
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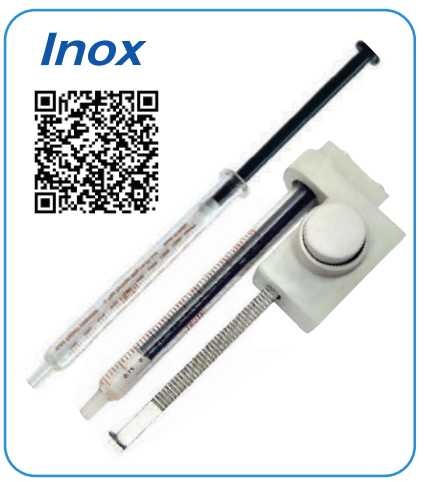
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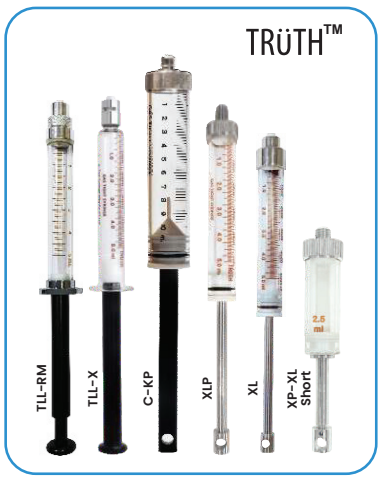
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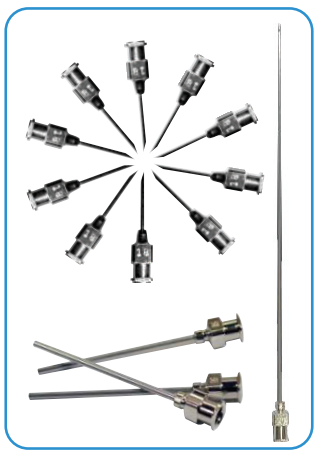
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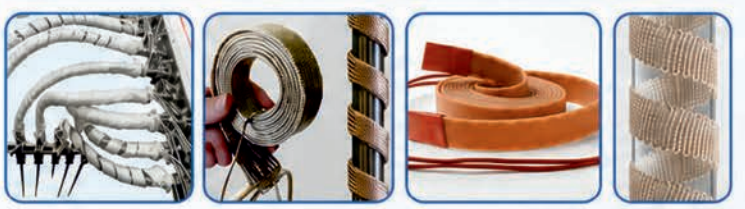
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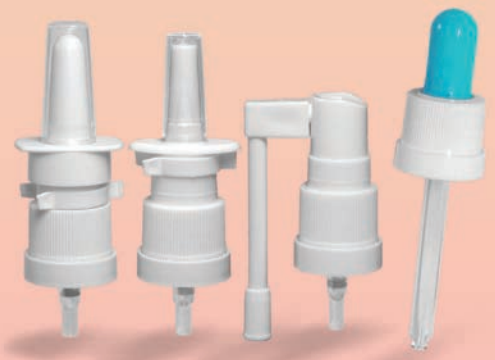
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Building a resilient global supply network for MCC

Highlighting the importance of supply chain security in ensuring the uninterrupted availability of Microcrystalline Cellulose (MCC), **Krishnakumar Patel,** Technical Services, JRS Pharma, India, explains how JRS Pharma's global manufacturing network, regional production facilities and technical support capabilities address supply risks and meet customer requirements

Since its introduction in 1964, Microcrystalline Cellulose (MCC) has revolutionised the pharma industry, serving as a vital ingredient in various drug formulations due to its unique properties like compressibility, flowability, and stability. Today, it is one of the most widely used excipients in pharmaceuticals, cosmetics, food, and other industries. Its invention has significantly contributed to enhancing the efficacy, safety, and overall quality of pharma products. Another remarkable feature of MCC is its biocompatibility, making it safe for human consumption. The fact that it is derived from a natural and renewable source (cellulose from plant fibers) further adds to its appeal as a pharma excipient.

MCC is a crucial universal commodity with high demand and long term need for availability at almost all times. Being used in very high volumes in oral solid dosage forms, identifying, predicting and managing certain risk factors, which are mentioned below are a big challenge for procurement teams and also an essential part of a future oriented supply chain management strategy. Years in recent past have shown many sudden situations to us like once-in-a-century pandemic and geo-political situations affecting businesses like never before. In addition to these, here are few risk potentials working adversely to global pharma operations –

- Climate change / extreme weather conditions
- Natural calamities like Earthquakes / Floods / Droughts
- Epidemics
- Civil wars
- Transportation shortages
- Resource availabilities
- Digital and energy system instability
- Cyber crimes
- Currency fluctuations
- Accident, Fire, Explosion scenario
- Population growth

To overcome those risk potentials, JRS Pharma provides solutions optimised for individual customers' global supply chain needs for pharma and other related industries. They offer a perfect high level partnership, combining synergies and advantages of a global manufacturing concept – based on standardised and quality regional production facilities:

> This regional manufacturing concept allows faster regional access and ensures optimised supply chain security. It also eliminates risk of supply due to plant maintenance or shutdown due to unavoidable circumstances or accident

Excellence in MCC know-how

JRS Pharma is one of the largest manufacturers of MCC across the globe. The know-how is based on more than 25 years of experience in development of own processes. JRS innovated and improved these processes with advanced and specially designed equipments. It gives much better control, excellence and reproducibility of the process, end-product resulting in consistent quality.

Reliable premium quality

Strict control on input raw material source, quality and other parameters also play important role on output consistency. The compliance with global compendial monographs and additional internal specifications, such as TUPs and high degree of brightness are tested by local quality control labs.

Technical support

In addition to these, JRS Pharma's two Technical Competence Centers (TCC) carry out functionality and performance testing on our excipients periodically. In collaboration with TCCs, five regional application labs provides in-time technical support and advice. Regionally placed technical and sales representatives get in touch with respective customer departments and assist them to fulfill their requirements too.

Industry leading supply security

Being one of the leaders in MCC manufacturers is enabled by multiple units located scattered across the world. Flagship MCC brands VIVAPUR®, EMCOCEL® and FLOCEL® Plus are manufactured at multiple production sites in three different continents follow standardised German production process technology. This regional manufacturing concept allows faster regional access and ensures optimised supply chain security. It also eliminates risk of supply due to plant maintenance or shutdown due to unavoidable circumstances or accident.

Cost-effectiveness

Regional manufacturing helps to offer better pricing to local customers as it minimises duties, currency conversion and freight costs.

Better customer service

JRS Pharma has its presence in almost all regions by either having their own sales office or through efficient channel partner. It enables customer service in regional time zone and avoids response gaps.

Customised solutions

In case of specific customer needs, JRS Pharma can support new business initiatives with tailor-made solutions. Time-to-time, they also come up with new grades to meet arising needs of the industry. Recent one in this line is PROSOLV® 730, which is MCC based high-functionality adsorbent.

Summary

As a dedicated global solution provider, JRS Pharma meets all needs for excellent support and service –

- Technical assistance
- Worldwide logistics and warehousing
- Local sales offices with dedicated customer service
- Certified quality and regulatory system

This helps to make business life much easier and more secure.



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Clean Room High Speed Doors for controlled manufacturing environments

Gandhi Automations offers self-repairing high-speed doors designed to minimise air leakage and maintain controlled environments in pharmaceutical and other manufacturing facilities

High Speed Doors designed and manufactured by Gandhi Automations are sturdy, dependable, and the ideal solution for medium and large entrances. The doors are manufactured with European collaboration, technology, and innovative and creative engineering.

