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Post event
Bengaluru Pharma Summit

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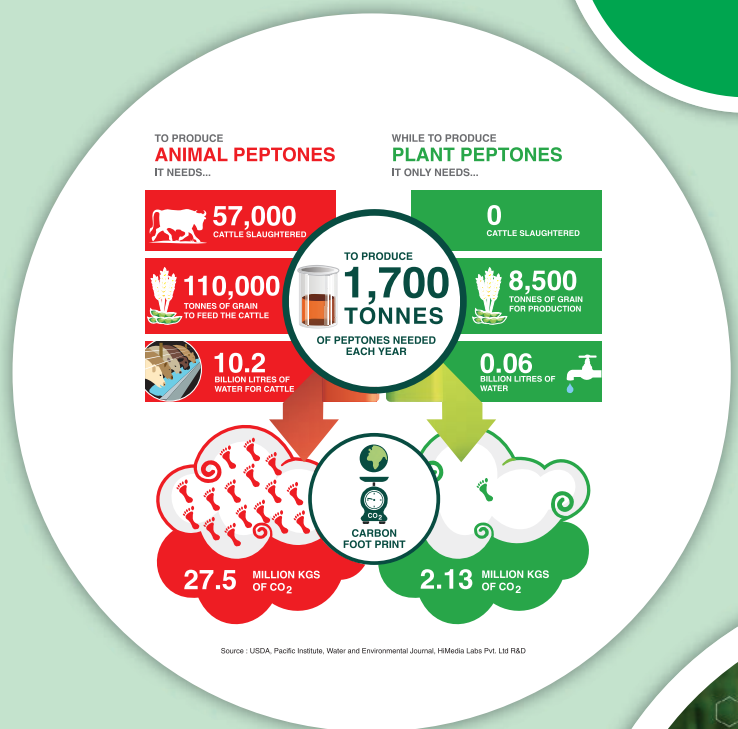

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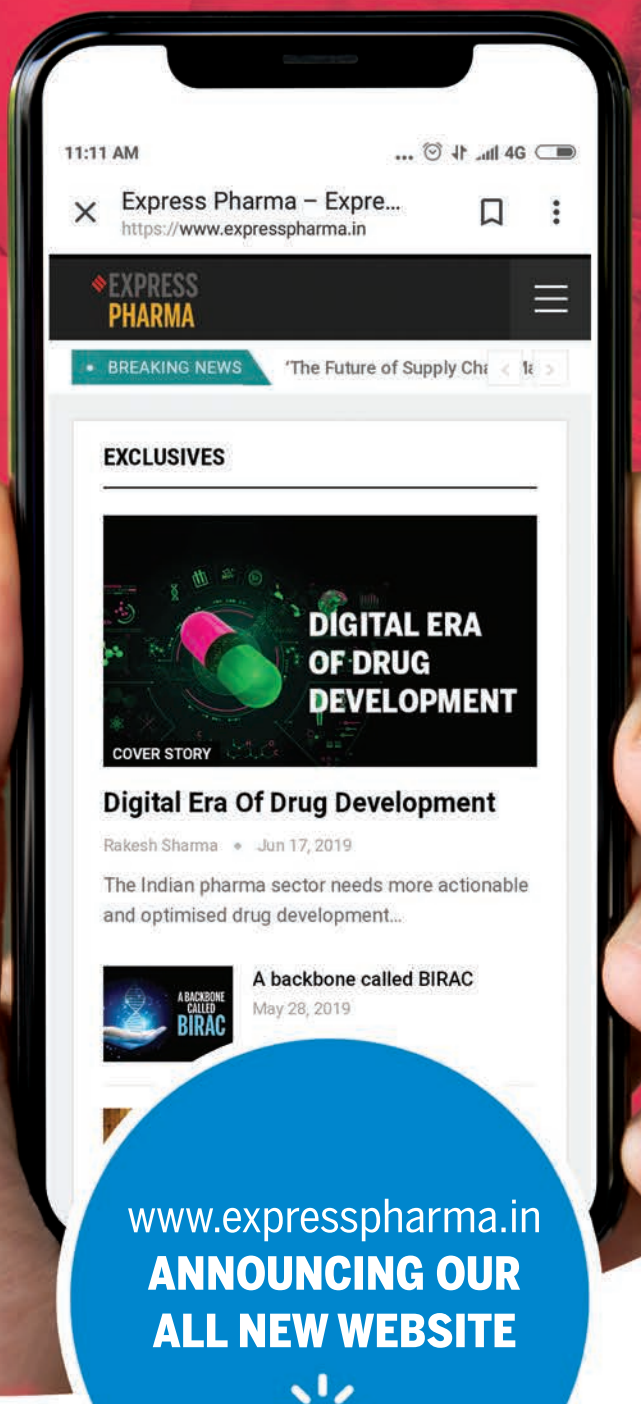

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Does India Pharma Inc need a new blueprint?

China's new five-year plan for its pharmaceutical sector, released on September 18, places innovation and globalisation at the centre of a major repositioning from scale to innovation-driven growth.

If this sounds similar to India Pharma Inc's stated volume to value transition, it is only to be expected, as both move from their generics moorings.

A few days later, on September 22, an open letter from nine European pharma companies, cautioned that "Europe (is) losing ground to global competition" as "over $600 billion in pharmaceutical investment has been announced in the US and China in the last two years alone." It makes the case that "European governments must create conditions that attract investment in next-generation medicines before it's too late."

Industry observers in India point out that what worries EU pharma leaders is a worry for India too. The question is, how will we respond? And will we respond fast enough?

China's move away from its traditional APIs and intermediates towards innovative medicines could in fact be a short term opportunity for India.

Commenting on this aspect of China's 15th five year plan Bharat Shah, MD, S Kant Healthcare and National President, IDMA pointed out that IDMA's members are MSMEs with strong technical skills, so moving into and competing in this API space is not difficult, but what they need is more regulatory support, low interest rates and faster approvals.

But Namit Joshi, Chairman, Pharmexcil went to the heart of the issue when he pointed out that China has state owned companies so when Indian pharma companies go up against their Chinese counterparts, they are actually competing with a country, not a company. Both Shah and Joshi were part of a panel discussion at the Peptides & Complex Generics Symposium 2026 (PCG 2026).

China is already on this path and the new plan is designed to accelerate this transition. Dr Mahesh Bhalgat, CEO and founder, AAPM Therapeutics and an independent consultant, terms it "a bold plan where China displays ambition to further significantly step up its innovation game." He also points out that the journey from being a leader in quantity (of pharma manufacturing) to a leader in quality (of pharma innovative assets) is already demonstrated by China having increased deal value considerably from single digit to $130+billion in 2025.

As per media reports quoting a Nomura research analysis, the plan lays out targets in 10 areas, including raising the average R&D expenditure-to-sales ratio, increasing the global market share of first-in-class and having more than five drugs with global annual sales exceeding $1 billion. These are framed as goals, without legal binding. The plan does not give details of how the companies are to achieve this nor an implementation path.

India Pharma Inc and policy makers must closely analyse the plan and modify India Pharma Inc's strategic blueprint because it would have crucial implications for India.

The open letter from nine EU pharma leaders and China's new five year pharma plan are the latest and clearest signals that the stakes are only getting higher

But China's government and regulators have traditionally supported the pharma industry with industry-friendly policies, geared towards growth. The plan does mention 20 pharma parks, which would no doubt help Chinese pharma companies meet these goals.

And where does India stand? The average R&D expenditure-to-sales ratio for most listed pharma companies in India is estimated to be below 10 per cent. The good news is that India is on the same path, with a clear push to move from volume to value.

In the near term, India's pharma sector seems to be weathering the current turbulence reasonably well. The latest Crisil Ratings report predicts that the pharma sector will see stronger dose of revenue growth at 11-13 per cent this fiscal, up from 8 per cent last fiscal, driven by accelerating exports and firmer domestic demand. The analysis is based on nearly 190 Crisil-rated pharma companies, accounting for about half of the sector's revenue last fiscal.

The caveat is that this growth spurt is unlikely to flow through fully to earnings, as inflation in raw material, energy and freight costs is expected to compress operating margins by 150-200 basis points (bps).

In tune with the experts in our cover story in this edition (Read story, Beyond US: New shores, new bets), India's exports now show a balance between regulated and semi-regulated markets, with approximately 57 per cent to the former, as per Crisil.

Also of significance is the fact that the sector's domestic and export revenues are almost equal. The strong domestic buffer will be crucial, as potential US tariffs on pharma exports still hang over the sector.

Zooming back to the open letter from nine EU pharma leaders and China's new five year pharma plan, these are the latest and clearest signals that the stakes are only getting higher.

Each country's healthcare leadership is lobbying their governments and regulators for more supportive policies, to double down on securing the sovereignty and sustainable future of its pharma and biopharma sector, so that they are positioned to best serve the medical needs of their patient populations.

India Pharma Inc too will need much more policy and regulatory support, with quality and pricing guardrails, to map a future path that is sustainable, plays to its strengths, and safeguards patients' lives in India and beyond.

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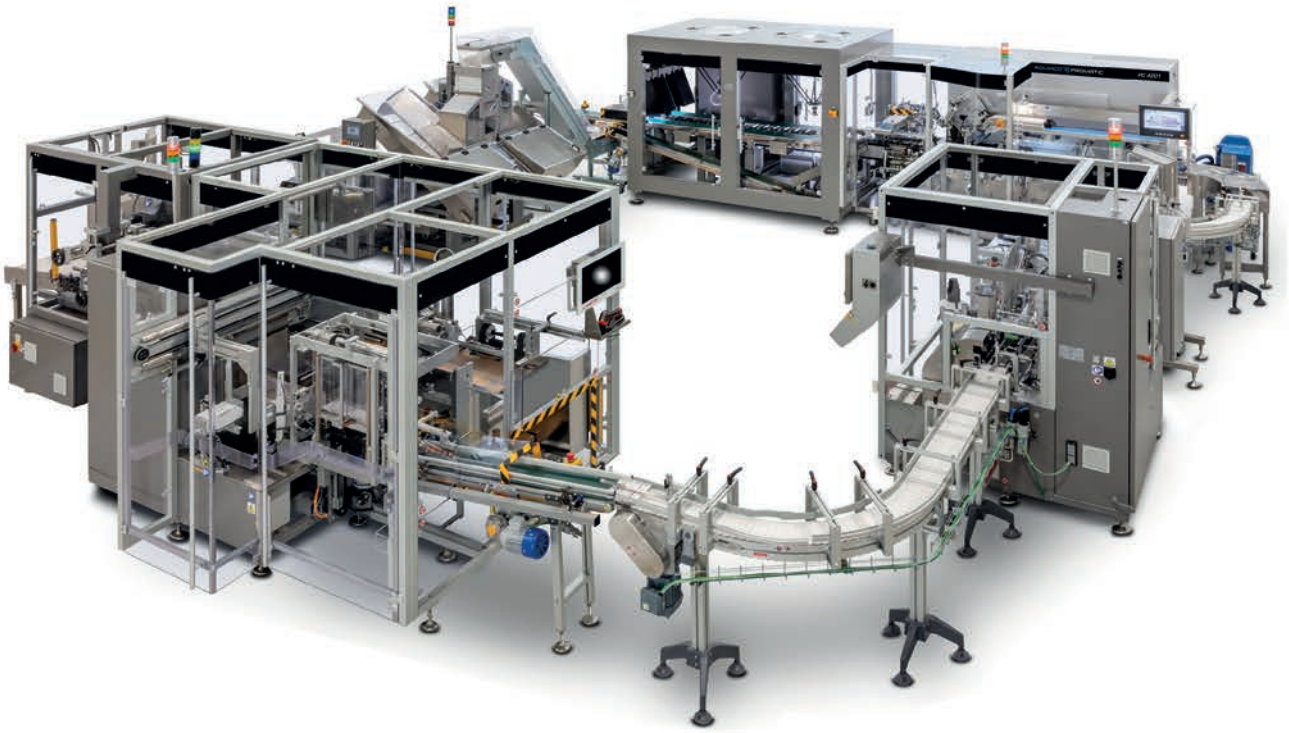

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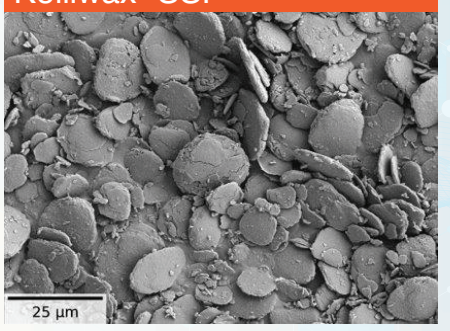

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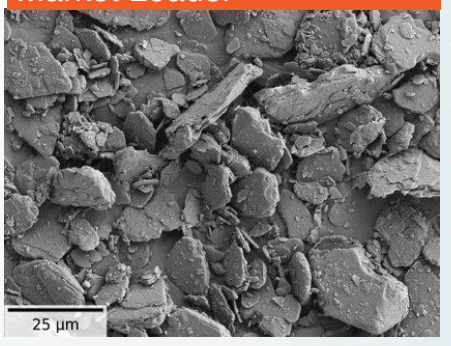

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Beyond cost what will shape India's pharma competitiveness?

Christoph Funke, Chief Technical Operations Officer, Lupin, explains why India's pharma industry needs to look beyond its cost advantage. He outlines how manufacturing intelligence, supply-chain resilience and stronger capabilities can help the industry compete in complex products and higher-value segments. In an exclusive interview with **Lakshmipriya Nair**

Lupin is moving towards a fully integrated, technology-enabled operations ecosystem. How is the integration of manufacturing, supply chain and procurement helping the company build greater agility and resilience in an increasingly volatile global environment?

The biggest change is that we no longer treat manufacturing, supply chain and procurement as separate functions. Under Global Technical Operations, we have brought Manufacturing, Supply Chain, Procurement, Engineering, Operational Excellence and EHS into one integrated operating model. This matters because some of the greatest opportunities to improve performance and efficiency lie at the interfaces between functions. By managing these interdependencies more effectively, we are able to improve throughput and resilience while making decisions across the value chain with a balanced focus on quality, service, compliance, cost and sustainability. This has helped us build a truly global operating model, allowing us to leverage capabilities, scale, best practices and insights across our network more effectively.

In today's environment, supply chain resilience starts with de-risking. This includes reducing dependency on single sources, strengthening supplier diversification, enhancing strategic sourcing and investing in backward integration where it creates long-term value. We view our suppliers of products and services as long-term partners

in value creation, and we invest in partnerships that enhance reliability, innovation and continuity across the supply chain.

Technology is the connective tissue that brings this model to life. Through digitalisation, automation and AI-enabled insights, we are improving visibility, accelerating decision-making and strengthening our ability to anticipate and respond to change. But technology creates value only when it improves outcomes for customers, patients and the business. Our focus is therefore not on technology for its own sake, but on applying it in ways that strengthen quality, service, resilience and performance.

Ultimately, resilience is engineered through the seamless integration of quality, technology, supply planning and people. This is how we strengthen throughput and ensure a dependable and uninterrupted flow of medicines to patients worldwide.

India has long competed on cost. From your experience across markets, is that advantage still enough? What will drive competitiveness over the next five years?

Affordability is fundamental to ensuring broad and equitable access to quality medicines. However, cost advantage alone is no longer sufficient to create sustainable differentiation. Across global markets, success is increasingly being defined not just by scale and cost efficiency, but by quality, reliability, scientific excellence, innovation, technology adoption and speed of execution.

In my opinion, four factors will shape the next phase of growth for the industry. First is patient centricity. Every decision across the value chain, from procurement and manufacturing to supply chain and quality, must ultimately be guided by patient needs. Organisations that can consistently ensure quality, reliability and uninterrupted access to medicines will be best positioned to build trust and create long-term value.