Better quality or yield is the primary reason for investing in a cleanroom space. It goes straight to your bottom line. Numerous manufacturing facilities now require a controlled environment in which you limit the amount of dust and dirt in the area of the manufacturing. Medical instrument manufacturing and packaging, electronics and computer manufacturing, food preparation, and some military applications are but a few of the instances that have strict requirements for maintaining a clean environment. You need to know the requirements for your specific product or process. Clean rooms have become an integral part of pharma manufacturing facilities.

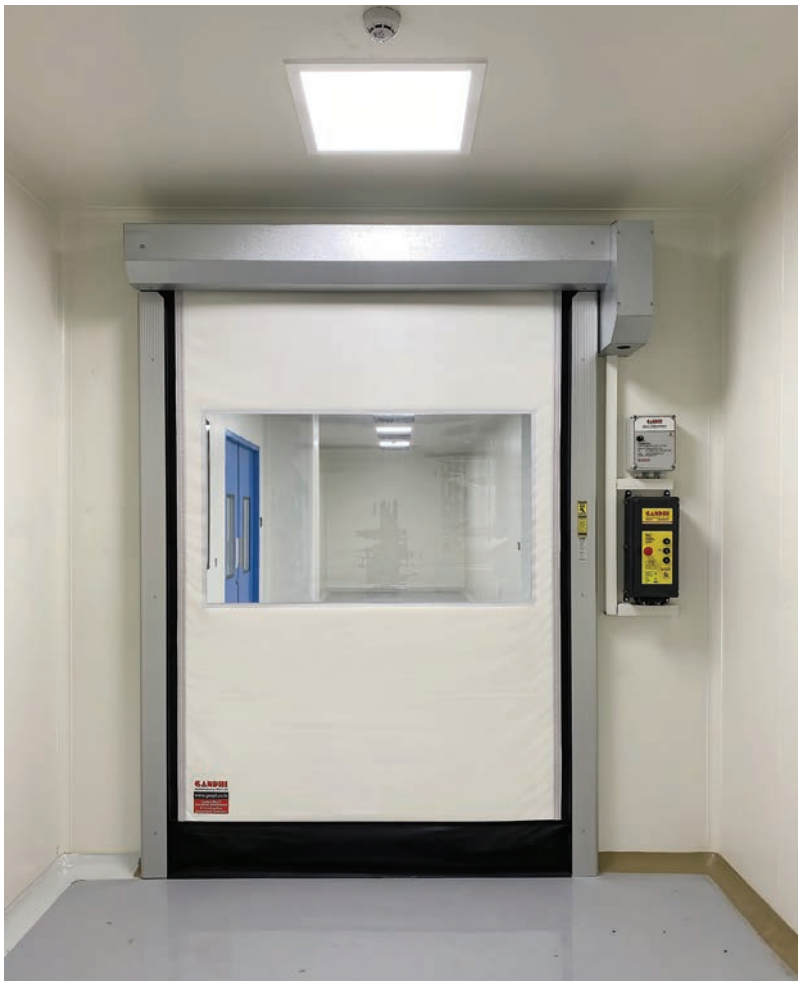
One of the most important aspects of cleanrooms is the doors you choose for the cleanroom facility. The time for which the door is open will play a critical role in avoiding dust, outside temperature, humidity, etc. The opening and closing of the door have to be quick enough to isolate the outside environment and internal facility.

At Gandhi Automations Pvt Ltd, we provide Clean Room High Speed Doors specifically designed for the above purpose. Our clean room high-speed doors are best suited for facilities where you need a controlled environment. The opening and closing of the door are quick enough to separate the outside environment from the internal facility.

Gandhi Automation's High-Speed Clean Room Doors are meticulously engineered, boasting the following features:

- Concept of low air permeability in pressurised rooms with positive and negative air pressure
- Designed to fit inside the columns
- Self-supporting construction
- Minimises air leakage
- Can be equipped with transparent PVC horizontal sections or vision windows
- Special side guides to tightly integrate the curtain
- High leak tightness due to the close filling curtain in the guide rails
- High door efficiency with and low permeability values, EN 12426 EN 12427: < 12 m3/m2 h ? 50 PA
- Control device enclosure in Stainless Steel SS 316

Gandhi Automations Pvt Ltd
Chawda Commercial Centre
Link Road, Malad (W)
Mumbai – 400064, India
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Website : www.geapl.com





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From Procurement to Partnership: Building Lasting Value with Lactose India Limited

The article highlights how Lactose India Limited is adopting a value-driven procurement approach, focusing on quality, supply reliability, strategic supplier partnerships and customer-centric solutions to deliver long-term business value

In pharmaceutical manufacturing, procurement is not simply about buying materials at the right price. Every purchasing decision can influence product quality, production continuity, delivery commitments and, ultimately, the experience of the customer. The right material, sourced from the right supplier and delivered at the right time, becomes part of the reliability that customers expect from their manufacturing partner.

The traditional lowest-bid approach can sometimes reward immediate savings while leaving the organisation to absorb the consequences later—through rework, delays, emergency purchases, excess inventory, quality issues or lost productivity. A more meaningful question is therefore not simply, "How much did we save?" but "What value did this decision create for our business and our customer?"

At Lactose India Limited, a Total Cost of Ownership (TCO) approach can help deliver greater value to customers by looking beyond the product price and focusing on the overall customer experience. By ensuring consistent quality, reliable and timely deliveries, shorter lead times, technical support, reduced rejection levels and dependable supply, Lactose India Limited can help customers minimize their operational risks, inventory costs and production disruptions. The objective is not simply to offer a competitive price, but to provide a reliable, high-quality solution that delivers greater value and long-term cost efficiency to customers.

For a pharmaceutical company, quality cannot begin only at the manufacturing stage. It starts much earlier, including with the selection and evaluation of suppliers and materials.

Procurement therefore needs to work closely with Quality, Production, R&D and Stores to ensure that purchasing decisions support the required specifications, consistency and compliance standards. Strong supplier selection and monitoring can help reduce avoidable quality issues and contribute to the consistency that customers depend on in their own manufacturing processes.



Looking Beyond the Purchase Price

From Vendors to Long-Term Partners

A reliable supplier relationship is built through performance, transparency and mutual understanding. Regular supplier reviews based on quality, delivery, responsiveness, documentation and service can help identify suppliers who consistently meet expectations.

For critical materials, the focus should go further. Understanding supply risks, monitoring single-source dependencies and developing practical alternatives where possible can strengthen continuity. This matters not only to procurement, but also to customers who de-



Quality Starts Before Production

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pend on a stable and predictable supply of pharmaceutical materials and products.

Procurement That Understands the Customer

Customer expectations do not stop at product quality. They also include consistent supply, dependable service, technical support and responsiveness.

This makes cross-functional collaboration essential. Finance brings the commercial perspective, Quality safeguards compliance and specifications, Production understands operational requirements, Stores provides inventory visibility, and R&D contributes technical knowledge. Procurement connects these perspectives to make decisions that consider the complete business requirement rather than focusing on price alone.

Technology can make this approach more practical. Better spend visibility, supplier-performance tracking, demand planning and streamlined approval processes can provide procurement teams with more reliable information.

When decisions are supported by consumption patterns, supplier history and demand requirements, procurement can plan ahead instead of responding only when a requirement becomes urgent. Better planning can support smoother operations and, in turn, more dependable service to customers.

Sustainability with a Practical Purpose

Sustainability can also become part of responsible procurement. Reducing unnecessary packaging, considering recyclable materials where technically appropriate, improving transportation efficiency and encouraging responsible supplier practices are practical areas to explore.

The objective is not sustainability for its own sake, but responsible decisions that reduce waste, improve efficiency and support long-term business value.

Creating Value Beyond the Purchase Order

For Lactose India Limited, procurement is ultimately connected to a larger commitment: delivering quality, consistency and dependable solutions to customers. The company's focus on quality, innovation, sustainability, compliance and strong customer relationships provides a natural foundation for this approach.

The goal is therefore not to move away from cost-conscious purchasing, but to look at cost in the context of quality, reliability, risk, sustainability and customer expectations. When procurement decisions are made with this wider view, suppliers become more than sources of materials—they become part of the value chain that supports customer success.

At Lactose India Limited, lasting value begins long before a product reaches the customer. It begins with making the right choices at every stage—from sourcing and supplier partnerships to quality, manufacturing and delivery. By combining commercial discipline with quality, innovation, reliability and a commitment to our customers, procurement can play an important role in building not just an efficient supply chain, but a stronger and more trusted partnership with every customer we serve.

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Truth Gas Tight syringe instrument

These are designed for accurate and repeatable injection of both gases and liquids into various instruments, especially those used in gas chromatography (GC) and other analytical techniques

A gas-tight instrument syringe is a precision tool designed for accurate and repeatable injection of both gases and liquids into various instruments, especially those used in gas chromatography (GC) and other analytical techniques. These syringes are engineered to create a leak-free seal, ensuring the integrity of the sample and the reliability of the analysis.

Volume		2.5ml	5ml	10ml	25ml
Scale length, mm		60	60	60	60
Total scale divisions		100	100	100	100
Major graduations, mL		0.25	0.5	1.0	2.5
Minor graduations, mL		0.25	0.1	0.2	0.5
Sub-Minor graduations, mL		0.025	0.05	0.1	0.25
Maximum tempreature	°C	115	115	115	115
	°F	239	239	239	239
Minimum tempreature	°C	10	10	10	10
	°F	50	50	50	50
Maximum Pressure rating	bars	14	14	14	7
	psig	200	200	200	100

Features

- For Parallel Sampling
- Withdrawal & Dosage in Multi Syringe Pumps For Dissolution Pumps, Hematology Analyzers, Tritrators, Flow Chemistry Equipments, Syringe Pump etc.
- Wetted Materials: 3.3 Borosilicate Glass, PTFE, Stainless Steel
- Accuracy / Precision +- 1% of total volume
- Pressure Up to 200 PSI Calibration Certificate on Request

For Precision Dosing in Fields of

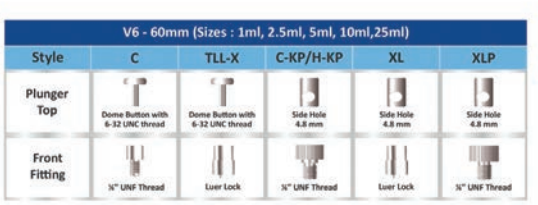
- Chromatography
- Industrial Instruments Diagnostics
- Medical Inspection
- Biochemical Field

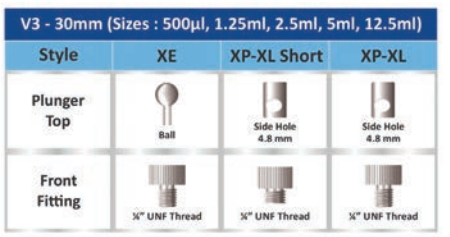
Top Syringe exports its products to over 40 countries worldwide and counting, keeping a single quality standard for local and export products.



The Instrument Gas Tight syringe is manufactured 100% in India by Top Syringe Mfg Co (P) Ltd. We are fully committed to supporting you with our full product range, spares, and technical assistance.

Syringes are customised as follows:





Address - Top Syringe Compound, W.E. Highway, Pandurangwadi, Mira road (East), Thane 401107 India.
Mob: 81046 82560
**Email : sales@topsyringe.com*
website: www.topsyringe.com

Inox - Repeating Syringe Dispenser

The precision fluid measuring device consistently dispenses samples up to 50 times.

The Inox Repeating Syringe Dispenser is a low cost, high accuracy accessory for repetitive dispensing. Each press of the button dispenses 1/50th of the syringe volume. The precision fluid measuring device consistently dispenses samples up to 50 times.

Repetitive accurate dispensing of 30ul - with Calibration certificate

It is the most versatile, handheld, semi- automated dispensers available in the market today. The repeating dispenser is compatible with the fixed needle (LTFN), luer tip (LT), or PTFE Luer Lock (TLL) syringes. The size available is of 1.5ml, which can dispense volumes of 30㎕ respectively with the "Inox" Repeating Syringe Dispenser. Every time you press the dispenser button, the "Inox" Repeating Dispenser mechanically advances the syringe plunger by 1.2mm. Based on a 60 mm scale length at full volume of the respective syringe, the 1/50th voulme is accurately dispensed. Most fluids can be effectively handled using either a 22 gauge needle. You can use with the Luer Tip (LT), syringes and to work with your specific needles.

Item	Volume	Graduation
Inox Repeater Dispenser	-	-
Center all Glass Tip (LT) Syringe	1.5ml	0.03ml
Fixed Needle (LTFN) Syringe	1.5ml	0.03ml
PTFE Luer Lock (TLL)Syringe	1.5ml	0.03ml

The "Inox" Repeating syringe dispenser has virtually unlimited applications when there is a need to deliver liquid volumes of 30㎕ repeatedly up to 50 times before refilling.

Features

- Wetting Material – PTFE, glass & ss needle
- Inox Repeater Dispenser mechanically advances the syringe plunger by 1.2mm
- On a 60mm scale length at full volume of the respective syringe, the 1/50th volume is accurately dispensed
- Autoclavable at 121°C for 20 minutes (LT & TLL only)
- Dosing Accuracy : Tolerance < 1% of dose
- Calibration certificate with each syringe.
- 1.5ml syringe can dispense volumes of 30㎕ respectively.
- Some typical uses includes:
- Preparing standard solutions
- Filling microliter trays
- Feeding cell cultures
- Spotting TLC plates
- Human leukocyte locus-A (HLA) tissue typing
- Dosing small animals (Intracerebral)
- Industrial applications include lubricating small bearings or parts, applying liquid solder, and dispensing mercury

Top Syringe exports its products to over 40 countries worldwide and counting,

keeping a single quality standard for local and export products.

The "Inox" - REPEATING SYRINGE DISPENSER is manufactured 100% in India by Top Syringe Mfg Co (P) Ltd.

We are fully committed to supporting you with our full product range, spares, and technical assistance.





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Truth Gas Tight Syringe – Manual Syringe

These are designed for accurate and repeatable injection of both gases and liquids into various instruments, especially those used in gas chromatography (GC) and other analytical techniques

Truth gas tight syringes are ideal for dispensing both liquids and gases. They have a precision-machined PTFE plunger tip which creates a leak-free seal. With the tight fit, the tip essentially wipes the interior of the syringe barrel free of sample. Barrels made of 3.3 expansion borosilicate glass. All syringes are precision within 1 per cent

Individual Calibration Certificate available on request.







Applications

- Manual gas-tight syringes are crucial for introducing samples into GC instruments for analysis.
- They are ideal for transferring liquids and gases in various laboratory settings where precise volume control is needed.
- These syringes are well-suited for handling volatile or gaseous samples that require a tight seal to prevent leakage or sample loss.
- Their resistance to chemical degradation makes them suitable for samples with complex matrices or those containing chlorinated solvents.

Top Syringe exports its products to over 40 countries worldwide and counting, keeping a single quality standard for local and export products.

The Manual Gas Tight syringe is manufactured 100 per cent in India by Top Syringe Mfg Co (P) Ltd. The company is fully committed to supporting its customers with their full product range, spares, and technical assistance.

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Blissfill – Calibrated Syringe Pipettes for repetitive laboratory dosing as per ISO 8655-9

With a dispensing range of 0.05ml - 10ml (50㎕ - 10,000㎕), the Self refilling syringe comes with an individual calibration certificate & has a dosing accuracy Tolerance of <0.4% of the Dose.