Second is quality. As we often say, compliance is the license to operate, but quality is what differentiates an organisation over time. Regulators, customers and patients expect consistent, world-class standards. Organisations that anticipate regulatory and industry trends, rather than simply follow them, will be better positioned to participate in more complex and higher-value segments.

Third is innovation. As the industry evolves, long-term competitive advantage will depend on our ability to develop innovative solutions for complex healthcare challenges. Simply replicating what already exists is unlikely to create lasting value. The future will belong to organisations that can combine scientific expertise, technology and deep customer understanding to deliver differentiated products, processes and solutions.

Fourth is capability. As digitalisation, automation and AI redefine manufacturing and supply chains, lasting advantage will depend not on technology alone, but on how effectively it is combined with scientific expertise, process excellence and skilled talent. Technology is a means to an end; the real measure is the impact created for customers and patients.

For years, India's cost competitiveness laid the foundation for its success as a global pharmaceutical manufacturing hub. The next phase of growth will be driven by our ability to deliver quality, innovation, reliability and advanced manufacturing at scale, particularly in complex generics, biologics, specialty medicines and emerging modalities.

The global pharma supply chain is being reshaped by geopolitics, China dependence and the push for local manufacturing. Where does this leave India?

Over the last two decades, India has built a strong reputation as a trusted supplier of high-quality medicines to patients around the world. At the same time, recent geopolitical developments have highlighted the importance of building greater resilience across supply networks, particularly for APIs and key starting materials. Today, there is a greater focus on reducing concentration risk and creating more diversified, reliable supply chains.

In this evolving landscape, India is well positioned to play a larger role. The country is already the world's third-largest pharmaceutical producer by volume, supplies nearly 50 per cent of all generic prescriptions dispensed in the United States, and is home to more than 750 US FDA-approved manufacturing facilities, the largest outside the United States. These strengths, combined with deep scientific talent, manufacturing scale

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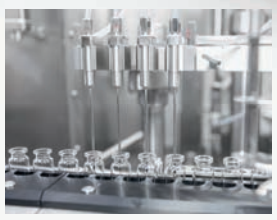

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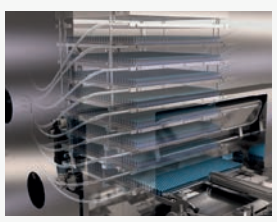

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Mr. Akshay Chikodi | akshay.chikodi@optima-packaging.com
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and regulatory expertise, make India a natural partner for companies looking to build more diversified and resilient supply networks.

As a trusted supplier to patients worldwide, the industry must continue to raise the bar on quality, reliability, compliance and supply continuity while investing in the capabilities needed to support future healthcare needs. If India continues to strengthen these foundations, it can elevate its position as a global manufacturing hub to a strategic partner in innovation, manufacturing and supply reliability for the global pharmaceutical industry.

Resilience comes at a cost. How should pharma companies decide how much resilience they really need without losing their cost advantage?

Resilience should be a calibrated capability, not a blanket strategy. The right approach is to understand where risks truly exist, assess their potential impact on patients and business continuity, and invest accordingly.

At Lupin, we use a risk-segmented lens. For high-volume, low-margin generics, cost efficiency remains the primary driver because patients depend on affordability. However, for critical therapies or products where we serve a large patient population and hold significant market share, the calculus changes. The higher the market share and the greater the potential impact on patients, the more deliberately we must focus on resilience. In such cases, the cost of a stockout or regulatory failure can far outweigh the cost of redundancy.

Data and technology allow us to build resilient supply networks in a targeted and efficient way. We use AI-driven risk modeling to map our supply chain end-to-end, identify genuine vulnerabilities and quantify actual exposure — investing in dual sourcing, safety stock or nearshoring only where risk justifies it, while optimising aggressively elsewhere.

The other lever is efficiency itself — automation, better yield management and leaner processes fund the resilience investments we need. The ultimate goal is to allocate resources where they can create the greatest impact, balancing affordability, supply reliability and patient needs in a disciplined and sustainable way.

Lupin and other Indian companies are moving into more complex products. What changes when you move from high-volume manufacturing to more complex, high-value manufacturing?

The model changes fundamentally. In traditional high-volume manufacturing, scale, standardisation and cost efficiency are the primary differentiators. In more complex products, success increasingly depends on scientific capability, deep process understanding, advanced technologies, manufacturing expertise and the ability to consistently meet stringent quality and regulatory standards.

Complex products also carry higher execution risk — longer development cycles, more demanding technology transfer, higher regulatory expectations, and manufacturing processes that require greater precision and control. This is why we're investing deliberately across complex generics, injectables, inhalation therapies, biosimilars, peptides and specialty products.

The shift to complex, high-value products is a shift from competing on efficiency alone to competing on capability. The organisations that succeed will be those that can consistently translate scientific innovation into high-quality, differentiated therapies for patients at scale.

Success therefore depends on the ability to connect science, quality, digital capability, manufacturing expertise and talent within one integrated operating system.

Technology, AI and automation are changing manufacturing. Where do you see the biggest opportunity to create real business value, rather than simply improve efficiency?

Technology, AI, and automation have traditionally been viewed from the lens of efficiency, but their greatest value lies in enabling better decisions, agility, and resilience across manufacturing operations.

One of the most significant opportunities is in creating more predictive and proactive operations. By combining AI, advanced analytics and real-time manufacturing data, organisations can anticipate potential issues before they occur, whether that is equipment reliability, process variability or supply risks. The value extends beyond cost savings to improving quality, reliability and speed of execution.

Another important area is end-to-end visibility across the value chain. Manufacturing does not operate in isolation, and the ability to connect demand signals, production planning, inventory, procurement and logistics enables faster, more informed decision-making.

Technology also has the potential to accelerate innovation. Digital tools can improve process understanding, support smoother technology transfers and help bring new products to patients more efficiently. At the same time, particularly in a highly regulated industry like pharmaceuticals, technology adoption must be accompanied by strong governance, data integrity, transparency, clear accountability and appropriate human oversight. Ultimately, we do not get paid for technology itself; we get paid for the positive impact it helps us create for customers and patients.

You have managed large, multi-country operations. What is the biggest shift you see coming in pharma manufacturing in the way companies invest, operate or compete?

The biggest shift is that pharmaceutical manufacturing is moving from a scale-driven model to a capability-driven one. As products become more complex, supply chains more interconnected, and regulatory expectations more demanding, competitive advantage will increasingly depend on an organisation's ability to combine scientific expertise, operational excellence, innovation and quality at scale.

Technology, automation and AI will undoubtedly reshape how companies operate, but technology alone does not create value. The real differentiator will be an organisation's ability to translate these tools into better quality, greater agility, stronger resilience and improved outcomes for patients. In that sense, the industry is moving from an era of manufacturing efficiency to one of manufacturing intelligence.

India is uniquely positioned in this regard, with a deep pool of young, highly talented scientific, technical and engineering professionals. At Lupin, we believe strategy and capability building must go hand in hand. As we expand our focus on complex products, advanced manufacturing and digital technologies, we are equally committed to investing heavily in our talent pipeline, developing future-ready skills and building the leadership capabilities required for long-term growth. This requires one connected operating model in which strategy, capability building and execution reinforce one another. Sustainable performance is created when teams take shared ownership across functions and geographies, rather than optimising individual parts of the organisation in isolation.

In line with that vision, Lupin's FY26 investments included capacity enhancement and debottlenecking, infrastructure modernisation, technology upgrades, automation and process efficiency. These investments are not simply about adding capacity; they are about strengthening capability, improving utilisation, enhancing supply reliability and supporting sustainable long-term performance.

Looking at India from both a local and global perspective, what is the one capability the industry must build now if it wants to remain a leading pharma manufacturing hub?

The one capability India must continue to build is the ability to combine manufacturing excellence with innovation. India's opportunity lies not just in manufacturing medicines efficiently, but in becoming a partner of choice for complex products.

Innovation does not always mean inventing entirely new technologies. It is also about finding smarter ways to apply technology, science and data to solve complex challenges more effectively. As products, processes and supply chains become more sophisticated, the companies and countries that succeed will be those that can manage an important paradox: delivering greater complexity, quality and resilience while remaining competitive and affordable.

That requires an ecosystem, not a single intervention: investment in technology, process science, digital systems, regulatory capability, infrastructure and people, alongside stronger collaboration between industry, technology providers, academia, regulators and specialised talent.

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Tenthpin's India expansion mirrors life sciences' digital shift

Tenthpin Management Consultants recently launched an AI, IoMT-based Centre for Life Sciences Innovation Hub in Bengaluru, aimed at delivering AI and cloud-driven solutions to help transform complex therapies into life-saving medicines. **Juergen Bauer,** Founder Chairman, Tenthpin spoke to **Viveka Roychowdhury** on Tenthpin's global delivery model and talent strategy for their fastest growing country. Their solutions in the SAP and life sciences space, including quality solutions and a platform connecting pharma companies with hospitals and doctors for advanced therapies

Tenthpin Management Consultants will complete a decade in 2027. Has digital transformation in the life sciences sector become less challenging?

Yes and no. It has probably become easier in terms of experience and willingness to adopt, but more difficult because there is so much more to consider. We sometimes differentiate between digital transformation and intelligent transformation, leveraging AI capabilities. One is now overtaking the other, so I think they are becoming mixed.

The life sciences and healthcare sectors have a very complex ecosystem. It is not like selling bicycles or cars, where things are relatively simpler.

There are also high regulatory and compliance requirements, which make change more difficult. The sector typically has deeper pockets and the ability to invest more than other industries, but it also has very high regulatory and quality standards, which often makes adoption slower.

With AI, we now see areas where the static and deterministic requirement to explain exactly what happened and how a decision was derived is not always there. This can make companies more reluctant to adopt change. If something goes wrong, it ultimately affects the patient, which is very different from a car breaking down.

How have solution providers and platform technologies modified their products to suit the nuances of the life sciences sector?

What is very important for software providers, and we ourselves have worked extensively with SAP for the life sciences sector, is addressing the industry's specific needs. If you look at the entire life sciences value chain—from research and development to operations and commercial activities—it is very different from other industries, with historically very siloed entities within companies.

You cannot simply take experience from one industry and apply it to life sciences. Having an industry focus and understanding its specific needs is therefore very important.

This also creates an opportunity for other software providers to offer best-of-breed or tailored applications, such as Aviva, MES applications or research applications. Today, there is no software provider in the industry that covers the entire value chain.

Tenthpin has co-developed products for the life sciences sector with SAP. What has changed over the past decade in the digital transformation journey? Have the business triggers and priorities of pharma leaders changed?

Could you pick three triggers? There are many triggers, but let's pick three.

First, from an operating model perspective, we are now truly seeing personalised medicine, with gene therapies and advanced treatments changing the operating model entirely for companies working with these treatment modalities.

In the past, I created pills and sent them to distributors without knowing which patient would take them. Now, I can take blood or tissue from a patient, bring it back into manufacturing, manipulate the DNA and return it to that specific patient. That is an entirely different operating model.

If you look at these treatment modalities and what is registered with regulators, a significant number will come to market in the next five to 10 years. We are working with some clients on this, and it is a very different way of delivering medicine to patients. It also has a significant positive impact on treatment efficacy.

The volume and economics will change significantly, altering the entire operating model for companies involved in these areas.

Second, supply chain challenges that became apparent post-COVID are changing operating models and, to some degree, manufacturing requirements.

We see more CDMOs being created, where private equity firms or other CDMOs acquire assets and manufacturing capabilities from big pharma. What was previously within one large pharma company can now be sold to multiple clients. That creates a different supply model, and supply chain resilience is critical.

Third, from a pure IT perspective, we are seeing more standard software capabilities being introduced into R&D, where there were previously many more bespoke developments. This creates an opportunity for some of the big software providers.

Those are the three major changes, although there are many others affecting us.

Has the time required to achieve ROI on such investments reduced over the past decade, or has it remained the same?

I'm not sure I can answer that. The typical consulting answer is: it depends. It can go both ways.

You can do more if you start smart and focused, but often there is a lack of patience. Companies make projects too big from the beginning, before

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they have learned what works, and that can make the process longer.

You can move faster, but pressure from the board or the need for change may not allow companies to try and then roll things out. The pressure is often greater at the beginning, and that can ultimately slow things down.

Moving to the biopharma space. Biopharma is more complex than pharma. What specific challenges can a planned implementation pathway and customised tools help address? Pharma companies have legacy IT systems, while biotechs may be able to leapfrog to newer digital tools but may not have the financial resources. What is your value proposition to a bootstrap biotech in India?

You are absolutely right. We work with small and pre-commercial biotechs, somewhat larger biotechs and big pharma.

Sometimes people in biotech companies who come from an operating model perspective, rather than a scientific background, have experience in big pharma. When it comes to data, IT, systems and operating models, you should not simply transfer the experience of a big company to a small one.

Making things overly complicated and applying models that have worked for big pharma to smaller companies can destroy their efficiency or reduce it dramatically.

A small biotech has a very different operating model from big pharma. It may have complexity on the R&D side, but operationally it can, and should, be very simple.

Understanding that is important. You cannot simply say, "It's pharma, it's life sciences, so I'll copy what I did in a big company." That can undermine efficiency and economics.

Moving to Tenthpin's India presence. You already have three centres—Pune, Hyderabad and Bengaluru. When did you start, in what order, and is the newly inaugurated Bengaluru centre a new site or an extension of the existing one?

We founded the company in 2017. We started in India in 2021 in Bengaluru, and in 2022 we went to Hyderabad and Pune.

In Bengaluru, we have now reached a size where we need a larger location to support our growth opportunities. We have been here for quite some time, so this is essentially an expansion of what we have done, but in a new locality, very close to Christ University. Proximity to universities is important because we recruit quite a few graduates from universities.

We are now trying to differentiate the expertise across Hyderabad, Pune and Bengaluru. We have more development and cloud expertise in Pune, and more business and process innovation expertise in Bengaluru. We also have what we call the Tenthpin AI Lab in India.

It is not black and white, of course, because it depends on the capabilities available in the market. But that is how we are trying to build these centres of excellence.

What has been the growth rate of Tenthpin over the past decade?

Globally, over the past 10 years, we have had a compound annual growth rate of above 25 per cent, or about 27 per cent annually. Some years have seen more growth and some less. This year, we expect to finish with 26–27 per cent growth again.

India started later than some of our other countries, but it has been the fastest-growing country over the past four years.

Overall, I would expect India to double in the next two years. Globally, I would expect 50–60 per cent growth over two years. India will grow faster than some other countries, and that is not just about cost; it is primarily about talent.

In terms of staff strength, how has Tenthpin grown globally and in India?

Globally, we currently deploy roughly 650 people, including some freelancers to cover gaps. In India, we employ about 175 people at the moment, and by the end of the year we should be at roughly 190.

Given that we have been working remotely for 70–80 per cent of the time since COVID, the whole concept of onshore, nearshore and offshore no longer exists for us.

Our clients do not see a difference between a Portuguese, American, British, German or Indian consultant working on their project. They all work at the same level. It is not about handing something over to India; people are integrated based on their skills. Skills that I previously had to find in Germany can also be recruited in India.

In some new technologies, it is as easy to recruit graduates in Europe and the US as it is here. But in some traditional or core skills, because so much was offshored to India over the past 20 years, those skills are no longer as readily available in countries such as Germany. For example, finding a German-speaking finance SAP consultant with five to 10 years of experience in Germany is very difficult because much of that knowledge has been offshored.

From our perspective, India also has a good education system and the right attitude. Some of the language barriers we saw 20–25 years ago no longer exist.

Given that we work remotely, a colleague from Bengaluru or Pune can dial into team meetings just like a colleague from Lisbon or London. There is no difference for the client. This makes it easier for us to recruit and deploy people, although it also makes creating a culture somewhat more difficult. It has to be a very global culture.

Give us a sense of the projects Tenthpin is doing in India. Are there specific choke points or challenges in SAP implementation, and how have they been addressed?