Blissfill is an automatic hand operated self-refilling pipette syringe designed for continuous repetitive dispensing at the laboratory. The inert liquid path ensures that there is no component contamination to the liquid and comes with a calibration certificate. The syringe with the integrated valve system proves to be an excellent solution for accurate delivery of repetitive fixed doses without any errors during use. The Comfortable Grip and ergonomic design ensure fatigue free working during serial precision dosing. The fast and reliable volume selection ensures highly accurate dosing. The robust construction makes it easily autoclavable. The Luer lock nozzle is made as per universal specs and ensures fitment of any laboratory needle (reusable or disposable). The Syringe comes with a 1 year warranty for manufacturing defects. The Liquid path consist of Borosilicate Glass, SS 304, Ni-Cr Plated Brass, FPM, PTFE & Silicone.

Liquid Path

Parts in Contact with Liquid	Material
Feed Tubing	Silicone
Glass Barrel	Borosilicate Glass
Washer, Barrel	FPM
Plunger	Stainless Steel
Valve System	Ni-Cr Plated Brass
Washer, Valve	PTFE
Spring & Ball Valve	Stainless Steel
Vent & Feed Cannula	Ni-Cr Plated Brass

Viscosity Data

Variable Model ml	Maximal Cinematic Viscosity * (CST)	Example of Liquids
0.3	1800	SAE 50 Oil
0.5	2500	Fluid Honey
1	1200	Silicone Oil
2	400(up to 600)[1)]	Glycerol
5	150 (up to 200)[1)]	SAE 20 Oil
10	20	Cream

Precision (CV%)

Volume Range(ml)	Precision (CV%)	
	Min. Vol	Max. Vol
0.1 - 0.5	<1,2%	<0,4%
0.1-1.0	<0,7%	<0,4%
0.3-2.0	<0,6	<0,4%
0.5-5.0	<0,5%	<0,2%
1.0-10.0	<0,5%	<0,2%

Features :

- As per ISO 8655-9
- Autoclavable at 121°C for 20 Minutes
- Dosing Accuracy : Tolerance <0.4% of Dose
- Silicone, Borosilicate Glass, FPM, Stainless Steel, Nickel Chrome Plated Brass
- No 'O' Ring Or Lubrication Needed During Use
- Plunger Tightness without O ring – hence no contamination when it comes in contact with drug/liquid. The smooth

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plunger travel and tightness is achieved through the high-precision stainless steel plunger and grounded glass barrel. No O-ring to mess with or replace ever

● Simple and natural movements: The activation of the Blissfill Self Refilling Syringe is performed with limited effort for efficient work even during long dispensing series. This ensures complete user comfort

● Fast and reliable volume selection: Volume is set within seconds. It will not vary while activating the syringe, thanks to the safety locking nut on the micro metric screw. Dose-by-dose reproducibility is excellent

● Glass Barrel & SS plunger – Insert ensures long life.

● Clear visibility of Dose & Fully Autoclavable. Sterilization possible while fully assembled in boiling water or in autoclave at 1210C (2500F).

● No need of servicing with Silicon Oil – same effortless movement is ensured every time.

● Liquid path 100% inert,

● Long Lasting & Low maintenance: The Blissfill Syringes are made of only 6 main parts, which are easy to disassemble & reassemble. The fast access to all elements allows rapid & efficient cleaning. Spare parts are available at reasonable cost

● Light weight & easy to use

● Fast & Reliable volume selection

● Packed individually in a convenient attractive box along with instruction manual.

● Calibration Certificate provided with each syringe.

● High quality construction: All components are made of superior quality raw material which are thoroughly checked by our qualified QC department prior to production. Each component is made from Superior Quality material including glass, plastics, metals etc. These are thoroughly checked during each stage of manufacturing for quality & specification

● Economical & Low replacement cost: Only the glass part will have to be changed instead of buying a new device. Truly an unbeatable Price to Quality Ratio Product

● Glass Protection: Interchangeable glass barrel is protected by a PVC sleeve (not autoclavable) to prevent breakage.

Dispensing ranges

Size	Graduation	Range
0.5 ml	0.05 ml	0.05ml (50µl) - 0.5 ml (500µl)
1 ml	0.05 ml	0.1 ml (100µl) - 1.0 ml (1000µl)
2 ml	0.1 ml	0.3 ml (300µl) - 2.0 ml (2000µl)
5 ml	0.25 ml	0.5 ml (500µl) - 5 ml (5000µl)
10 ml	1.00 ml	1.0 ml (1000µl) - 10 ml (10,000µl)

The Blissfill Syringes come in 2 styles

1. Feed Tube Set
2. Bottle Mounted set,60ml PP Reservoir

Blissfill Feed Tube Tube Set

● This Product is for use with Feed Tube. This model comes with accessories that facilities repetitive dosing from bottles or jars using feed tubes, sinker valve, feed cannula etc. The sinker valve ensures it reaches and stays at the bottom of the jar during the time of usage. This would ensure that the entire liquid in the jar would be used making it highly effective.

● The model is compatible for use with aqueous, oily, viscous or heavy iron solutions as well as a variety of suspensions using special viscous spring. The long life and durability of the product makes it the most economical model available. Reusable needles included in select models.

Blissfill Bottle Mounted Set,60ml PP Reservoir

The Bottle Mounted Self-Re?lling syringe is another liquid feeding model consisting of a detachable threaded Bottle container with air tight lid. Large open mouth of the container ensures easy repeat ?lling of liquid without any wastage of time. The dribble valve inside the container allows smooth ?ow of liquid to the injector without any error.





Blissfill Vial Holder vial

The Blissfill Vial Holder Set is another liquid feeding model. Consisting of a vial holder, integrated vented needle, locking ring and bottle lock, this 'Vial Holder' model is used to draw liquid out of the original liquid manufacturer's vial. The Vial Holder body is at an optimal angle. The locking ring on the vial ensure the vial dose not get dis engaged from the Vial Holder body. The integrated vented needle ensure smooth operation of the dosing. The detachable slant Vial Holder Body fits standard vials. The safety locking nut ensure reliable and highly accurate repetitive prefixed dose dispensing

Applications Include:

● Reagent Distribution

● Hot Agar

● Sterile Work

● Filling of Well Plates

● HPLC Vial Preparation

● Small Batch Injection Vilas

● Distribution of Sterile Hot Agar

● Distribution of Cell Culture Media

Top Syringe exports its products to over 40 countries worldwide and counting, keeping a single quality standard for local and export products.



The Blissfill syringe is manufactured 100% in India by Top Syringe Mfg Co (P) Ltd. We are fully committed to supporting you with our full product range, spares, and technical assistance.

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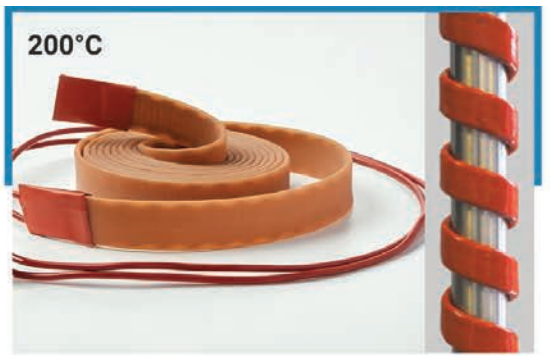
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Flexotherm heating tapes & Cords

Tempo's Flexotherm™ heating tapes and cords provide a safe, flexible, and efficient solution for maintaining solvent temperature across a wide range of industrial processes.









Typical applications of heating tapes and cords in industrial solvent handling

Handling and processing solvents in industrial environments requires precise temperature management. Many solvents are sensitive to fluctuations—too cold, and they may thicken or crystallize; too hot, and they may degrade or evaporate. Tempo's Flexotherm™ heating tapes and cords provide a safe, flexible, and efficient solution for maintaining solvent temperature across a wide range of industrial processes.

Why Tempo heating tapes and cords?

Unlike bulky heating systems, Tempo heating cords and tapes are thin, robust, and easy to wrap around drums, pipes, valves, or vessels. They deliver uniform heating, reduce the risk of cold spots, and can be paired with Tempo's digital or thermostatic controllers for precise monitoring and safe operation.

Typical applications in solvent handling

1. Drum and container heating
Solvents stored in poly or metal drums can become viscous at low temperatures. Tempo drum heating jackets and tapes keep contents at the right viscosity for safe pumping, mixing, or decanting.

2. Pipeline and transfer line heat tracing
Solvent transfer lines are prone to cooling and blockages. Flexotherm™ heat tracing cords maintain consistent flow and prevent condensation or freezing.

3. Valve and flange heating
Critical fittings often act as cold spots. Tempo heating tapes eliminate these risks, ensuring solvents move smoothly through the system.

4. Reactor and vessel heating
In chemical processing, Tempo customized heating solutions wrap neatly around reactors, tanks, or vessels to deliver controlled, uniform heating.

5. Laboratory solvent applications
From Soxhlet extractors to heating mantles, Tempo lab heating products support safe solvent extraction, distillation, and analysis.

6. Gas cylinder warming
For solvent-related gases such as SF6, propane, or nitrogen, Tempo cylinder warmers improve pressure stability and minimize losses due to condensation.

Advantages with Tempo Solutions

- **Viscosity control:** Prevents thickening, crystallization, or freezing of solvents.
- **Energy efficiency:** Localized heating ensures minimal energy loss.
- **Safety:** Avoids leaks and blockages from cold solvent lines.
- **Flexibility:** Easy to install on pipelines, drums, reactors, or valves.



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Virosil Pharma: A revolutionary, eco-friendly fumigant

Virosil Pharma has proved to be effective in controlling aerial bacteria and fungus present in sterile rooms. The area becomes completely sterile within 60 minutes of spraying without causing any irritation to the eyes, nose and skin - unlike conventionally used formulations

ABSTRACT

In the past years, the pharma and healthcare industry has witnessed tremendous growth and there have been tie-ups with a number of multinationals for production and R&D facilities to be nurtured in India. Organisations are applying for ISO standards and upgrading themselves to the latest norms related to health and hygiene.

Microbial contamination and pollution play a significant role in the pharmaceutical industries. Control of microbes has always been the biggest challenge to these industries. A load of microbes are present in areas such as production, storage/packaging, R&D, Q.A/Q.C., filling etc. They are present everywhere in the air, surface, water, instruments, linens etc.

Hence the disinfectant used should be so precise that it should not only take care of the microbial contamination but also be user and eco-friendly. Virosil Pharma meets all the required standards for the pharmaceutical industry.

ABOUT US

Sanosil Biotech, a Mumbai-based company, has launched a range of multipurpose disinfectants which are eco-friendly, chlorine-free and completely biodegradable and have applications in the pharma and healthcare industry as well as in the food processing industry. It is manufactured in India in technical collaboration with SANOSIL AG of Switzerland. SANOSIL AG in Switzerland is the patent holder and has joint venture agreements in more than 15 countries such as France, Italy, Spain, Holland, Norway, South Africa, Australia, Saudi Arabia, Oman, the UAE, etc. The product is being used in various countries by reputed institutions and has been thoroughly tested under strict regulations imposed by European Health bodies.

PRODUCT DISCRIPTION

Virosil Pharma is a multicomponent fumigant and disinfectant. The oxidizing agent used is hydrogen peroxide, which is bonded with stabilizing agents to form a complex solution. A long-lasting effect is ensured by the addition of silver, which acts as a catalyst in trace amounts. The bactericidal effect of silver is based on the fact that the monovalent silver ion Ag+ binds very firmly to bacterial proteins by a covalent or co-ordinate bond, and thus inactivates or precipitates these.

◆ Its effectiveness against bacteria, viruses, amoebae, fungi and algae; i.e. its extremely wide range of application makes it easy to handle for the end user; i.e. only one product is needed, where so far 2, 3 or various products were necessary.

◆ Owing to the good stability of the product, a long storage time can be guaranteed. As the product remains stable at high water/air temperatures, and as its effectiveness is even increased at high temperatures.

◆ Due to its long-term effectiveness and pronounced characteristics to prevent recontamination, this product is perfectly suited for disinfection of drinking water and wells.

◆ Virosil Pharma is ecologically harmless. Its principal constituent - hydrogen peroxide - does not pollute waste water, because it breaks down into water and oxygen (H2O and O2), i.e. it produces no noxious by-products.

◆ The two basic substances (H2O2 and Ag) enhance their advantages (*synergism). The bactericidal effect comes into action quicker and more intensively than if either substance was used on its own.



ADVANTAGES

Eco- friendly - It is totally biodegradable since (H2O2) breaks down into water & oxygen
Chlorine free
Non-toxic (no irritation to skin or eyes
No effect on pH
Non carcinogenic and non mutagenic
Excellently rinseable with no remains

PROPERTIES

Can easily be dosed
Does not foam
Decomposes into water and oxygen
It is excellently rinseable with no remains
Treats any other material with consideration

USFDA DRAFT GUIDELINES

Clean Area Classification	Microbial limit Cfu / 10 cu.ft.	Microbial limit Cfu / 10 cu.m.
100	< 1a	< 3a
1000	< 2	< 7
10,000	< 5	< 18
100,000	<25	<88

a = samples from class 100 environments should normally yield no microbiological contaminants

WHO 2002 MICROBIAL LIMITS

Grade	Max. no. of microorganisms permitted / m3
A	Less than 1
B	5
C	100
D	500

EU GMP 2002

Grade	Air sample cfu / cu.m.	Settle plates (90mm) cfu / 4 hours	Contact plate 55mm cfu / plate	Glove print Cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

Fumigation with Virosil Pharma, the perfect Salternative to Formalin

Fumigation is one of the most

important factors associated with pharma industries, it plays a vital role in maintaining the sterility of areas and is directly related to production.

Sanosil Biotech is the first company to pioneer the novel concept of eco-friendly fumigation. The company has great respect for human health and the environment. The CEO, Dev Gupta, an MBA from the Bentley Graduate School of Business, Boston, has been actively marketing the brand nationally. According to Gupta, "Virosil Pharma has simplified the lives of so many people who work in the pharmaceutical industry as they are guaranteed sterility with the minimum risk exposure". As there was a high risk to the staff involved in the use of Formaldehyde/Glutraldehyde for sterilization and disinfection.

Owing to the stringent integrated micro contamination control and biosafety requirements, it is desirable to have micro-contamination control procedures and methods that could be monitored, evaluated and assessed periodically, which are convenient, cost-effective and safe.

A glimpse at the standards put down by various would monitoring agencies would help an individual or an organization help decide on choosing the most appropriate control procedure/methods. The important microbial limits which have been prescribed by various agencies is as follows:

To meet those requirements aerial disinfection (fumigation) with formaldehyde was the most convenient method. With the regulatory having restricted the use of formaldehyde and also putting into place the monitoring levels of formaldehyde after fumigation makes it a procedure with its own limitations.

Formaldehyde is a known carcinogen (IARC & NTP). Formalin is toxic by inhalation, toxic if swallowed, may be fatal if swallowed, causes eye burns, may cause blindness, strong sensitizer, causes irritation to skin, eyes, and respiratory tract. Repeated or prolonged exposure increases the cancer risk.