Today, we predominantly work for GCCs and international corporations. We have some smaller Indian clients, but not many yet. We mainly work internationally, with Japanese, Chinese, European and American companies.

A lot is happening here through our AI Lab. This is not just for clients; we are also changing how we deliver projects by leveraging AI capabilities and AI agents to reduce groundwork or heavy lifting in areas such as data modelling and documentation creation.

Some of our new innovations and product developments have also been developed here and are going out to the global market in the quality space. Then there are the traditional ERP and SAP consultants we have here, as in any other country.

You said you are currently working mainly for GCCs in India, rather than local pharma companies. Do you see that mix changing?

Yes. The more we become a bigger player here and the more capabilities we develop, the more we can serve the local market. That is definitely an objective.

Because we started later than in some other countries, demand from those markets was very high initially. But as we grow here, we will increasingly work with local companies.

What specific solutions are being added through the new centre, and why the need to expand now?

It is primarily about our ability to grow faster. We are also addressing some new industry-specific requirements.

By working with local universities, we are building an innovation hub where we take industry demands and what is required globally and build those into our consulting capabilities and solutions in India.

Tenthpin has co-developed and deployed cloud solutions such as SAP Batch Release Hub (BRH), SAP Intelligent Clinical Supply Management (ICSM) and SAP Advanced Therapy Orchestration (ATO), as well as Tenthpin's AI-powered, GxP-ready software solutions. What new solutions are in the pipeline?

At the moment, we have our own solution in the quality space.

We are also working on an innovation related to advanced therapies and gene therapies. We are developing a product that links pharma companies with healthcare providers, allowing a hospital or doctor to order the treatment directly from the provider.

We want to make it open and agile so that any pharma company can link into it. As more of these treatments become available, healthcare providers and hospital doctors should not be overwhelmed by too many different applications. We are therefore trying to create a standard.

We are also moving more into the clinical space. We are working on clinical supply, as well as financial and patient-based accounting. We are developing ideas, innovations and solutions that will broaden and go deeper along the value chain in these areas.

So, along the procurement chain, when you move into hospitals and healthcare delivery, would it also involve pharma companies being able to anticipate demand cycles?

Yes. You look at both sides. Along the value chain, you move beyond the pharma company into hospitals, healthcare providers and distributors.

On the other side, you also look back into R&D, starting with development and potentially later moving into research.

viveka.r@expressindia.com
viveka.roy3@gmail.com

Why industry-academia collaboration will shape India's next R&D chapter

Suneela Thatte, VP & Head, Merck Healthcare R&D India in an exclusive conversation with **Swati Rana,** speaks about the skills the next generation of R&D professionals will need, the role of universities and industry partnerships, and what India must do to strengthen its position in global healthcare innovation

India has traditionally been seen as a strong talent pool for the global pharmaceutical industry. What needs to change for India to become a stronger global hub for healthcare R&D and innovation?
Today, India is well established as a major global talent and capability hub. The number of global pharma and healthcare GCCs operating here, and the growing complexity of the work they bring, reflect that well. We are no longer contributing scale alone. We are increasingly contributing to the science, the thinking and the decisions that shape global healthcare R&D.

What needs attention now is depth. Two things can make a real difference. First, institutions such as the NIPERs must be strengthened as true centres of excellence, so that more advanced work in biologics, translational science and data-driven research finds a stronger home here within our ecosystem. Second, initiatives such as the Biopharma SHAKTI mission need sustained follow-through, because capability in specialised emerging science is built over years, not through one cycle of investment.

Alongside this, addressing supply chain dependencies, particularly around critical APIs, will be important for India to hold a more central role in global R&D.

The foundation is in place. What matters now is consistent follow-through.

As pharmaceutical R&D becomes more complex and technology-driven, what new skills will the next generation of R&D professionals need?
Science is changing faster than any curriculum can keep up. Deep scientific grounding in biologics, genomics and translational research remains non-negotiable, but it must now be complemented by fluency in computational biology, AI-enabled analytics and digital tools that can compress timelines and improve probability of success.

This is not an either-or shift. Tomorrow's breakthroughs will come from scientists who are comfortable with interpreting data and algorithms, and equally strong in understanding the science. They also need to collaborate across borders as

the normal way of working. R&D today is continuous, not sequential. For example - Our teams here work on the same datasets and participate in the same decision-making forums as global counterparts. That requires confidence beyond execution: the ability to shape thinking, challenge assumptions and own outcomes.

What role should universities play in preparing students for areas such as clinical research, pharmacovigilance, regulatory affairs, data science and other emerging R&D functions?

Universities no doubt play a foundational role, but they need to move beyond teaching concepts alone and also teach context. A student can understand pharmacovigilance in theory, but real exposure shows how a safety signal is evaluated, documented and acted upon. That kind of applied understanding is difficult to build entirely within a classroom, which is why closer industry engagement is so important.

What universities can do well is build the foundation: strong scientific fundamentals, analytical thinking, and curiosity that stays sharp even as functions evolve. Where they truly add value is by inviting industry in early, through curricula that reflect real R&D functions, faculty who stay connected to practice, and structured collaborations that let students engage with live problems, not simulated ones.

The strongest outcomes happen when academia and industry design that exposure together.

How can stronger industry–academia partnerships help bridge this gap and make students more industry-ready?

Industry academia collaboration provides the students an opportunity to interact with and learn from seasoned professionals

solving real R&D problems, in various R&D functions such as pharmacovigilance, medical writing, regulatory affairs, scientific communication etc. That shift changes how a student thinks, not just what they know.

This is why we have built Catalyst with a growing network of academic partners, including prestigious institutions such JSS Academy of Higher Education & Research (AHER), Dayananda Sagar University, Manipal Academy of Higher Education (MAHE), NITTE and NMIMS Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management (SPPSPTM). The idea is simple: keep academic rigor intact but give students a chance to apply what they are learning against real industry expectations early enough that the gap between classroom and career starts to reduce.

Done well, these partnerships do not just prepare students for interviews. They prepare them to contribute from day one. Through Catalyst, we have already seen this play out: some of the students trained through the programme have gone on to join us and are doing exceptionally well.

Merck has partnered with eight academic institutions and launched the Catalyst programme in few of them. What are the learnings from these collaborations about the skills and expectations of today's students?

Working with academic institutions through Catalyst has taught us a few important things about today's students. What stands out first is scientific curiosity, and a genuine eagerness to work on problems that carry real-world impact, not just theoretical ones.

What's equally clear is that students are looking beyond technical knowledge. They want to build skills like problem-solving, collaboration, adaptability, and communication-capabilities that matter as much as domain expertise in today's innovation environment.

We have also seen that students respond best to experiences that are interactive and industry connected. Direct engagement with practitioners helps them understand not only possible career pathways, but also what the workplace actually expects from them in terms of problem-solving, collaboration, accountability and communication.

If there's one thing these collaborations have reinforced, it's this: academia-industry partnerships don't just build skills, they build readiness and confidence for the professional roles ahead.

Beyond employability, can academia–industry collaboration help strengthen India's overall innovation capacity? If so, what would a successful model look like?

Yes, and this is where the real potential lies. Employability is often the visible outcome, but the deeper value of these partnerships is in building research culture, curiosity, and problem-solving ability that extends beyond any single job outcome.

A successful model is one where industry does not just guest lecture but co-designs the learning experience around real R&D problems.

When this becomes consistent, not episodic, universities start producing not just job-ready graduates, but young professionals who can think originally. That, over time, is what strengthens a country's innovation capacity.

Looking ahead, what should industry, academia and policymakers do together to ensure that India has the talent needed for the next phase of pharmaceutical and healthcare R&D?

We are no longer dealing with talent availability alone; the bigger issue now is coordination. The pieces already exist: policy frameworks like Biopharma SHAKTI, institutions like the NIPERs, and industry programmes building early-career pipelines. What is missing is better alignment between them. In my experience, real progress happens when good ideas are connected into one system, instead of being left to work in separate lanes.

Policymakers need to treat talent infrastructure with the same urgency as R&D infrastructure. Academia needs to treat curriculum renewal as a continuous process, tied directly to where science and technology are moving. Industry needs to move from occasional engagement to sustained ownership of talent pipelines, not only at the point of recruitment, but much earlier in the learning journey.

The real shift happens when these three stakeholders stop working in parallel and start working to a shared timeline. We already have strong initiatives in place. What we need now is that they move together, with discipline, coordination and urgency.

If we get this right, the impact will not be limited to any one organisation or institution. It will show up in the quality of science we produce, in the confidence with which young researchers step into complex roles, and in how the world begins to see our ecosystem: not just as a place where healthcare R&D happens, but as a place where it is shaped.

swati.rana@expressindia.com
Swatirana.express@gmail.com

India's biotech innovation may be hidden in its biodiversity

Dr Villoo Morawala Patell, founder of Avesthagen and Avestagenome Project International, discusses how India can turn its biodiversity into an innovation story, while taking ownership of the science and moving discoveries from the lab to the market, in an exclusive interview with Neha Aathavale **Neha Aathavale**

You have studied the Parsi population for quite a few years. What has the data taught you that surprised you?

Actually, being a Parsi myself, and being a biologist and a geneticist, I knew what lay within these genomes due to endogamy, because I have worked on diversity. So I know that a gene in humans or a gene in bacteria will have common features. So those common features can be elucidated. So when you have endogamy, where the population is completely, you know, almost similar because they've married internally for so many years. I mean, when did we arrive in India? It was the 8th century. So it was a big opportunity there, because also the community was rapidly vanishing. It was endangered. So I thought that was the moment and we just started on the collection.

It took planning and it was done fully bioethically and was the topmost quality multi-omic collection. So we collected nine tubes per person, seven millilitres each. We took 60 pages of the data. It was a methodical collection, a biobank creation. And we reached around 4,700 across nine cities in India. So that itself took a while.

And then it was after that we went into the sequencing of 100 mitochondrial genomes and created a very deep, reference standard of the genome, both male and female. So all that has revealed something extraordinary, that what we

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suspected was validated to some level by the early biomarkers that surfaced, that all of, because they live long, so they do have longevity markers in the mitochondrial data that we did. And they also have autoimmune conditions, which was also well known, but biomarkers were found in this population, and colon cancer. And IBS. So all those markers showed up. And so now we have to validate that.

We have embarked on an AI-enabled drug discovery, which could result in anything. It could result in antibodies, monoclonal, or it could be cell therapies, it could be stem cell therapies, CAR T therapies, but we are embarking on that. With the original data, which we have, so the biobank was created.

What I was trying to stress on today, you have to own where you begin. The idea has to be yours for innovation to succeed. Of course, the innovation cycle is 20 years. I mean, now with AI, we can shorten it to say 7 to 8 years, maybe. But again, very focused. It has to be very focused.

If you're doing Alzheimer's, you have a set of team there. But through partnerships, you cannot do this on your own. The ownership of the data remains with you. The ownership of the pipelines remains with you. But you have to partner for various things to drive an effective molecule, unique innovation into the market in the 8th year or 10th year.

Parsi dataset is unique. Can this model work with other Indian populations as well?
Absolutely, it will work. So for example, there are these tribal populations that are haemophilic.

You can go into those populations, do a proper collection. The thing is to do it properly, not half-heartedly. And you do a full scientific collection with background data, you know, create the biobank, create the database, put it all together.

So that becomes the unique treasure. And on that,

you apply science to elucidate information out of it, to create novel drugs. That's where I started.

India is a biodiversity story. It is one of its biggest trends. But how we do it, where we do it, and how we use the data, capitalise and analyse the data, it's in the analytics. It's in the analytics. And the ability to see across, you know, which AI is enabling now. Earlier we used to do it ourselves by writing the code.

But today you can do it. You can see, like, if supposing the haemophilic tribal population could have a gene in common with the Parsis in their rare disease. So you could make a connect. So that is possible also.

You have taken genomics into diagnostics, food and agriculture as well. How do you turn a genomic discovery into something people can actually use?
See, the first outcome is the diagnostics. So the biomarkers, say, for example, for colon cancer that we have, we should pick them out and validate them. Now that goes as part of the panel. So there are already panels existing, say, for colon cancer. It adds to the panel. Also, people are different.

So if you were to do a colon cancer test and I were to do it, different genes would light up because different biochemical pathways result in different outcomes. So then the doctor would know which pathway is where your, I mean, a person's colon cancer biomarkers lie, and they can give the proper precision drug therapy. That's how it will apply.

Because all are not the same. There are 20 types of diabetes. Similarly, from that panel where the diagnostic biomarkers come on, you can predict which pathway you fall under.

You know, we may all fall under groups of people who fall under this pathway. Your family may be on this path and our family may be on another path, and then the drug appropriately has to be done. Now doctors, of course, also have to increase their range of knowledge in all of this.

That is another story.

What's your advice for Indian biotech founders trying to raise global PE and strategic capital?
See, I do it all the time. It's my job. For every idea, for every say, as I was mentioning, the colon cancer, for that I've written a project.

So where do I go with that? I mean, I've raised global capital, but at the stage where I am today, it's different, I've got too many things as an outcome. So my 50 products, they need different types of capital. So there maybe it's strategic.

What do I need that capital for? Scale, manufacturing, and marketing. That is a different beast altogether, different set of investors. There, international capital won't be interested.

It will have to be your local capital, unless you're going overseas. That brand is an overseas brand, and then you can go for Indian. But you will have to rely on local or strategic investors internationally who may be wanting to enter India, and who may say, okay, we want to position ourselves in this area, and they may pick up that technology from you, or they will invest.

There are multiple models that will emerge there. It's not one thing. It's not, I want capital one way. There are multiple ways. There's the grant, sustain the foundation, keep writing grants. Don't lose your science.

In your journey, you may fail. I mean, your molecule may, but if you have that grant chugging underneath, the grants must chug on underneath. That's sort of the basic bread, not even butter.

Then you go into these licensing partnerships, where you licence and pick up some money, co-develop, that kind. Third money is venture capital money. Fourth money is private equity, and the fifth is strategic partnerships.

Private equity, strategic go together. They play together, and it depends on what stage you're at and which product and where. So there's no one general prescription.

And of course, today, as I was saying, there are the MSME markets. Go for them. At some point, just jump. And the government should facilitate MSMEs, not ask for 'what's your revenue here?' This is not about revenue. This is about a product that's been created. You want to go to the market. The public will decide whether they want to invest in you or not. It's not the government law that can stop.

So the government should facilitate startups to go to the markets as soon as possible through the MSME exchange or through the GIFT City exchange or whatever new exchange. They have to create new exchanges to facilitate product-led companies to move. Because how can they scale? How can they manufacture? If not, you want them to waste another 10 years of their life? No.

Where does India still fall short in converting scientific research into commercial biotech success?
I think it's happening. The science from the labs is coming out in certain institutions. But there is still a lot of work to do. Also, the people doing that science in the labs, they have to be sufficiently motivated. They are not people who execute, the do-or-die type.

They are scientists from certain types of families where the families don't encourage you to take risks. They don't have the wherewithal. So, that's where it stalls.

So now, you should create, perhaps, within that institutional system, a leader who can pick up and who is like a networker also. Every institute should have a business development and/or IP licensor head. And that guy should move around and pick up whatever looks interesting.

And he should be a networker. He should move to companies. He should travel, putting these out into the market.

That's the only way we can move forward fast. A proper business, corporate-type business development. Not your from academia, one guy picking up, trying to flop.