COMPARISON	
VIROSIL PHARMA	**FORMALIN**
Eco-friendly, Non-toxic	Highly toxic
Room gets sterilized within 1 hour after fumigation	Requires overnight fumigation
Requires no de-fumigation	Requires de-fumigation
Person can be present during fumigation	Causes skin, eye irritation even after next day of fumigation
Time Saving	Time consuming
Multiple Applications	Application restricted

Virosil Pharma has been a direct alternative to Formalin Fumigation. Virosil Pharma has proved to be effective in controlling aerial bacteria and fungus present in sterile rooms. The area becomes completely sterile within 60 minutes of spraying without causing any irritation to the eyes, nose and skin - unlike conventionally used formulations. Virosil Pharma can even be successfully used in AHU which are responsible for optimal and steady air exchange in production facility, of which the ducts, air shafts, humidificator, filters, etc. are often contaminated with loads of bacterial and bio-films.

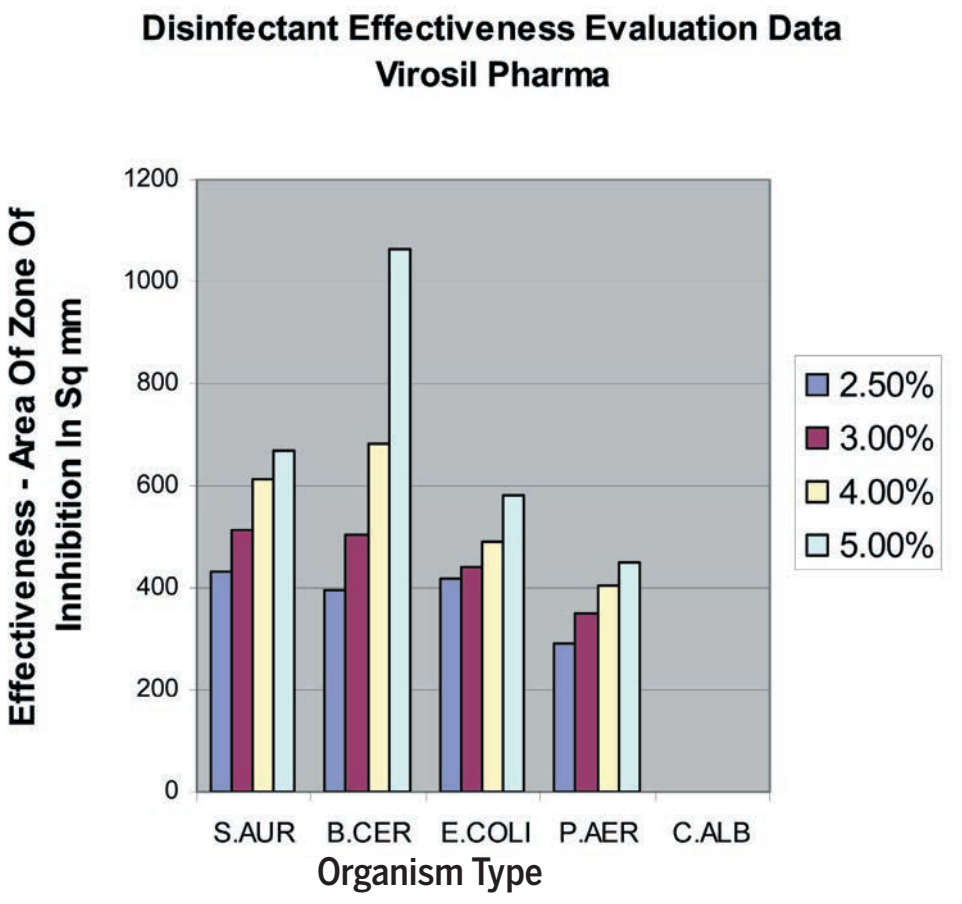
The main aim of Virosil Pharma is to increase productivity by cutting down disinfection time while at the same time providing a totally microbe-free environment.

Virosil Pharma is also very effective in disinfection of all critical surfaces that come in contact with pharma products. There is no requirement to re-wash equipment and surfaces disinfected with Virosil Pharma since it is H2O2 based and decomposes into water and oxygen.

Virosil Pharma has been tested by several reputed and renowned institutions in India with respect to its disinfection and fumigation applications in Pharmaceutical Industry

Because of all these factors, Virosil Pharma has attained maximum satisfaction of the customers in controlling the microbial contamination in their respective applications. The introduction of an eco-friendly, non-carcinogenic and totally biodegradable versatile product, like Virosil Pharma, has not only brought an end to the era of conventional biocides but has completely solved the disinfection requirements which these healthcare industries were prone to.

A GRAPHICAL VIEW ON DISINFECTANT EVALUATION DATA - VIROSIL PHARMA



	S.AUR	B.CER	E.COLI	P.AER	C.ALB
2.50%	429.83	397.4	418.15	289.38	0
3.00%	514.44	502.4	440.92	349.48	0
4.00%	615.44	683.14	490.625	404.5	0
5.00%	669.32	1063.07	580.77	452.16	0

Targets

Sanosil Biotech is marketing this disinfectant under the 'Virosil Pharma' brand name and is targeting the entire industrial belt of India. The company has already set up a distribution and infrastructure network having establishments in Maharashtra, M.P., Hyderabad, Chennai and Delhi.

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Testo offers measurement solutions for environmental monitoring in pharma facilities

The testo 400 and testo 440 instruments support air flow measurement, indoor air quality monitoring and HVAC assessments, while Testo's NABL-accredited Pune laboratory provides local service and calibration support

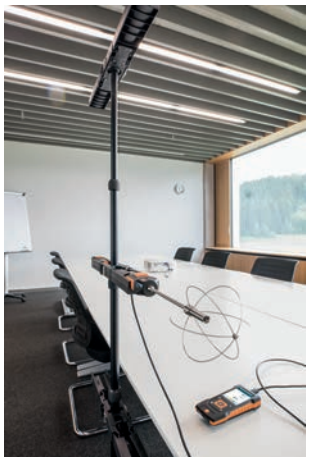
Maintaining accurate environmental conditions is essential in pharmaceutical facilities where air quality, comfort parameters, and process reliability play a critical role. Testo's advanced measurement solutions - testo 400 and testo 440 provide reliable, efficient, and standard-compliant measurement of air flow and indoor air quality parameters.

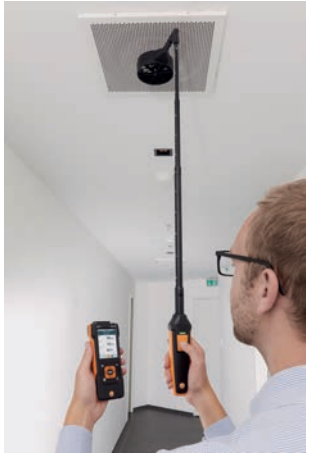


The testo 400 universal IAQ measuring instrument is designed for a wide range of air flow and comfort measurements. With smart technology, intuitive measurement assistants, and an extensive range of digital probes, it enables precise measurement of parameters such as air velocity, temperature, humidity, CO2, and other IAQ values.











Its guided measurement menus simplify complex applications, while the integrated evaluation system helps users achieve accurate and consistent results. The instrument also supports seamless documentation, allowing measurement reports to be prepared and shared directly on-site, improving efficiency and traceability.

The testo 440 climate measuring instrument combines versatility with user-friendly operation and wireless probe technology. It enables convenient measurement of air velocity, temperature, humidity, CO2, turbulence, and other environmental parameters. With pre-configured measurement functions and flexible probe options, testo 440 supports accurate assessments across various controlled environments.

Together, testo 400 and testo 440 deliver precision, flexibility, and digital convenience, helping pharmaceutical professionals ensure reliable environmental monitoring and maintain the highest standards of quality and compliance.

Supporting pharmaceutical excellence through smarter measurement technology

Maintaining controlled environmental conditions is fundamental to pharmaceutical manufacturing. Accurate HVAC measurements support cleanroom performance, energy efficiency, employee comfort, and compliance with industry standards.