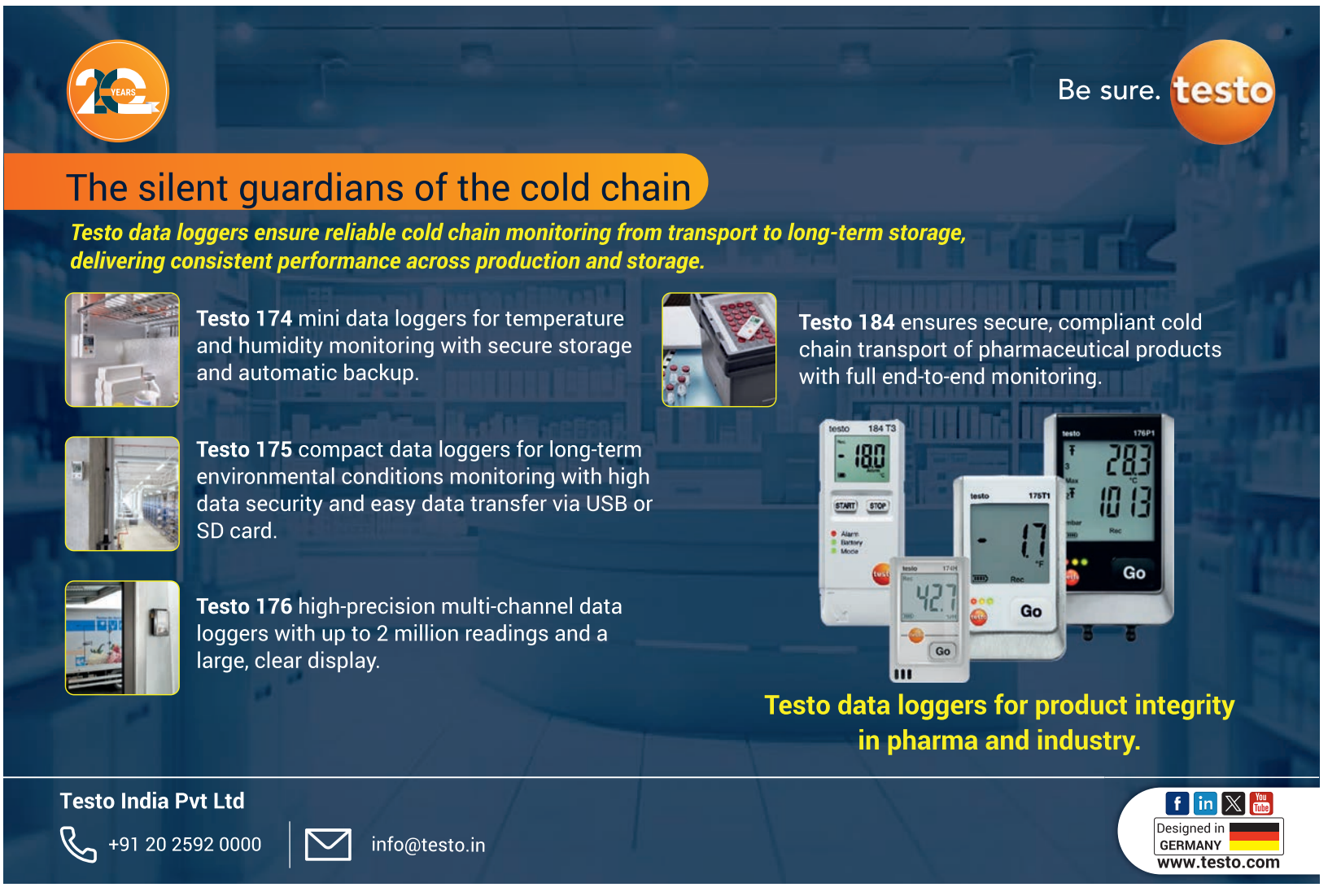
That won't work. A corporate deliverer.

neha.aathavale@expressindia.com
nehaaathavale75@gmail.com

India's biotech growth story is now a manufacturing story: G Balaji

As production becomes more complex and highly regulated, digitalisation and automation are emerging as critical enablers. **G Balaji,** SVP, Energy Industries, ABB India in an exclusive interview with **Swati Rana** discusses how Pharma 4.0, connected manufacturing and integrated plant infrastructure can help India's biotech sector translate scientific innovation into commercially viable production

How do you see India's biotechnology sector evolving as it moves from scientific breakthroughs towards large-scale commercial manufacturing?
We have witnessed a remarkable transformation in India's biotech industry over the past decade, driven by the expansion of the start-up ecosystem and the emergence of high-value opportunities across the life sciences. Biosimilars, in particular, have become an important part of India's growing biomanufacturing capabilities. The opportunity now extends well beyond healthcare, with increasing demand across food and nutrition, sustainable materials, bio-based chemicals, and precision fermentation. As these sectors mature, manufacturers will need to expand production capacity while maintaining quality, consistency, and cost competitiveness. That requires industrial-scale execution. Companies that can scale reliably, meet global quality standards, and bring products to market faster will have a significant advantage in international markets. India is well placed to combine its strong scientific talent base with advanced digital manufacturing and automation capabilities to realise the broader potential of its life sciences sector.



Manufacturing excellence is becoming just as important as scientific innovation in determining long-term success.

What are the biggest operational challenges biotech manufacturers face when scaling production, particularly in maintaining consistency, quality and regulatory compliance?
One of the biggest operational challenges in biomanufacturing is maintaining consistency as production scales. Even small deviations in critical process parameters can impact yield, product quality, and batch-to-batch reproducibility, leading to costly investigations, rework, or production delays. The challenge is compounded by stringent regulatory requirements, where every recipe modification, process adjustment, or equipment change must be fully documented and traceable. Manufacturers need a clear audit trail showing what changed, who approved it, and how it affected production. At the same time, they must manage vast amounts of process and quality data while maintaining data integrity and end-to-end traceability. Successfully scaling production therefore requires more than adding capacity; it demands robust process control, real-time visibility, and rigorous change management to ensure quality, compliance, and operational efficiency at every stage.

What role do you see Pharma 4.0 and digital manufacturing playing in shaping the next generation of biotech production facilities in India?
Biomanufacturers often manage multiple processes simultaneously. The challenge is maintaining consistent quality, ensuring compliance, and having complete visibility into what's happening across the plant without creating additional operational overhead. That's where I believe Pharma 4.0 delivers its greatest value. A connected manufacturing environment enables information to flow seamlessly across the facilities, leading to faster decisions, stronger compliance, and more reliable production outcomes.

We've seen this firsthand at a life sciences facility, where ABB integrated nine manufacturing blocks onto a common automation platform. Rather than operating as separate islands of information, production, utilities, environmental monitoring, and quality-related data were integrated into a unified control system. This gave operators and plant managers a real-time view of site-wide operations, making it easier to identify deviations, understand the impact of process changes, and maintain traceability throughout the manufacturing lifecycle.

Why are data visibility, traceability and data integrity becoming increasingly critical for biotech manufacturers, and how can digital technologies address these requirements?
Data is no longer just a record of what happened; it is the foundation for better decisions, faster scale-up, and more consistent outcomes. Reliable, traceable, and accessible data is critical to maintaining product quality and compliance. When a process deviation occurs, for example, manufacturers need immediate visibility into every material, process step, and operating condition associated with a batch. A unified automation platform enables this by connecting operations, capturing information in real time, reducing manual errors, and creating a trusted data foundation across the manufacturing lifecycle. In highly regulated environments, compliance with standards such as FDA 21 CFR Part 11 requires secure electronic records, electronic signatures, and time-stamped audit trails. By bringing production data, workflows, and quality processes together, manufacturers can strengthen data integrity and end-to-end traceability while remaining audit-ready. Built-in cybersecurity, secure data management, reporting, and automated compliance capabilities further help create a more connected, transparent, and resilient manufacturing environment.

What opportunities does automation create for biotech companies looking to transition towards larger-scale or continuous production models?
Think of automation as the brain of a manufacturing operation, continuously coordinating thousands of interconnected activities across the plant. Just as the brain enables different parts of the body to work together seamlessly, automation connects processes, equipment, and data to keep production running smoothly and consistently. It helps maintain tight control over critical conditions, reducing variability and enabling faster, more reliable decision-making. This is especially important in continuous production, where operations must run 24x7 seamlessly without interruption. More broadly, automation allows manufacturers to scale with confidence, transfer processes more effectively, strengthen compliance, and respond more quickly to changing market demands. It is not simply a tool for operating a larger facility but the foundation for turning scientific innovation into repeatable, commercially viable production.

Why is it important for biotech manufacturers to take an integrated approach to plant infrastructure, connecting production, utilities and other critical systems?
A biomanufacturing facility functions as a connected ecosystem, where production is only one part of the equation. Supporting systems such as utilities, power infrastructure, building management, and process controls must operate seamlessly together to create the stable, controlled environment required for efficient and reliable manufacturing. A "one plant, one system" approach brings these elements together through a common automation platform, providing a unified view of the entire ecosystem. The result is a single source of truth across the facility, improving visibility, strengthening data integrity, and creating a scalable foundation for growth. An integrated architecture also lowers maintenance costs, simplifies upgrades, and eliminates the need to train personnel on multiple automation platforms. By standardizing operations on a common platform, manufacturers can accelerate onboarding, enhance workforce flexibility, and maintain consistency across sites. Ultimately, an integrated plant is not only easier to operate but also more resilient, efficient, and better equipped to support the rapid scale-up and agility that modern biotech manufacturing demands.

swati.rana@expressindia.com
Swatirana.express@gmail.com

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Building the pharma talent India needs for the digital era

Dr Supriya Shidaye, Principal, Vivekanand Education Society's College of Pharmacy, discusses how AI, automation and digital technologies are reshaping pharmacy education, while closer industry-academia collaboration can help prepare students for the changing pharma workplace, in an exclusive interview with **Neha Aathavale**

As Indian pharma companies now move towards AI and automation and even connected manufacturing, what talent gaps are you seeing emerging at the plant level and are companies struggling more to find digital skills or professionals who can combine the pharmaceutical knowledge with technology?

With this emerging AI, automation, industrial internet of things, the entire pharma industry landscape is changing very rapidly. This change is happening not just at manufacturing level, but it is taking place at every stage of the entire product life cycle that is at the research and development, drug discovery, manufacturing, quality control, in process quality control, supply chain and further regulatory guidelines or regulatory compliances. Obviously the things are being done in much shorter time with more precision and more accuracy.

When we talk about industry, it is all data driven. Earlier also conventionally a lot of data was getting generated, because equipment is running, they are being monitored for various parameters. So data is getting generated, then there is a quality control happening, in process quality control happening, then supply chain the product is being delivered.

Everywhere there are logs, maintenance logs, batch manufacturing records, master files, data has been always getting generated. But in the past the approach was about using that data to understand whether the product complies with the required standard and what went wrong, but that was a kind of reactive type of approach. But now the industry has been changing rapidly and now industry is making the right use of AI, machine learning, internet of thing for more kind of predictive approach, responsive approach.

> The industry now requires a person who not only has a very good in depth knowledge when it comes to science, but also he has a very good smart way to work by adopting the technology and arriving at a right decision by using the technology

It is not only about AI or digital knowledge which will sustain or only the technical knowledge which will sustain, because AI has a lot of role to enhance your decision making, to expedite the efficiency of your work. So it is going to complement your skill, it is not going to substitute your skill. So every person has to have a very strong scientific knowledge, there cannot be a substitute for scientific knowledge, but AI is going to help you in a number of ways like the data is being studied by AI and it is helping you in decision making, informed decision making.

People should have digital literacy, AI literacy. Once the data is being analysed by the system and it is showing you some kind of results, you should have an ability to interpret those results and arrive at some decision. So if you are not able to observe it carefully, critically analyse it further and arrive at some informed decision, then somewhere there will be a gap in your efficiency as well as your delivery of the output.

The industry now requires a person who not only has a very good in depth knowledge when it comes to science, but also he has a very good smart way to work by adopting the technology and arriving at a right decision by using the technology and these decisions because they are based on data, there will be more accuracy, there would not be just the assumptions, but there is an evidence based decision that is possible.

Industry is moving in that way, in that direction and this person has the requirement of a person who has both science based knowledge as well as digital literacy to convert that knowledge into informed decisions.

Pharma 4.0 as I see it is bringing production, engineering, quality, IT and data functions together. How far should a pharma manufacturing professional be expected to work beyond their traditional domain and which capabilities will increasingly be required to nurture that specialised talent?

When we are talking about 4.0, it is all about automation, it is about digitalisation, it is about continuous manufacturing, it is about smart ways of handling the product and delivering the results. The industry when it is moving ahead with these skills, the personnel also should align themselves with all these requisites.

When you said that it is a blend of technology, engineering, this engineering is also very much important because these equipments that are being designed, they

are not an equipment which have all controls and these controls are also generating lot of data, there are sensors, we call it as industrial internet of things.

These sensors are giving you red flags, they are predicting that there is something going wrong and you are able to understand that there is a beginning of something going wrong and you need to stop the operation at that stage and take some corrective action. So, all these red flags you are able to get because of that 4.0 and 4.2 talks about continuous manufacturing. Now, in India and abroad also more commonly it is seen in manufacturing of oral solid dosage forms like tablets.

This is the entire pipeline operation, it starts from raw material and then the mixing, then milling, then granulation, then again milling, then blending with lubrication and then compression and then further levelling, packaging, levelling everything is happening on a single line.

There is something called process analytical technology which is developing very fast. So, we have NIR near infrared Raman where those probes are able to at entire pipeline everywhere they are able to understand, they are able to monitor the micro changes in the pipeline, what is going to be the bottleneck, where these micro changes are happening, what is the trade of changes taking place and bridge pad will be able to tell you whether everything is going on well and there is a go status or no go status, there is some micro change happening, there is some kind of missing of some kind of required specification.

This is how development happens where a lot of core engineering knowledge is required. So, for designing these equipment and installing those sensors, the displays, the PLC boards. This is what is the integration of engineering with the science and pharmaceutical technology and that is only giving us a lot of data.

Data logs are getting generated and so when it comes to regulations, regulation is becoming very easy because earlier may be conventionally, traditionally whenever there is an inspection people used to run around and generate the data, but there is no such need every minute you are ready for any kind of regulatory compliances or audits because you have a data logs and there is a very high degree of data integrity because everything is available digitally.

You cannot manually say there is no intervention except that you have to read it and interpret it and take the decisions that are the intervention, but otherwise data integrity is going on very well, the trained analysis is possible, audit trails are available. That is how industries benefited a lot due to this 4.0 developments and automations.

As AI and digital systems enter regulated manufacturing environments, how should the industry balance digital capabilities with fundamentals like GMP and data integrity, validation and mostly cyber security? Is the current talent pool equipped to manage this convergence?

I am an educationist. I would like to share with you that the Pharmacy Council of India is an apex body for pharma programs in all India and now in this year 26-27 academic year they have come up with a revised syllabus and that revised syllabus is introducing AI and ML at almost every semester.

Students are going to start from basics of Python and its application and then they are going to also study data analysis, further they are going to study AI and ML and then application of AI in clinical research, pharma for vigilance, regulatory and healthcare. So, students will be definitely getting equipped with all these skills required with the new syllabus that has emerged. That does not mean the previous students who have stepped into the corporate are not equipped with that.

We always had a platform called Swayam. That is the government of India created MOOCs platform, Massive Online Open Courses. So, through that platform our students were studying all these AI and ML related subjects through self-study and completing some certificate courses.

Also there are number of online educational edtech companies like Coursera, UpGrad which has given many such programs our students and when I talked about VES College of Pharmacy and my role as a chairman of board of studies of Pharmacy of University of Mumbai, four years back I had designed one course on AI in healthcare which was a value added course for University of Mumbai affiliated pharmacy colleges.

Almost every college offers a value added course. In our college every year we offer it and we integrate it or we collaborate with our engineering college, VES Institute of Technology and their faculty members come and deliver that course.

That is how we are trying to train our students to get adapted to these new trends because that is important.

When you talk about cyber security, the government of Maharashtra also takes lot of initiatives and they always insist that our institutions should also conduct the programs on cyber security because students are now more available online because online resources are huge in number.

There are chances that while using digital transactions and on accessing online data somewhere their mails can get hacked, their data can get hacked or if they are working for their organisation there also such threat is always there of hacking of the data.