With the testo 400 and testo 440 measurement solutions, Testo provides pharmaceutical professionals with reliable tools for ventilation assessment, indoor air quality monitoring, HVAC commissioning, and qualification processes.

By combining intelligent technology, extensive probe compatibility, guided measurement workflows, and digital documentation capabilities, Testo continues to help industries achieve greater measurement confidence and operational efficiency in critical environments.

Service & Calibration made easy

Testo also has an established state-of-the-art NABL accredited service & calibration LAB in accordance with the standard ISO/IEC 17025:2017, that takes care of the after sales support locally from Pune. Testo service & calibration facility is highly cost effective as it delivers international standards very conveniently within a week's time. Instruments of any brand/make can be calibrated and serviced locally maintaining necessary standards.

The accredited parameters include Humidity, Pressure, Absolute Pressure, Contact Type Temperature, Non-Contact Type Temperature (Infra-Red Thermometer, Thermal Imager). In fact, ours is the First and Only Lab in India to get NABL Accreditation for Dew Point Temperature as well.

For more details, login to our website www.testo.com or write back to us on info@testo.in

Stevanato Group

Shimadzu Total Solutions for pharmaceutical impurities

Dheeraj Handique, Sr Manager - Sales & Marketing, Shimadzu India outlines the solutions and technologies that offer an integrated analytical approach to genotoxic impurities, nitrosamines, NDSRIs, residual solvents, and extractables and leachables

Pharmaceutical impurity control is essential for ensuring drug quality, patient safety and regulatory compliance. Impurities may originate from raw materials, synthetic processes, catalysts, solvents, degradation reactions, manufacturing equipment and packaging materials. Their analysis becomes particularly challenging when concentrations are extremely low, sample matrices are complex, or stringent reporting limits apply.

Genotoxic impurities (GTIs), nitrosamines, nitrosamine drug substance-related impurities (NDSRIs), residual solvents, extractables and leachables (E&L), and elemental impurities require complementary analytical technologies.

Shimadzu offers an integrated portfolio of GC-MS/MS, automated headspace sampling, LC-MS/MS and ICP-MS systems to support pharmaceutical laboratories from method development and impurity screening to targeted quantification and quality control.

1. Genotoxic impurities: Sensitive and selective analysis

Genotoxic impurities are substances that may damage genetic material and potentially increase carcinogenic risk. They can originate from starting materials, reagents, intermediates, side reactions or degradation pathways during pharmaceutical manufacturing.

The ICH M7(R2) guideline provides a framework for assessing and controlling DNA-reactive mutagenic impurities. Analytical methods must be appropriate for the compound-specific acceptable intake, maximum daily dose and product risk assessment.

The Shimadzu GCMS-TQ8050 RX is suitable for targeted analysis of volatile and semivolatile GTIs compatible with GC. Triple-quadrupole technology using multiple reaction monitoring (MRM) supports selective quantification in complex pharmaceutical matrices.

Applications include suitable alkylating agents, reactive process impurities and volatile organic contaminants. For polar, non-volatile or thermally labile GTIs, LC-MS/MS provides a complementary analytical approach.

2. Nitrosamines and NDSRIs: Addressing critical quality challenges

Nitrosamines have become a major concern in pharmaceutical manufacturing because certain compounds in this class have significant carcinogenic potential. Their presence may be associated with nitrite contamination, amine-containing materials, process conditions, recovered solvents or interactions between formulation components.



Small-molecule nitrosamines, such as NDMA and NDEA, and NDSRIs require carefully selected analytical methods based on their volatility, structure, stability and matrix characteristics.

GC-MS/MS for volatile nitrosamines

The GCMS-TQ8050 RX supports selective quantification of suitable volatile nitrosamines through MRM-based detection. Retention times, reference standards and characteristic transitions contribute to reliable identification and quantitative analysis.

LC-MS/MS for NDSRIs

Many NDSRIs are less volatile or more thermally sensitive than small-molecule nitrosamines. LC-MS/MS is therefore often an appropriate starting point for their quantification.

The LCMS-8060 RX supports sensitive, targeted analysis using MRM. It can also be applied to suitable non-volatile nitrosamines, polar GTIs and other trace-level pharmaceutical impurities.



LCMS-8060 RX — Targeted trace analysis

High-resolution LC-MS can complement targeted triple-quadrupole analysis when investigating unexpected compounds or confirming molecular composition.



GCMS-TQ8050 RX — GC-MS/MS analysis

Headspace Trap–GC-MS/MS for volatile impurities

Headspace sampling reduces direct introduction of non-volatile sample components into the GC system. When combined with a trapping step, suitable volatile analytes can be concentrated before separation, potentially improving analytical response.

The method must be evaluated for recovery, trapping efficiency, breakthrough, carryover and thermal stability. Headspace Trap is a complementary option rather than a universal solution for every nitrosamine.

3. Residual solvents: Automated headspace analysis

Residual solvents are volatile organic chemicals used or generated during the manufacture of APIs, excipients and finished drug products. Their levels must comply with applicable pharmacopeial requirements and product specifications.

USP General Chapter ⟨467⟩ provides a framework for residual solvent testing.

This integrated configuration combines gas chromatographic separation with automated headspace sample introduction. Volatile solvents partition into the gas phase before injection, helping minimise the introduction of non-volatile matrix components.

Applications include residual solvent testing in APIs and finished products, monitoring solvent removal during drying, stability investigations and pharmaceutical process troubleshooting.

GC-FID is commonly used for routine residual solvent testing,

Stevanato Group

while GC-MS provides additional identification capabilities. GC-MS/MS may be useful when greater selectivity is required, and Headspace Trap can be evaluated for suitable applications requiring enhanced analyte concentration.

The final method should demonstrate appropriate specificity, sensitivity, precision and accuracy for its intended purpose.

4. Extractables and leachables: Protecting product quality

Extractables are substances released from materials under defined extraction conditions, while leachables migrate into pharmaceutical products during manufacturing, storage or use.

Potential sources include plastic containers, elastomers, rubber stoppers, tubing, filters, seals, adhesives, lubricants and coatings. E&L investigations may require the analysis of both organic compounds and inorganic elements.

GC-MS/MS: Suitable for volatile and semivolatile extractables, including selected residual monomers, plastic additives, solvents and degradation products. Headspace and thermal desorption approaches can support volatile-compound screening.

LC-MS/MS: Suitable for selected non-volatile, polar and thermally labile organic leachables. High-resolution LC-MS can complement targeted testing when investigating unexpected compounds.

ICP-MS: Supports the investigation of relevant inorganic elements released from packaging and product-contact materials.

USP General Chapters ⟨1663⟩ and ⟨1664⟩ provide frameworks for extractables and leachables assessments. Study design should consider material composition, extraction conditions, analytical thresholds and potential patient exposure.



Nexis GC-2060 with HS-20 NX — Automated volatile analysis

5. Elemental impurities: ICP-MS for trace-level analysis

Elemental impurities may enter pharmaceutical products through catalysts, raw materials, excipients, process equipment, water systems and packaging. Their control is important when exposure to particular elements may pose a toxicological risk.

The Shimadzu ICPMS-2040 supports trace-level analysis of relevant elements in pharmaceutical materials following appropriate sample preparation.

Applications include residual catalyst monitoring, elemental impurity testing in APIs and finished products, and investigation of inorganic contaminants from packaging and manufacturing equipment.

ICH Q3D provides a risk-based framework for elemental impurities, including permitted daily exposure concepts. Analytical procedures must address sample digestion, matrix effects, spectral interferences and applicable reporting limits.

ICP-MS complements GC-MS/MS and LC-MS/MS by addressing inorganic contaminants that organic mass spectrometry methods are not designed to measure.