It is very important that students are aware about how to protect your data, what should be revealed, what should not be revealed, how you can have security measures and what are those measures, how you have to encrypt your files, password protected.

That kind of education is also equally important because we know that when we are travelling somewhere the Google comes to know where we are and Google starts giving us the information about the shopping malls, theatres and everything in that area. That means whatever we are doing on WhatsApp or online through any kind of online platform it is getting recorded and AI is able to understand your whereabouts.

Students should know. We also keep telling students when you are generating a research paper or you are using chat GPT for example, for redrafting or paraphrasing your research publication it is you should be careful you cannot directly put your entire abstract there or a lot of very big length of article there because once you put it in the AI chat GPT has also captured it as a data.

Sometimes your own data will be shown as plagiarised because chat GPT has captured it.

These are the threats also when the technology is moving on and everything is available through smart means that data somewhere is getting generated. So, protection of data becomes very important and we know that there is an act about privacy of data.

Even industry and employers are worried about what data of your employee or your organisation should be revealed and what should not be revealed, what comes under the umbrella of disclosure allowed, what should not be allowed for instance Aadhaar number you are not supposed to disclose.

Cyber security when it comes to this is a challenge to everybody, the employer, the employee, the student, the educational institutions, the management and we need to be careful about it and digital literacy that is indispensable and we need to train students and our syllabus is now framed. So, their students will be completely updated by the time they graduate.

India is no longer looking only to strengthen its manufacturing base, but also trying to enhance its capabilities in innovation and product development. What kind of talent will this shift require and is the current industry academia ecosystem equipped to prepare professionals who can contribute both to manufacturing and innovation?

Innovation since last 4, 5 years I can say that innovation has become a very important component in the educational systems.

Especially so, when our government of India and Honorable Prime Minister promoted Make in India, start up India policies and the Ministry of Education also incorporated Institution Innovation Council, Ministry of Education's Innovation Council.

Through that Innovation Council every institution was required to set up their own institutional innovation cell and not just that to promote that kind of activity. The Ministry of Education earlier it was MHID, now it is the Ministry of Education. So, they also encouraged colleges to take part in the ranking framework based on your Institutional Innovation Council activity that is called IIC short form.

Every institution including our institution we are taking part every year in the IIC activities ranking framework. So, through that framework every institution conducts a lot of programs to encourage students to think differently.

Entrepreneurship related programs, design thinking then we invite people having their own start ups and how. So, how commercial adaptability is important, how do you convert the prototype into a commercially viable product, that kind of training

is being given the entire business canvas is being taught to students while they are graduating and that is how innovation is innovative.

For entrepreneurship the skills and the kind of knowledge that you need that institutions are providing.

Now, when it comes to innovation as an attitude, we know that it is not taught in the classroom, but it is all about the kind of spark that you have about creativity, critical thinking, and problem solving. You are always very creative when it comes to thinking out of the box.

Students are deliberately made to think about the community based problems, what is going around and based on that do you find out some unmet need that society is facing and for which solution is right now not available and it need not be very hi-fi thing because at first year and second year level what advanced research you can think about.

It need not be about genomics, proteomics or bioinformatics. It can be about small small things like some kind of smart watch which has an alarm which takes up your vital and gives you some kind of indication like there is something wrong with tachycardia.

So, you need to consult a doctor or in my college I developed one film which was just a plain film of a polymer, but it was water insoluble and it was a peelable and biodegradable polymer.

Our idea was just to apply the film and then go into and do the work where you have to deal with some detergents or some for the agricultural community, some fertilizers, manure, soil. So, your hands will be protected and it is not a glove, but it is just a film which is mixing with your skin.

It is almost invisible. You do not have a feeling here you are wearing something, but your hands are completely protected and after work is over and you do not have to now deal with the hasardous material just peel it off and it is biodisposable.

Such types of innovations have a lot of concepts that are strong, but the work can be very simple: just dissolve, mix and make a solution. So, these kinds of innovations we are asking students to think about.

That is what is called design thinking. We are trying to create them about finding out some problem statement for which solution is available and what can be that solution, that solution oriented approach that is being taught to students by giving various examples, the contemporary examples in day to day life like food products, nutraceuticals, formulations, drugs, medicines, devices.

Innovation, We know that when there is necessity there is an invention, but we are going beyond that like we are trying to tell them that you have to whatever is your idea you just try to experiment it do not just neglect it.

That is what a tinkerer's lab is. We are giving them the platform, we give you chemicals, we give you equipment, you just do it and see whether you are able to convert it into a product or you are able to convert it into some prototype which can be seen as this is how it will work.

We have heard about digital twins right, what is a digital twin? It is a mock or prototype of the simulated model which before physically we make it that digital twin tells you that this is how the process will appear, this is how the product will appear and this is how it will work.

We are also trying to tell them you make a twin which is in the form of a prototype and then later on maybe in the phases we have our own incubation centre Hashu Advani Business Technology Incubation Centre where you can incubate and we can convert it into a viable solution.

That is how institutions are encouraging innovation, VES College of Pharmacy has our own institution innovation council, we conduct many sessions, we invite speakers who have their own startups, we also conduct workshops on design thinking and we nurture that innovation thought.

Our second year student recently when we had a design thinking workshop she came up with the idea of a digital watch and she is saying in that digital watch we will have a strips blister pack of the anti asthma drug like salbutamol and it will also have a kind of sensor.

So when a person is having bronchospasm because of an allergen to which he or she has been exposed to, the sensor will be able to capture that anatomical change and it will show a red brick.

The person who is allergic to certain things will come to know, okay I am going to land up in an asthma attack.

So I will just dial the next dose and I will inhale it through the asthma digital valve. So the idea was so good that we took her to the Tinkerer lab and also we introduced her to some other engineering college students of VES and we found a team and we would now tell them, now go ahead and try to design a certain type of watch.

That is how we are encouraging students.

As India seeks to strengthen its position as a global pharma manufacturing hub, could talent become a constraint to the adoption of smart manufacturing and what should industry and academia start doing to ensure that the talent pipeline keeps pace with its transition?

Very good question. The Pharmacy Council of India is telling us, it is making it mandatory that every institution should have 10 MOUs with the industry and hospitals.

Out of that 10, at least 5 should be with the industry. Now these MOUs should not be just the on paper record, but it should be an active MOU.

My suggestion is that industry should adopt at least 3 to 4 colleges, may be based on geographical location or may be because of the, based on the research interest that these institutions are having and their research forte and then industry should hand hold these academia.

Each industry if it adopts 2 or 3 institutions and they hand hold them, it is like a sharing of the expertise, sharing of the facilities, sharing of the knowledge and that can become a very good collaborative model.

Because we know abroad in the US, so many products, so many vaccines, even for example Covishield vaccine that was, that has emerged from one institutional research. Institutions have got a lot of creativity.

Institutional faculty members have got a lot of new ideas, but they lack its commercial translation into commercial products, whereas industry has expertise in commercialising it.

What I feel is that industry should set up the industry training center in the colleges and they can identify one such college in the cluster of 10 colleges and then this training center should give training to all the students available in that cluster.

The host institute may be considered based on its location and its overall expertise and the trainers available with their experience in research and in that institution the industry can invest through their CSR funding or any other source and install all industry compliant CSR compliant equipment, having all digital monitors, sensors, then PLC controls.

So that it is not the primitive machine or equipment that academic institutions can afford to have, but it is actually GMP CSR compliant equipment that industry uses.

But this training should be provided while the student is studying here. So that is what hands on training.

Merely going for an industry visit will not help in fulfilling that requirement. But if you have such type of center and it is catering to 10 nearby institutions, students can be visiting to this host institute for some 2 days workshops, additional their work for which this center can cater to their need for scaling up, for giving them better product with proper log and proper data which is printed and available as a digital copy.

While they are studying they come to know what are the industry practices and industry also should talk about QMS.

Academic institutions should set up the quality management system through their instrument rooms, pilot plant. So in our college we have already consulted Mr. Sunil Putkar who is a regulatory auditor and under his guidance we are setting up QMS systems, quality management systems in our instrumentation and pilot plant and record keeping.

Then we are going to ask students to maintain it.

These are industrial practices. So in the college level itself they should come to know how the records are maintained, documents are made, done, then common technical data, CDDs, files are made. So everything should be trained.

How SOPs are made, standard operating procedures. So that training is required plus hands on training to handle the equipment because the industry has set up that kind of training.

My vision is that in our college there should be a translational research and development center.

This center will cater to translating your research into commercially viable products. That is one thing for which we are working on.

And second thing is that industry training center where we can tie up with the company and we can provide this facility for the nearby colleges. We can volunteer to train them. That is what my vision is.

neha.aathavale@expressindia.com
nehaaathavale75@gmail.com

India now needs to move from being a manufacturing powerhouse to an innovation powerhouse

Suresh Pattathil, Managing Director and General Manager, AbbVie India, in an interview with **Kalyani Sharma,** discusses India's transition from a manufacturing-led pharma powerhouse to a hub for drug discovery, the role of government-backed risk capital, and the need to improve disease awareness and access to innovative therapies

Over the last three decades, Indian pharma has built significant manufacturing capabilities. What should be the next phase of growth for the industry?

Over the last three decades, Indian pharma has made significant strides, particularly in manufacturing capabilities and its ability to supply medicines to markets across the world. India is the third-largest pharmaceutical market by volume, manufactures almost 65 per cent of global vaccines and supplies almost 45 per cent of US generics.

However, we need to recognise that we are playing in only about 10-15 per cent of the global pharmaceutical market, which is worth around $1.4 trillion. While we have been leaders in the volume-driven segment, we now need to move towards the value part of the market.

This is the right time for India to focus on discovering and developing medicines from within the country, bringing forward more innovative and value-added products and developing cutting-edge therapies for patients globally.

We have become a manufacturing powerhouse and have also developed strong capabilities in areas such as biosimilars and development. Now, we need to take the next step and start innovating for new markets.

Are we now seeing more serious investment in drug discovery? What is still needed for India to become a genuine drug-discovery hub rather than just a pharmaceutical market?

> We have become a manufacturing powerhouse and have also developed strong capabilities in areas such as biosimilars and development. Now, we need to take the next step and start innovating for new markets

A few years ago, around 2022-23, the government recognised that the journey from the laboratory to the market is a long one. It requires significant investment and risk capital.

That is where the Promotion of Research and Innovation in Pharma-MedTech (PRIP) scheme came in. The government decided to support research and development in pharmaceuticals and medical devices, with the objective of helping products move from the molecule or discovery stage in the laboratory towards the market.

More recently, the government has also rolled out the BioPharma Shakti initiative, which involves significant government support for the sector. This kind of risk capital is important to seed new innovation in India. Without such support, it is difficult to get innovation off the ground.

Therefore, initiatives such as PRIP and BioPharma Shakti can play an important role in creating the conditions required for drug discovery and innovation in India.

You have previously been involved in setting up R&D and manufacturing operations in Hyderabad. What did that experience teach you about building an innovation ecosystem in India?

This was during my previous stint with another company. It was a completely different experience for me because I was involved in setting up a greenfield project. We had an R&D centre in Mumbai, which we moved to Hyderabad. It was primarily focused on formulation development and incremental innovation.

One of the key learnings was the importance of government support in making such projects happen. Hyderabad offered a conducive environment for a greenfield investment. We were able to get land and the necessary permissions relatively quickly, while the ecosystem also provided the right environment for people to come and work.

Hyderabad offered many of the elements required to support R&D and innovation. I believe several other states, including Karnataka, Uttar Pradesh, Madhya Pradesh and Gujarat, are also creating ecosystems that can enable similar greenfield investments in R&D and innovation.

You have launched several medicines in India. How has the environment for bringing innovative therapies to patients changed, and what challenges remain?

I have been involved in launching several global molecules in India. One thing that has not changed, and probably never will, is the need for disease awareness and therapy shaping.

There are still many patients who require treatment but are not even aware that they are suffering from a particular disease. This is true across conditions such as diabetes and hypertension, as well as glaucoma, which is particularly close to my heart.

For example, there are around 12 million people suffering from glaucoma, but only about two million are diagnosed and treated every year. This means a large number of people remain undiagnosed and are at risk of losing their vision without knowing that they have the disease. Therefore, disease awareness remains critical. We need to ensure that patients are aware of their condition, that the right treatment options are available to them, and that newer medicines find the appropriate place within the treatment pathway.

These are the factors that will continue to determine how successfully innovative and global therapies reach patients.

Kalyani.sharma@expressindia.com
journokalyani@gmail.com

BEYOND US NEW SHORES, NEW BETS

The US remains a key market for Indian pharma. But changing conditions are pushing India to diversify its global footprint. The core question is what should that footprint look like five years from now?

By **Neha Aathavale**

For years, the story of Indian pharma and the US has been told through the lens of opportunity. However, as the terms of that relationship begin to shift, so too does the certainty around a market Indian pharma has long known.

The *American Dream*, once imported almost as freely as the products and ideas that helped build it, now sits rather awkwardly beside "*Make America Great Again*". The change is not confined to rhetoric, with the much-awaited India-US trade deal still being worked out and its fine print yet to be settled.

So perhaps the question facing Indian pharma is not simply whether to look beyond the US, but which shores to reach next, how to make landfall, and how to build a business once there.

How exposed is Indian pharma to the US?

Before asking where Indian pharma can go next, it is worth establishing how much of its global business has been shaped by the US.

For decades, serving the US market has meant building capabilities around its regulatory requirements, manufacturing standards and commercial systems. Those capabilities have, in turn, travelled with Indian companies as they entered other markets.

Harish Jain, President, FOPE, points out that India's pharma exports now span around 191 countries and are estimated at $32-33 billion in 2025-26. The US, however, accounts for around 45-55 per cent of the business of some leading Indian companies.

"The thing is, the market that made Indian pharma globally competitive may also be the market that exposes its geopolitical pricing and regulatory risk."

That exposure is being tested by tariffs, localisation requirements and generic price erosion. However, the US relationship has also given Indian pharma an important advantage: experience and credibility in a closely regulated market.

Market size is one important consideration, but the focus is on how effectively Indian pharma company can address that opportunity and build a sustainable long-term presence

Archana Jatkar
Associate Secretary General, IPA

As our growth strategy, We build a portfolio of markets the same way we build a therapeutic portfolio — so no single regulatory regime or currency bloc or trade barrier can take out our revenue base

Amit Patni
Co-founder & Chairman of Nirvana Venture Advisors and Founder of Raay Investments

It's the time of collaboration. And we need to know our capabilities, our differentiators and our benefits for the customer or a consumer.

Namit Joshi
Chairman, Pharmexcil

Our next export strategy cannot be sell more generics to more countries, it has to be build deeper healthcare partnership with more countries

Harish Jain
President, FOPE

And that is why, for Jain, exposure to the US is not a strategic risk in itself, but a position from which Indian pharma can diversify without withdrawing from the market.

Namit Joshi, Chairman, Pharmexcil, offers another reason why the US will remain central to this equation, by highlighting the scale of the ecosystem built around generic medicines.

"See, if you believe in the theory of assumptions, then it looks a very remote possibility that we will lose the total market share in US because to rebuild a sort of ecosystem for generic medicine manufacturing, I think a lot of investments goes into that particular segment."

Uday Harle, CEO of Shilpa Biologicals, brings the same question to the level of products and future value pools. For him, diversification does not mean finding another market of the same scale as the US.

"I don't think there is a single market that replaces the US. The bigger opportunity is a diversified global portfolio, particularly as the pharmaceutical value pool increasingly shifts towards biologics and other advanced therapies."

The focus, therefore, shifts from replacing the US to understanding what other markets can offer, and what it takes for Indian pharma to build a sustainable presence in them.

What makes a market worth entering?

If diversification is the direction, market size alone cannot determine where Indian pharma goes next.

For Archana Jatkar, Associate Secretary General, IPA, the starting point is the combination of patient need, commercial viability and regulatory predictability. A large market may offer scale, but that does not necessarily translate into a sustainable opportunity for an Indian company, particularly

when pharma investments are made over long time horizons.

"Market size is one important consideration, but the focus is on how effectively Indian pharma company can address that opportunity and build a sustainable long-term presence."

Regulatory access, pricing, reimbursement and competition therefore, become an important part of the assessment. So does the company's own portfolio. Jatkar argues that companies need to examine where they have a genuine competitive advantage.

"We also need to assess where the Indian pharma has a genuine competitive advantage, right? Whether it is in generics, complex generics, are we good in APIs, biosimilars or what areas?"

The difference between market size and actual export opportunity can be seen across geographies. Jatkar points to Europe and Africa as an example.

"If you look at Europe, it has a larger gross market in say this year of financial year 2026, while Africa generated higher net export earnings for India. It shows why market selection must go beyond the headline of market size."

The criteria therefore extend beyond demand. A company has to assess whether its products fit the market, whether it can navigate its regulatory system and whether it has the commercial infrastructure to build a sustainable presence.

The capacity that is freed up using that very same US approval will enable us to enter markets which were earlier not being either served or either they were not being approached itself

Dharmesh Kharwar
Jt Secretary, FPME

The opportunity is not about choosing America or the rest of the world. It is about building the science, quality, regulatory capabilities and partnerships to serve both effectively

Dr Uday Harle
CEO, Shilpa Biologicals

Beyond the familiar coast

That makes it difficult to identify one country as a replacement to the US. Europe offers scale but is fragmented across markets and pricing systems. Africa brings population and healthcare needs. ASEAN offers proximity and growing healthcare demand, while Latin America provides further diversification. The Middle East is linked to healthcare investment and localisation, while Japan presents a longer-term opportunity for companies prepared to meet its regulatory requirements.

"So, the point I'm trying to make is, these are different opportunities for the Indian industry, and I do not see choosing one upon the other," concludes Jatkar.

The decision also depends on the company's starting point. Dharmesh Kharwar, Joint Secretary, FPME; distinguishes between entering a new market and expanding an existing presence. Approvals, dossiers, infrastructure and reference-country requirements can shape the regulatory pathway, while the commercial model depends on whether a company works through a distributor, importer, local partner or its own sales force.

For Jain, the focus should be on the Global South, particularly ASEAN, Africa and Latin America, with Brazil as a key market within the latter.

The opportunity, however, is not simply about competing on price. Jain argues that India's experience in regulated markets has created credibility that can support a broader role.

"But they (other countries) are not looking for cheaper medicines. They are looking for reliable supply, regulatory credibility, as I said earlier, India has such an enormous amount of regulatory credibility due to US business, technology partnerships, and increasingly local manufacturing."

Therefore as Jain highlights, "our next export strategy cannot be sell more generics to more countries, it has to be build deeper healthcare partnership with more countries."

For Shilpa Biologicals, that portfolio already extends across Europe, Japan, Latin America, the GCC and Middle East, ASEAN, Australia, Canada and Africa. Harle points to healthcare modernisation in the GCC, increasing biologics adoption in Latin America and demand for advanced therapies across Asia, with partnerships already developing across these regions.

"So the opportunity beyond America is not theoretical — it is already developing," he confirms.

Diversification is already taking shape

The idea of a diversified portfolio is also visible in the experience of companies that have had to rebalance their export portfolios. Joshi points to the loss of US revenue alongside growth in other regions.

"Last year, we diversified basically because we lost approximately 1 billion of revenue from the US. There was a big growth of 9 per cent."

Latin America, particularly Brazil, was among the markets that recorded growth.

"But then parallelly, we have a double digit growth in certain Latin American market, in particular Brazil, I would say. We have grown by 17 to 21 per cent in all of Latin America. And particularly Brazil, if you talk, about 21 per cent growth, was registered."

Europe remains another significant part of the export portfolio.

"And in parallel to Brazil, then Europe still stands tall as a partner. Approximately more than $6 billion of pharmaceuticals to Europe, and which is growing again with a rate of 14 per cent to 15 per cent." Joshi adds.

He also points to the recovery of some African markets that had lost momentum.

"Plus, certain African markets, which we lost to this issue of cough syrup, the trust was lost. I think we have regained all those markets and we see now a double digit growth in same continent where we were losing earlier."

For Amit Patni, Co-founder and Chairman of Nirvana Venture Advisors and Founder of Raay Investments, whose company is building its international business, the approach is centred on markets where the route to entry and portfolio fit make sense rather than simply pursuing the largest markets. "In the international business as strategy, We aren't chasing the biggest markets rather focusing on the emerging markets or some of them call it as ROW markets. Here we chase the ones where the registration pathway is fastest and where our therapeutic categories fill a real gap."

His approach takes into account regulatory predictability, the quality of distribution partners, therapeutic gaps, currency and payment stability, and the structure of institutional purchasing.

The broader strategy is to avoid replacing one concentration with another.

"As our growth strategy, We build a portfolio of markets the same way we build a therapeutic portfolio — so no single regulatory regime or currency bloc or trade barrier can take out our revenue base."

But a portfolio of markets alone does not create a viable international business. Companies still need to convert that geographical spread into businesses that can sustain themselves.

From approval to business

For companies entering new markets, securing regulatory approval is only the beginning. Kharwar points to instances where companies have spent years registering products without achieving the sales they had expected.

"There are some examples where companies have spent, 24 to 36 months and even more on registrations, spend a lot of money trying to get their long list of portfolio products thinking these are niche therapies or mass therapies. But then there is absolutely actually no sales happening to the quantum of which there was expectation of."

The issue, he argues, is treating market entry primarily as a regulatory exercise. Once approvals are secured, companies still need to decide who will lead the operation, how products will be priced, how much working capital is required and how the business will manage local credit cycles and tender dependence.

"The real solution lies in the capital allocation and the entire business planning post the registration and the approval of these products."

Kharwar estimates that the regulatory and quality component represents a smaller share of the overall commercial planning.

"So my thumb rule is that the regulatory part and the quality part is just about 20 per cent of your cost of that business planning. But 80 per cent would be actually sales, marketing, distribution and a credit cycle capital allocation."

For younger companies, there is an additional hurdle: establishing trust before there is a track record. Patni highlights that, "For a young company, the barriers are less about product and business offerings but more about trust and infrastructure. Everyone wants to avoid to be a first customer."

Patni's approach is to build credibility through experienced international business development leadership and face-to-face engagement at trade shows, while positioning the company as 'R&D-led, partner-executed' rather than overstating the infrastructure it owns.

The financial equation also affects the pace of expansion. Registration fees, dossier licensing, samples and other market-entry costs begin accumulating before revenue starts flowing, while distributor payment cycles can extend for months. For a young company, that makes the choice of market and partner as important as the choice of product.

This also changes the role of partnerships. Joshi argues that geopolitical uncertainty makes operating in isolation less practical. "It's the time of collaboration. And we need to know our capabilities, our differentiators and our benefits for the customer or a consumer."

For Kharwar, that collaboration can extend beyond conventional distribution into local manufacturing, business set-ups and government-to-government projects.

"The key should be that we should be the first preferred choice partner for any local manufacturing, any business setup, any innovation, as compared to anyone else."

Jain predicts this shift in the Global South. Rather than reproducing the traditional model of manufacturing in India and selling through distributors, he argues that companies will increasingly need to work with local partners across functions.

"I think that we should be looking at this next business model is how we can partner on the technology side, how we can partner on the formulation development, regulatory capability, manufacturing, local partnership and overall, what we should be looking at is a long-term healthcare platform."

The emerging model is therefore more complex than simply registering products in more countries. It involves choosing where to invest directly, where to work with partners and where Indian manufacturing and capabilities can be combined with local infrastructure.

The road to $120 billion

Five years from now, the measure of India's global pharma footprint may not be how many markets it serves, but what it contributes to each of them.

The IPA has set a target of a $120 billion industry by 2030. Reaching it will require both continued generic volumes and greater participation in higher-value products and capabilities. Joshi sees both elements as necessary, with the next phase requiring a combination of volume and value.

While generic exports will continue to drive volumes, higher-value segments could provide the next source of growth. Kharwar sees particular potential in large molecules. "The number is not aspirational. It's doable. And I would like to put it a little bit more granularly that I would say that the opportunity lies in the large molecules." He states it confidently.

For Jatkar, the change is also about the role India plays in global healthcare.

"Our aim is also to move from being a major supplier to being a trusted global partner, delivering quality and affordable medicines, someone who is driving innovation and keeping patient welfare at the centre."

Overall, she distils the ambition into a simple operating principle: "These companies will have to understand locally and they will have to execute consistently. So think globally, understand locally and execute consistently."

neha.aathavale@expressindia.com
nehaaathavale75@gmail.com

India's pharma exports by region (FY 2024–25)

Region / Economic Zone	Estimated Share (%)	Approximate Value (USD Billion)	Regulatory / Market Profile
North America	~34.0% to 35.5%	$10.51 Billion	Highly Regulated Market
Europe	~19.5% to 21.0%	$6.15 Billion	Highly Regulated / Semi-Regulated
Africa	~17.0% to 18.5%	$5.33 Billion	High Volume Emerging Market
Latin America & Caribbean (LAC)	~7.0% to 8.2%	$2.28 Billion	High Growth Emerging Market
ASEAN & South Asia	~6.5% to 7.5%	$2.13 Billion	Traditional Regional Market
Middle East / West Asia	~4.5% to 5.5%	$1.52 Billion	Emerging Market
CIS & Baltics (Post-Soviet)	~4.0% to 4.8%	$1.34 Billion	Non-Traditional Market
Rest of the World / Oceania	~1.5% to 2.5%	$1.21 Billion	Mixed Trade Zone

Sources:
DoP (Dept. of Pharmaceuticals, Ministry of Chemicals & Fertilizers): Sector metrics from the DoP Annual Report and cluster tracking.
PHARMEXCIL (Pharma Exports Promotion Council): Export data under the Ministry of Commerce via the PHARMEXCIL Statistical Handbook.
PIB / Ministry of Commerce: Official trade performance releases and Economic Survey evaluations.

India pharma sets its sights on innovation

Industry leaders, scientists and technology providers came together at the **Bengaluru Pharma Summit** to discuss how India can move from volume and cost leadership towards innovation and value creation, reports **Kalyani Sharma**

Lamp lighting ceremony: (L-R) Dr Rhonda Duffy, COO, Biocon; Mr Suresh Pattathil, MD & GM, AbbVie India; Dr Villoo Morawala Patell, Founder, Avesthagen and Avestagenome Project International; Dr Murali Ramachandra, CEO, Aurigene Oncology; Dr Mahesh Bhalgat, CEO and Founder, AAPM Therapeutics and Mr Henil Doshi, Director, Pioma Chemicals

India's pharma industry is known across the world for the volume of medicines it makes and the cost at which it makes them. The question now is how to build on that base and move towards original science and higher-value work.

That question ran through Bengaluru Pharma Summit 2026, organised by Express Pharma at The Chancery Pavilion, Bengaluru, on 25 August. The summit was held under the theme India Pharma Rising: Competing in a New Global Order. Sessions ranged from biologics quality control and drug delivery to cleanroom practices, with three panels on the innovation network behind a molecule, the biopharma pivot and the rise of global capability centres (GCCs) in Indian pharma.

The day began with a welcome address from Express Pharma and a lamp lighting ceremony, attended by Henil Doshi, Director, Pioma Chemicals; Suresh Pattathil, MD & GM, AbbVie India; Dr Villoo Morawala Patell, Founder, Avesthagen and Avestagenome Project International; Dr Rhonda Duffy, COO, Biocon; Dr Murali Ramachandra, CEO, Aurigene Oncology and Dr Mahesh Bhalgat, CEO and Founder, AAPM Therapeutics.

Defining India's next global edge

The opening Leadership Lens session, on 'Defining India's next global edge', was moderated by Suresh Pattathil. The panel featured Dr Villoo Morawala Patell; Dr Rhonda Duffy and Dr Murali Ramachandra.

The discussion began with the shift the industry itself needs to make: from volume and cost leadership towards innovation, originality and value creation. Speakers pointed to India's genetic diversity and population data as a chance to discover novel drug targets, molecules and precision therapies. Cancer, diabetes, rare diseases and antimicrobial resistance were named as areas where India can build leadership in innovative therapeutics.

Taking innovations from discovery to market will need greater risk capital, long-term funding and stronger collaboration between industry, academia and government, the panel said. Faster regulatory processes, ease of doing business and stronger IP and data protection will also matter if India is to compete globally on innovation.

A cellulose excipient built for consistency

Henil Doshi presented Hydrocel, the company's multi-functional cellulose technology for formulators. Doshi said a good excipient reduces development time, while a great one reduces development risk, and that Hydrocel was designed with this philosophy in mind.

He said Hydrocel is engineered for reproducibility and built for compliance, and designed with drug release in mind. Made from wood pulp, it

L-R: Mr Suresh Pattathil, MD & GM, AbbVie India (MODERATOR); Dr Villoo Morawala Patell, Founder, Avesthagen and Avestagenome Project International; Dr Rhonda Duffy, COO, Biocon • Dr Murali Ramachandra, CEO, Aurigene Oncology

Mr Vasudevan (Vasu) Ramanujam, Global Business Head, Innovation Acceleration Services, UST

Henil Doshi, Director, Pioma Chemicals

Dr Sundaram Palaniswamy, Senior Global Product Manager – Analytical Chemistry, Merck Lifescience

Krutik Prajapati, Manager (Techno Commercial), Vikram Thermo (India)

Dr Parthasarathy Sampathkumar, Head Group - COE, Biocon

Mr Prashanth Bajaj, Business Unit Director, Lindstrom Services India

Dr Pravin Mhapankar, Director, Thermolab Scientific Equipments

has higher fibre strength and a uniform degree of polymerisation, which gives consistent functional performance, he added.

Quality control for biologics and biosimilars

Dr Sundaram Palaniswamy, Senior Global Product Manager - Analytical Chemistry, Merck Lifescience, spoke on the analytical characterisation of critical quality attributes (CQAs) in biologics. He said Merck and Supelco cover the entire large molecule quality control pipeline, from sample preparation to reference standards, under one roof.

Palaniswamy noted that biosimilar approval pathways differ by region, though both the US and the EU require quality, non-clinical and clinical comparability data against the originator. For India's biosimilar push, Merck offers on-site support, trial samples and regulatory documentation for CDSCO, FDA and EMA submissions, he said.

Controlling drug release with polymer combinations

Krutik Prajapati, Manager (Techno Commercial), Vikram Thermo (India), spoke on drug release modulation through DRUGCOAT RSPO/RLPO. He explained that DRUGCOAT RL and RS polymers can be used as binding agents to modulate drug release, and that combining the two gives better control than using either alone.