Impurity category	Recommended analytical platform
Suitable volatile and semivolatile GTIs	GC-MS/MS
Suitable volatile nitrosamines	GC-MS/MS; Headspace Trap–GC-MS/MS where appropriate
NDSRIs and suitable non-volatile nitrosamines	LC-MS/MS
Residual solvents	Headspace GC-FID or GC-MS
Volatile and semivolatile organic E&L	GC-MS/MS, GC-MS or suitable thermal desorption methods
Non-volatile organic E&L	LC-MS/MS
Elemental impurities and inorganic E&L	ICP-MS



ICPMS-2040 — Multi-element analysis

6. An integrated analytical workflow

Shimadzu's total solutions approach combines complementary technologies to address diverse pharmaceutical impurity challenges.

An effective workflow begins with risk assessment and analyte identification, followed by method selection, sample preparation, analysis, confirmation and quantitative evaluation.

Methods should be validated or otherwise qualified according to their intended use, considering specificity, sensitivity, accuracy, precision, recovery, matrix effects and robustness. Appropriate data processing, review and record-management procedures are also essential.

Conclusion

Pharmaceutical impurity analysis demands complementary technologies capable of addressing volatile, non-volatile, organic and inorganic contaminants.

The Shimadzu GCMS-TQ8050 RX, Nexis GC-2060 with HS-20 NX, LCMS-8060 RX and ICPMS-2040 provide a coordinated analytical portfolio for investigating genotoxic impurities, nitrosamines, NDSRIs, residual solvents, extractables and leachables, and elemental impurities.

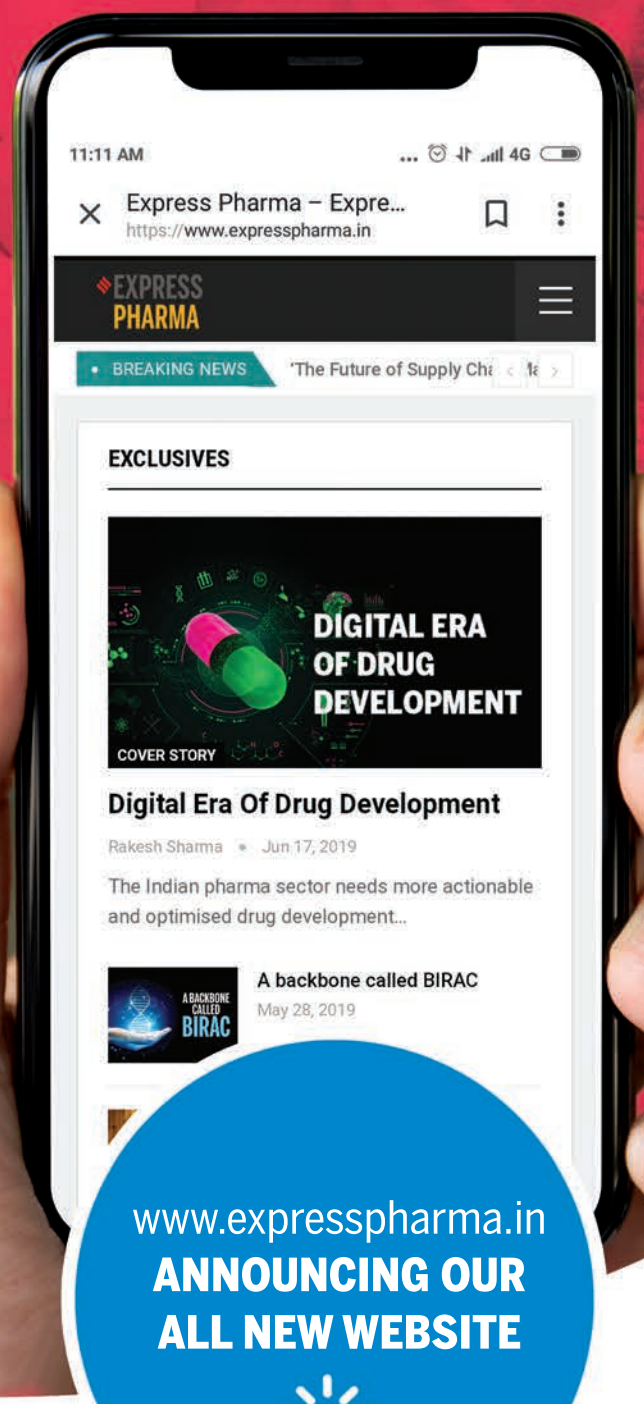
By integrating these platforms with suitable sample preparation, method development and regulatory risk assessment, pharmaceutical laboratories can strengthen impurity identification, improve quantitative confidence and support consistent product quality.

Shimadzu Total Solutions for Pharmaceutical Impurities brings together advanced instrumentation and complementary analytical workflows to support pharmaceutical development, manufacturing, quality control and patient safety.

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Automed systems: Engineering value through pharma automation

The Bengaluru-based company outlines its approach to pharma engineering, process automation, equipment intelligence and customer partnerships, guided by its philosophy, Knowledge Solves

Engineering the Future of Pharma with Value-driven Automation

Pharmaceutical manufacturing is evolving rapidly, driven by increasing regulatory expectations, the growing complexity of potent compounds, the need for operator safety and the demand for greater operational efficiency.

In this changing environment, equipment manufacturers must go beyond supplying machinery to become engineering partners who understand processes and deliver long-term value.

Automed Systems Pvt Ltd, based in Bengaluru, India, brings over 25 years of pharmaceutical engineering experience, delivering customised equipment and automation solutions to the pharmaceutical, biotechnology, food and chemical industries. Guided by its philosophy, Knowledge Solves, Automed combines process understanding, engineering expertise and responsive customer engagement to address complex manufacturing challenges.

Engineering solutions across the pharmaceutical process

Automed's portfolio spans three key areas:

- **High containment/Aseptic & Operator Safety:** OEB 4/OEB 5 isolators, sampling and dispensing isolators, flexible isolators, glove boxes, VHP-based decontamination solutions and glove integrity testing systems designed around product containment and operator protection.
- **Powder Processing & Material Transfer:** Pneumatic Transfer Systems , Tubular drag conveyors, powder conveying systems, blenders, sifters, milling and granulation enclosures, and specialised material handling and lifting solutions.
- **GMP Washer & Process Automation:** GMP washing systems for bins, canisters and glassware, automated material handling, robotic-assisted lifting and positioning systems, and customised special-purpose pharmaceutical equipment.

From automation to equipment intelligence

The next evolution in pharmaceutical manufacturing is not simply about automating processes, but making equipment more connected, measurable and intelligent.

Automed is advancing this direction through its focus on industrial IoT, equipment intelligence and predictive maintenance. By monitoring relevant operating parameters, manufacturers can gain better visibility into equipment health and performance.

Its developing predictive maintenance models focus on applications such as filter loading, blower performance, equipment utilisation, glove integrity and asset health. The objective is to identify early warning signs, support condition-based maintenance, reduce unplanned downtime and improve equipment availability.

Automed is also developing digital capabilities around secure equipment connectivity, data acquisition and cloud-based analytics, with a vision of connecting equipment operating data, maintenance history and technical documentation within a common digital ecosystem.

Value-driven engineering. Knowledge-led partnership.

At Automed, engineering value extends beyond the initial equipment investment. Every project begins with understanding the customer's process, operational challen-ges and regulatory requirements. Through value engineering, customised design and process-oriented recommendations, the company aims to deliver solutions that balance performance, reliability, maintainability and lifecycle costs.

The customer relationship also extends beyond equipment delivery. From conceptual designs and preliminary layouts before procurement to manufacturing, installation, commissioning and after-sales support, Automed believes in being a knowledge partner throughout the equipment lifecycle.

Engineered for the future

As pharmaceutical manufacturing moves towards connected and intelligent operations, Automed is combining its established engineering capabilities with emerging digital technologies to create practical, reliable and value-driven solutions.

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