Drug release varies inversely with polymer concen-

L-R: Dr Maneesh Paul. S.,M.Sc., Ph.D., FIDSA; CEO, Microvioma (MODERATOR); Kavitha Iyer Rodrigues, Founder & CEO, Zumutor Biologics; Dr Anandkrishna Kulkarni, VP & Head-Global Program Office and Operational Excellence, Syngene International; Dr M.S. Vijaykanth, M.Pharm, Ph.D., Sr VP and Head R&D Formulations, OneSource Specialty Pharma; Dr Mohamed Adil, MD, Bangalore Bioinnovation Centre; Dr Rakesh Kumar Bhasin, Head GF R&D, Biocon Pharma; Dr Huzaifa S Choonia, AVP and Head, Drug Substance MSAT, OneSource Specialty Pharma; Dr Shailendra Gaur, Director, Process Science, Aspergen Inc (Cipla and Kemwell's JV)

L-R: Dr Sanjib Banerjee, COO (Biopharma Services), Veeda Lifesciences (MODERATOR); Dr Jayashree Aiyar, CSO, Syngene International; Dr Maloy Ghosh, CSO, Zumutor Biologics; Dr Rajkumar Aland, Assistant VP, Bioplus Life Science; Aditya Viswanath Garimella, Associate Director, Corporate Quality Control, OneSource Specialty Pharma; Dr Amarnath Chatterjee, Head analytical sciences Cipla Biosimilars, Cipla; Dr Subhra Prakash Chakrabarty, Director and Head, Antibody Engineering, Aurigene Oncology

L-R: Dr Mahesh Bhalgat, CEO and Founder, AAPM Therapeutics (MODERATOR); Dr Gursharan Singh, GM - Medical Sciences, Clinical Development, Biocon; Dr Raghavender Gunda, Head-R&D QA, VJ Biosciences; Shrenik Kole, VP and Head Sterile Product Development, Micro Lab; Dr Goutam Pujari, VP, Clinical Research and R&D, Apotex Research; Siddalingaswamy, VP Operations, Zuventus Healthcare Limited (Emcure Group); Dr Nandakumar Sundaramoorthy, Associate VP, OneSource Specialty Pharma; Kesavalu Purushothaman, GM – Formulation Development, Lyrus Life Sciences;

tration, Prajapati said, and the polymer ratio can be optimised based on the solubility and permeability of the drug.

Trust as India's innovation credential

Dr Parthasarathy Sampathkumar, Head Group-COE, Biocon, spoke on 'Beyond the Pharmacy of the World: How India Can Become the World's Most Trusted Innovation Partner'. India can earn that position through a focus on quality and excellence, and through collaboration, he said.

Trust in pharma is not built on occasional excellence, Sampathkumar said. It comes from consistent choices across quality, culture, partnerships across the industry and patient focus. He described innovation as resting on four pillars. The first is frontier science that explores novel targets, and the second is translational R&D that scales discovery into development. The third is platform science across biologics and biosimilars, and the fourth is frugal science that delivers world-class rigour at lower cost.

Loganathan S, AVP, Onesource Biopharma

Turning visibility into operational insight

Vasudevan (Vasu) Ramanujam, Global Business Head, Innovation Acceleration Services, UST, spoke on 'Tale of Two CDMOs: Building Boundless Visibility'. Compliance creates trust, but understanding creates value, he said, calling for a move beyond visibility to real operational insight.

Ramanujam described a capacity framework that explains and recovers productive time by tracking changeovers and sequence gaps, along with batch execution patterns. A second approach, focused on prevention, identifies emerging risk early using signals such as vial density, flow monitoring and congestion at choke points. He said this has already been proven in live restricted access barrier system (RABS) and isolator deployments.

Managing the human barrier in cleanrooms

Prashanth Bajaj, Business Unit Director, Lindstrom Services India, spoke on rethinking cleanroom garment management. Innovation is not only technology, he said, it is accountability.

Bajaj noted that cleanroom garment management is becoming a strategic part of human contamination control. The next level of innovation, he said, is to manage the human barrier scientifically and digitally, end-to-end throughout its lifecycle.

Stability testing across climatic zones

Dr Pravin Mhapankar, Director, Thermolab Scientific Equipments, spoke on 'Empowering Excellence Through Innovation in the Pharmaceutical Industry'. He explained that stability testing helps establish a drug's shelf life and recommended storage conditions by tracking how quality changes with temperature and humidity over time.

ICH stability zones classify regions from temperate to hot and humid, each needing specific test conditions to give accurate, region-relevant results, Mhapankar said. He added that Thermolab has a strong presence across major climatic zones in Asia and globally.

Why CDMOs are moving to the centre

Speaking on 'The strategic shift: Why CDMOs are becoming central to pharma growth', Loganathan S, AVP, OneSource Biopharma, said drug delivery combinations (DDCs) are the fastest-growing CDMO seg-

ment. US DDC sales are rising 16 per cent annually, driven mainly by GLP-1s and biologics, he said.

Loganathan said OneSource offers end-to-end capability, from cell line development through drug device assembly to commercial manufacturing. The company combines strong technical acumen with worldwide quality and regulatory expertise across its manufacturing operations, he added.

From molecule to medicine

The first panel discussion, on 'The new innovation economy: Building the ecosystem behind the molecule', was moderated by Dr Maneesh Paul S, CEO, Microvioma. The panelists were Kavitha Iyer Rodrigues, Founder & CEO, Zumutor Biologics; Dr Anandkrishna Kulkarni, VP & Head-Global Program Office and Operational Excellence, Syngene International; Dr M.S. Vijaykanth, Sr VP and Head R&D Formulations, OneSource Specialty Pharma; Dr Mohamed Adil, MD, Bangalore Bioinnovation Centre; Dr Rakesh Kumar Bhasin, Head GF R&D, Biocon Pharma; Dr Huzaifa S Choonia, AVP and Head, Drug Substance MSAT, OneSource Specialty Pharma; and Dr Shailendra Gaur, Director, Process Science, Aspergen Inc (Cipla and Kemwell's JV).

Panelists said strong programme governance is critical to speeding up innovation, as it brings clear accountability, structured risk assessment and faster go/no-go decisions at each stage of drug development. Startups, they said, should be treated as innovation engines and not as small pharma companies, with CROs and CDMOs providing the expertise, platforms and regulatory support needed to move molecules forward.

The panel identified developability, scalability, regulatory strategy and IP protection as the biggest gaps in taking a molecule to a medicine, and said all four need to be addressed early and in parallel. Technology transfer, they added, must go beyond product performance to ensure commercial reproducibility, with strong process controls, critical process parameters and analytical requirements built into development.

On handoffs across the industry, panelists said a common technology-transfer framework can help, but it must combine a standard core set of information with requirements specific to each modality, whether small molecules, biologics, biosimilars or cell therapies. Standardisation should focus on architecture and format and not on the science, they said, since every molecule, formulation and process is distinct and needs flexibility based on its stage of development and modality.

Looking ahead, the panel said future competitive advantage will depend increasingly on how efficiently knowledge and data are preserved and transferred, and less on who discovers a molecule first. India needs a more integrated and dynamic innovation network that brings together academia, startups, CROs, CDMOs and pharma companies, they said, so that processes stay consistent while there is room for new technologies and modalities.

Can India move from manufacturing to inventing?

The second panel discussion, on 'The biopharma pivot: Can India move from manufacturing medicines to inventing them?', was moderated by Dr Sanjib Banerjee, COO (Biopharma Services), Veeda Lifesciences. It featured Dr Jayashree Aiyar, CSO, Syngene International; Dr Maloy Ghosh, CSO, Zumutor Biologics; Dr Rajkumar Aland, Assistant VP, Bioplus Life Science; Aditya Viswanath Garimella, Associate Director, Corporate Quality Control, OneSource Specialty Pharma; Dr Amarnath Chatterjee, Head, Analytical Sciences, Cipla Biosimilars, Cipla; and Dr Subhra Prakash Chakrabarty, Director and Head, Antibody Engineering, Aurigene Oncology.

The panel said India has the potential to become a global leader in biosimilars and biopharma over the next 10 to 15 years, building on its strong pharmaceutical manufacturing base. To get there, the country needs to move beyond its generics-led model and build stronger capabilities in novel drug discovery, development and innovative biologics.

Startups can speed up innovation by working with CROs and CDMOs through co-development and risk-sharing models, panelists said, rather than spending heavily on their own laboratories and infrastructure. Regulatory reforms, stronger IP policies, closer industry-academia collaboration and better access to advanced technologies were named as critical to an innovation-driven biopharma sector.

On talent, the panel said India needs to develop and retain a highly skilled scientific workforce, including through policies that can bring back Indian scientists with global drug discovery and development experience. On technology bets, it said India should invest across antibody-drug conjugates (ADCs), cell and gene therapies, mRNA and multispecifics rather than back a single modality, as the next major breakthrough cannot be predicted.

Indian pharma companies also need a phased move from generics to innovation, panelists said, balancing existing revenues with higher-risk investments in novel drug discovery through a structured allocation of resources.

How GCCs are changing India pharma

The final panel discussion, 'The Bengaluru Bet: How GCCs are redefining India Pharma Inc', was moderated by Dr Mahesh Bhalgat, CEO and Founder, AAPM Therapeutics. The panel featured Dr Gursharan Singh, GM - Medical Sciences, Clinical Development, Biocon; Dr Raghavender Gunda, Head-R&D QA, VJ Biosciences; Shrenik Kole, VP and Head Sterile Product Development, Micro Labs; Dr Goutam Pujari, VP, Clinical Research and R&D, Apotex Research; Siddalingaswamy, VP Operations, Zuventus Health-care Limited (Emcure Group); Kesavalu Purushothaman, GM - Formulation Development, Lyrus Life Sciences; and Dr Nandakumar Sundaramoorthy, Associate VP, OneSource Specialty Pharma.

Panelists said pharma GCCs in India need to move beyond execution and take ownership of portfolio strategy, clinical development and medical affairs. India's proven strengths in global clinical trials, regulatory approvals and biosimilars, they said, make a strong case for shifting higher-value pharma work from the US and Europe to Indian GCCs. GCCs could potentially deliver 50 to 60 per cent savings in FTE costs while improving efficiency, using India's talent pool and emerging AI capabilities.

Complex R&D activities such as novel formulations, complex injectables and sameness or similarity studies should increasingly be brought into Indian GCCs, the panel said, to move them up the value chain. AI, automation and digitisation are emerging as key enablers across clinical, quality, manufacturing and analytical functions, including automated review, investigations and faster batch release.

GCC talent in India is also taking on global leadership responsibilities, panelists noted, with areas such as clinical development, regulatory strategy and pharmacovigilance being significantly driven from India. The next phase of GCC growth will depend on combining talent with advanced technology, including generative AI, data analytics, computational tools and AI applications in pharma operations. Stronger collaboration between GCCs, pharma companies, startups, academia and institutions such as the IITs and IISc can speed up innovation and help build India into a global pharma centre of excellence, they said.

The way forward

The sessions at Bengaluru Pharma Summit 2026 covered very different ground, from excipients and stability testing to GCCs and biosimilars, yet they pointed the same way. India already has a strong manufacturing base and a proven record in global clinical trials, regulatory approvals and biosimilars. What it needs to build now is the ability to originate new molecules and therapies, and not only to make them at scale.

The requirements named along the way were specific. Companies need a phased move from generics to innovation, balancing current revenues with higher-risk investment in novel drug discovery. Funding has to include more risk capital and long-term money to carry discoveries to market.

On the policy side, speakers called for faster regulatory processes and ease of doing business, along with stronger IP and data protection. Skilled scientific talent has to be developed and retained, including by bringing back Indian scientists with global experience.

Collaboration came up again and again. Startups can work with CROs and CDMOs through co-development and risk-sharing instead of building their own laboratories, and a common technology-transfer framework can make handoffs smoother. GCCs, pharma companies, startups and academia, including institutions such as the IITs and IISc, can work together to speed up innovation. AI, automation and digitisation were seen as enablers across clinical, quality, manufacturing and analytical work, and the panels also said how well knowledge and data are preserved and transferred may matter more than who discovers a molecule first. With the next major breakthrough impossible to predict, the advice was to invest across modalities and not back just one.

The shift from making medicines to inventing them will be gradual, and it will run alongside the existing generics business and not replace it. The summit closed with a vote of thanks, followed by networking high tea.

Kalyani.sharma@expressindia.com
journokalyani@gmail.com

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#BengaluruPharmaSummit

EXPRESS PHARMA WORLD EXPO

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.

India's moment in medicine: Building a world leading cell and gene therapy ecosystem

India is at a turning point in cell and gene therapy, with homegrown CAR-T therapies and growing infrastructure laying the foundation for a globally competitive CGT ecosystem. Immuneel's Qartemi, approved by CDSCO in January 2025, is India's first globally benchmarked CAR-T cell therapy. **Amit Mookim,** CEO, Immuneel Therapeutics, shares his perspective on what India needs to do next to build a world-leading CGT ecosystem

Cell and Gene Therapy (CGT) represents perhaps the most profound shift in medicine since-antibiotics. For patients living with blood cancers, inherited disorders, and rare genetic diseases, these therapies are not incremental improvements - they are the possibility of acure.

India is no longer a bystander in this revolution. But to become one of its defining leaders,we must act with the same clarity of vision that built our pharma and vaccine industries into global forces.

A market whose time has come

The global CGT market stood at approximately $13.9 billion in 2024 and is projected toreach $105.8 billion by 2033, growing at a CAGR of 21.5 per cent. Within Asia-Pacific, the market reached $4.59 billion in 2024 and is forecast to approach $40 billion by 2034. India's own CGT market reached $818 million in 2025 and is expected to nearly triple to $2.7 billion by2034.

The urgency is underscored by our disease burden. India recorded an estimated 1.56 million new cancer cases and 874,000 deaths in 2024, according to a landmark ICMR studypublished in JAMA in August 2025 - with projections of 2.46 million annual cases by 2045.

Blood cancers alone account for approximately 120,000 new diagnoses and over 70,000deaths per year. For the majority of patients who relapse after standard treatment,advanced cell therapies represent the only realistic hope for remission.

China's acceleration was powered not by scientific talent alone - which India equally possesses - but by infrastructure investment ahead of demand, faster regulatory pathways,and dedicated regional manufacturing clusters. India cannot afford another decade as a spectator

The question before us is not whether India needs a CGT ecosystem. It is whether we will build one worthy of this moment.

What China's rise should teach us

No country offers a more instructive mirror than China. Through deliberate government-aligned investment, China had approximately double the CGT clinical studies of the United States in 2024, with new trial registrations rising 42 per cent year-on-year. Its NMPA approved10 CGT products through 2024, including six CAR-T therapies. Investigator-initiated CGT trials in China enrolled over 30,000 participants since 2018 - twice the number of typical regulated trials - dramatically de-risking the pipeline. China's CGT market reached $2.5billion in 2025, growing at a CAGR of 276 per cent from 2020.

China's acceleration was powered not by scientific talent alone - which India equally possesses - but by infrastructure investment ahead of demand, faster regulatory pathways,and dedicated regional manufacturing clusters. India cannot afford another decade as a spectator.

India's proof points are already here

What is often under appreciated is how much India has already achieved.

In October 2023, Nex CAR19 - developed by Immuno ACT, incubated at IIT Bombay in collaboration with Tata Memorial Centre - became India's first indigenously developed CAR-T cell therapy to receive CDSCO approval. The decade-long effort, guided in part by the US National Cancer Institute, produced a humanised CD19-targeted therapy demonstrating a67 per cent objective response rate in clinical trials, with complete remission in approximately half of patients. It is available at roughly ₹40 lakh, compared to ₹5 crore or more abroad.

In January 2025, Qartemi (varnimcabtagene autoleucel), developed by Immuneel Therapeutics and licensed from Hospital Clínic de Barcelona, became India's second approved CAR-T therapy and the first benchmarked to global standards.

The IMAGINE trial, conducted across hospitals in India, demonstrated an 83.3 per cent overall response rate at90 days in patients with relapsed or refractory B-cell Non-Hodgkin Lymphoma. Priced between ₹35 and ₹50 lakh, Qartemi brings a globally competitive, potentially life-saving therapy within reach of Indian patients for the first time.

On the infrastructure front, Bharat Biotech inaugurated India's first vertically integrated CGT and viral vector production facility at Genome Valley, Hyderabad in March 2025, with a phased investment of $75 million - producing GMP-grade AAV, lentivirus, and adenovirusvectors, with five pipeline products targeting launches by 2028. CSIR-IGIB has simultaneously executed a technology transfer agreement with the Serum Institute of India for

clinical translation of novel gene therapies.

India's bio-economy has grown from $10 billion in 2014 to over $130 billion in 2024,projected to reach $300 billion by 2030. The National Biopharma Mission has supported nearly 10,000 biotech startups in developing vaccines, cell therapies, and bio therapeutics.

These are not isolated achievements. They are the early proof points of an ecosystem coming together.

The pillars of leadership

Building on this foundation requires alignment across five dimensions.

Manufacturing as a strategic asset. The global CGT manufacturing market is expected to grow from $5.9 billion in 2025 to $26.6 billion by 2035. India's advantage in cost-competitive pharma manufacturing - proven through vaccines and biosimilars - must now extend into viral vector production, cell processing, and gene-editing platforms. Domestic manufacturing is the single most important lever for making these therapies accessible at scale.

Smarter regulation. The Bio E3 Policy, approved by the Union Cabinet in August 2024,explicitly identifies CGT as a strategic priority and positions India as a global bio-manufacturing hub. Regulatory bodies have issued national guidelines for CRISPR-based therapies. The next step is dedicated CGT review pathways, specialised assessment teams, and accelerated approvals for breakthrough therapies - not lighter regulation, but more predictable, science-driven oversight.

Translational funding. India's greatest unresolved gap remains the valley of death between discovery and clinical development. A dedicated National CGT Translation Fund - covering vector development, preclinical validation, process development, and early clinical trials -would catalyse an indigenous pipeline that neither industry nor academia can build alone.

Talent at scale. India currently lacks sufficient CGT scientists, viral vector engineers, GMP manufacturing specialists, and trained clinicians. Co-designed training programs between universities, industry, and government - a national talent mission for advanced therapies -would be among our most durable competitive advantages.

Affordability as a global differentiator. The most advanced CGT products today cost between $300,000 and $700,000 in the US - sums that place them beyond reach for the vast majority of humanity. India has repeatedly demonstrated that world-class innovation and affordability are not mutually exclusive.

If we develop scalablemanufacturing and indigenous platforms, we can become the first major nation to make advanced CGT accessible to significantly larger patient populations - not just domestically,but across the developing world.

The ecosystem imperative

Two CGT approvals in eighteen months. A $75 million manufacturing facility operational in Hyderabad. An ICMR-backed translational pipeline. A bio-economy policy with CGT at its center. The foundation is laid and the infrastructure is rising.

What remains is the will to connect these elements into a coherent national strategy - and the speed to act before the window closes.

India's pharma industry did not become the world's pharmacy by accident. It was built through deliberate policy, bold public investment, and the willingness of entrepreneurs to take risks that no one else was prepared to take. The same formula applies here.

India does not need to merely participate in the Cell & Gene Therapy revolution. We have the talent, the institutional depth, the manufacturing expertise, and - if we choose - the ambition to lead it.

The next decade will write the answer.

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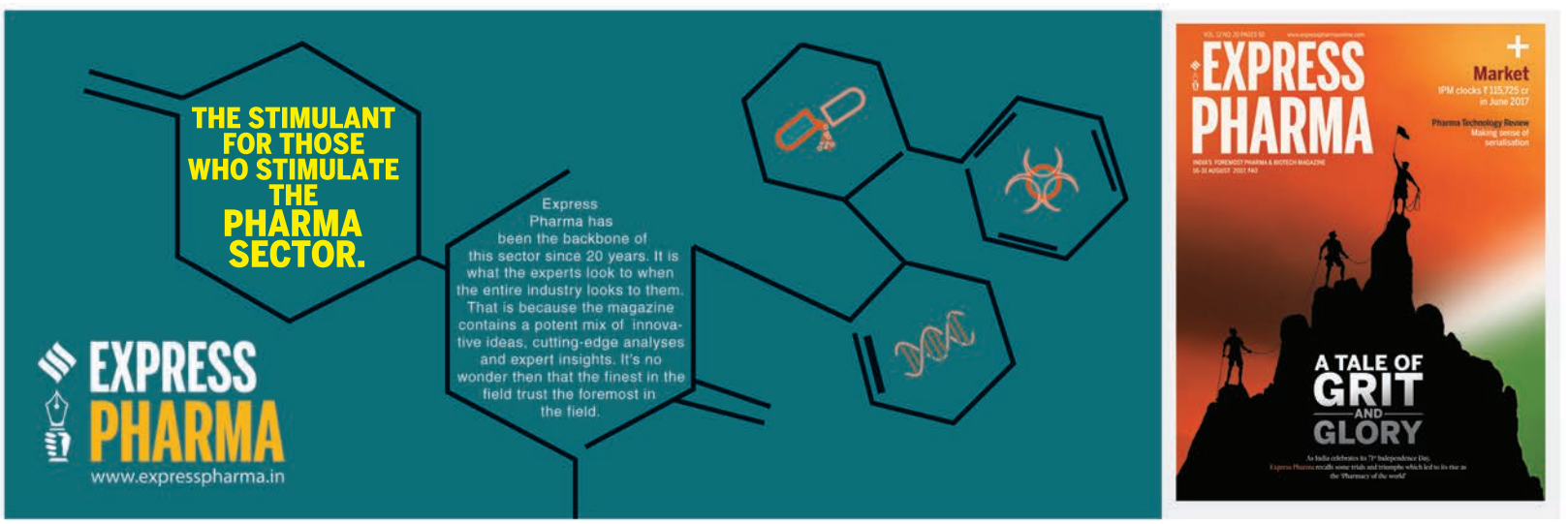

Pharmacovigilance systems for India: What companies need to have in place

Dr J Vijay Venkatraman, Managing Director & CEO, Oviya MedSafe examines the evolving pharmacovigilance expectations in India and highlights the systems, processes and accountability companies need to demonstrate regulatory readiness

The 3 June 2026 CDSCO circular reiterating the requirement for an effective pharmacovigilance system under Paragraph 6.11 of Schedule M of the Drugs and Cosmetics Rules has brought a fundamental question into sharper focus for pharmaceutical and biotechnology companies in India: what must an organisation actually have in place to demonstrate a functioning pharmacovigilance system?

The answer extends well beyond adverse event reporting, timelines and regulatory submissions. A company must be able to show how safety information is identified across the organisation, transferred to pharmacovigilance personnel, scientifically evaluated, reported within applicable timelines, documented, quality-controlled and kept under effective oversight throughout the product lifecycle.

This question is especially relevant for companies that manufacture, import or market medicinal products in India. They are expected to ensure that safety information arising from product use can be collected, processed, evaluated and forwarded appropriately. For organisations in which pharmacovigilance has not yet developed into a mature independent function, meeting this expectation requires a deliberate review of responsibilities, procedures, interfaces and regulatory preparedness.

For many companies, the immediate task is therefore to determine whether their present arrangements can reliably capture safety information, support timely regulatory reporting and withstand regulatory scrutiny.

A pharmacovigilance system is not merely a database, a reporting mailbox or a set of SOPs kept ready for inspection. It is an organisational arrangement through which a company identifies where safety information may arise, ensures that such information reaches the right people, evaluates it scientifically, reports it when required and continuously reviews whether the system is working as intended.

In simple terms, if a company places a medicinal product in the market, it must also have a mechanism to listen to what happens to patients after that product is used. The question then becomes how that information reaches the organisation and what happens to it once it arrives.

Pharmacovigilance begins long before the first case is processed

In many companies, the first instinct is to think of pharmacovigilance as something that begins when an adverse event report reaches the PV team. In practice, the system has to begin much earlier. It begins by asking a simple question: from where can safety information reach the company?

A doctor may mention a suspected adverse reaction to a medical representative. A patient may call the company helpline. A product quality complaint may contain a medical outcome. A market research or patient support programme may reveal lack of efficacy, misuse, overdose, pregnancy exposure, or another medically relevant situation. A literature article may report an adverse event involving a marketed product. Even a company's own social media channel may become a source of safety information.

The challenge is that safety information does not always arrive in technical language. Reporters may use words such as side effect, problem, complaint, not working, reaction, intolerance, or many other expressions. Therefore, a company must train its people to recognise potential safety information and forward it appropriately, even when the information is incomplete or indirect.

This is why sources of safety information must be identified, owned, monitored and periodically assessed for effectiveness. Telephone calls, email inboxes, medical information channels, quality complaints, websites, social media, commercial teams and contractual partners all need clear ownership. Recording every phone call may not be mandatory, but relevant information received during a call must be captured accurately, documented promptly and made retrievable. The organisation should also be able to demonstrate that these channels are actually working as intended and that safety information is reaching pharmacovigilance personnel appropriately.

One of the most common mistakes organisations make is assuming that pharmacovigilance is owned exclusively by the PV department. Because potential safety information can enter through many channels, the pharmacovigilance system must extend across the organisation. Commercial teams, medical information personnel, quality teams, customer service functions, distributors and business partners may receive relevant information before the pharmacovigilance team does. Each function must therefore know what to recognise, how quickly to forward it and who is responsible for ensuring that it reaches the appropriate pharmacovigilance personnel.

Defining ownership and accountability

Once the routes through which safety information may enter the company are understood, the next requirement is clear accountability for ensuring that the information is acted upon. Every organisation should clearly define:

- Who is responsible for oversight of pharmacovigilance activities?
- How are safety decisions made?
- How are responsibilities delegated?
- How are pharmacovigilance obligations communicated internally?

In the Indian context, particular attention should be paid to the responsibilities of the Marketing Authorisation Holder (MAH) and the Pharmacovigilance Officer in Charge (PVOIC).

While specific activities may be outsourced, accountability cannot.

This is an important principle that companies should remember when developing their pharmacovigilance framework.

In India, accountability should be assigned based on the relevant licence and regulatory responsibility for the product, rather than assumed to rest simply with the company that manufactures or markets it. Depending on the business model, this may involve a manufacturer, importer, loan licensee, contract manufacturer, marketer or another entity with defined regulatory responsibility. Where different companies manufacture and market the product, their respective pharmacovigilance obligations must be clearly understood and documented so that safety information is not lost between commercial and regu-

latory arrangements.

This determination should be made explicitly when the pharmacovigilance system is designed, because uncertainty over which entity owns regulatory reporting, oversight and safety-data exchange can create gaps precisely when a case requires prompt action.

The PVOIC also requires careful attention. The role should not be treated as a nominal appointment. According to the Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products, the PVOIC should be a medical or pharmacy professional trained in the collection and analysis of adverse event reports. Where the PVOIC is a pharmacy professional, there should be appropriate access to a medically qualified person for causality assessment when required.

Beyond regulatory compliance, the PVOIC frequently serves as the focal point for coordination between safety information sources, management, quality systems and regulatory reporting activities. As organisations grow, the effectiveness of this role often influences the effectiveness of the broader pharmacovigilance system.

Why SOPs alone do not constitute a pharmacovigilance system

Clear accountability must then be translated into documented procedures that explain how pharmacovigilance activities will be performed in practice.

SOPs are written to be followed, not to be filed. They should specify responsibilities, escalation pathways, reporting timelines, decision-making processes, communication requirements and quality activities clearly enough for personnel to follow them consistently.

For companies operating across multiple countries or as affiliates of global organisations, company-wide procedures may need to be supplemented by local work instructions. This helps ensure that corporate requirements and India-specific regulatory obligations are both addressed without creating avoidable conflicts or procedural gaps.

A safety database is not a pharmacovigilance system

With responsibilities and procedures defined, the organisation needs an appropriate means of recording, managing, tracking and reporting adverse event information. This is where a safety database becomes important.

A safety database serves as the system of record for adverse event information and supports case management, reporting, tracking and oversight.

A safety database is necessary, but purchasing one does not by itself create a functioning pharmacovigilance system. Its effectiveness depends on sound governance, defined processes, trained personnel, data quality and management oversight.

The effectiveness of a database ultimately depends upon:

- Data quality
- Defined processes
- Trained personnel
- Quality oversight
- Management commitment

Technology is an enabler, not a substitute for governance.

Documentation and inspection readiness

As these arrangements become operational, the company must be able to document how the pharmacovigilance system is organised, how responsibilities are fulfilled and how performance is monitored.

The Pharmacovigilance System Master File (PSMF) serves as a comprehensive description of the pharmacovigilance system and provides regulators with an overview of how pharmacovigilance activities are organised and managed. It brings together key elements of the system, including the organisation and responsibilities, sources of safety information, relevant computerised systems and databases, pharmacovigilance processes, system performance and the quality system.

Alongside the PSMF, organisations should ensure that training records, quality records, reconciliation activities, vendor oversight documentation, and procedural controls remain current and consistently maintained.

Inspection readiness is not a separate exercise undertaken in the weeks before an inspection; it is the natural outcome of a well-designed pharmacovigilance system that has been documented, monitored and maintained consistently over time.

Outsourcing activities is not the same as outsourcing accountability

The same principles of defined responsibility, documented processes and oversight apply when pharmacovigilance activities are outsourced. External support can provide specialised expertise and scalable capacity, but it does not transfer the organisation's regulatory accountability for the product.

Case processing, literature monitoring, aggregate reporting, medical review and other pharmacovigilance activities may be delegated to qualified service providers, but accountability remains with the organisation responsible for the product.

Effective vendor oversight, performance monitoring, quality agreements and governance structures are essential elements of any outsourced pharmacovigilance model. Outsourcing should therefore be viewed as a management responsibility rather than merely a procurement exercise, with ongoing oversight remaining just as important as vendor selection.

Where multiple parties are involved in manufacturing, marketing, distribution or licensing arrangements, pharmacovigilance agreements or safety data exchange agreements become especially important. These documents should specify how safety information will move between parties, timelines for exchange, points of contact, escalation pathways, and responsibility for regulatory reporting.

Sustaining the pharmacovigilance system

Establishing the system is only the first step; the company must also ensure that it continues to operate effectively as products, partnerships and business volumes change.

This also requires appropriately trained and competent personnel; competence should be demonstrated rather than assumed.

A robust quality framework supports continuous improvement through:

- Internal audits
- Deviation management
- CAPA processes
- Training programmes
- Vendor oversight
- Periodic review of system performance

Without these elements, even well-designed systems may gradually deteriorate over time. Quality management helps the company maintain regulatory compliance by identifying weaknesses, correcting deviations and ensuring that the pharmacovigilance system continues to perform as intended.

Building before it becomes urgent

Perhaps the most important lesson for organisations is that pharmacovigilance systems should be developed before they become an immediate regulatory necessity.

Many organisations begin investing in pharmacovigilance only after inspections, partner requirements or regulatory expectations create immediate pressure. Systems established reactively can often address short-term compliance needs, but systems built proactively are typically more sustainable and effective over the long term.

As product portfolios expand, distribution networks grow, partnerships evolve and market exposure increases, pharmacovigilance requirements become more complex.

Smaller organisations do not necessarily require large pharmacovigilance departments or complex infrastructures. However, even a small system should contain all of the essential elements required for effective operation. It is often better to build a complete system at a modest scale than an incomplete system at a larger scale.

Technology should support this system rather than define it. Organisations could use technology where it genuinely improves efficiency, quality or control, including newer tools such as artificial intelligence. However, such tools should be adopted to solve clearly identified business or compliance challenges, not merely because they are available.

Pharmacovigilance should therefore be viewed not merely as a compliance obligation, but as an essential component of patient safety, product stewardship and responsible business practice.

Taken together, the minimum practical expectation is that a company can answer seven questions clearly:

1. Who is accountable for pharmacovigilance?
2. Where can safety information enter the organisation?
3. How is it transferred and assessed?
4. Which procedures and tools govern the work?
5. How are partners and vendors controlled?
6. What records demonstrate that the system is operating?
7. How are deficiencies identified and corrected?

If any answer is unclear, the pharmacovigilance system is not yet fully established.

Conclusion

For pharmaceutical and biotechnology companies in India, the immediate priority is to establish a complete and workable pharmacovigilance system that meets regulatory expectations throughout the product lifecycle.

The regulatory requirement is clear, but its purpose is equally important: every company that places a medicinal product on the market must be able to understand, monitor and continuously evaluate its benefit-risk profile. Behind every adverse event report, product complaint, signal or safety concern is a patient, and a functioning pharmacovigilance system is how the company fulfils that responsibility.

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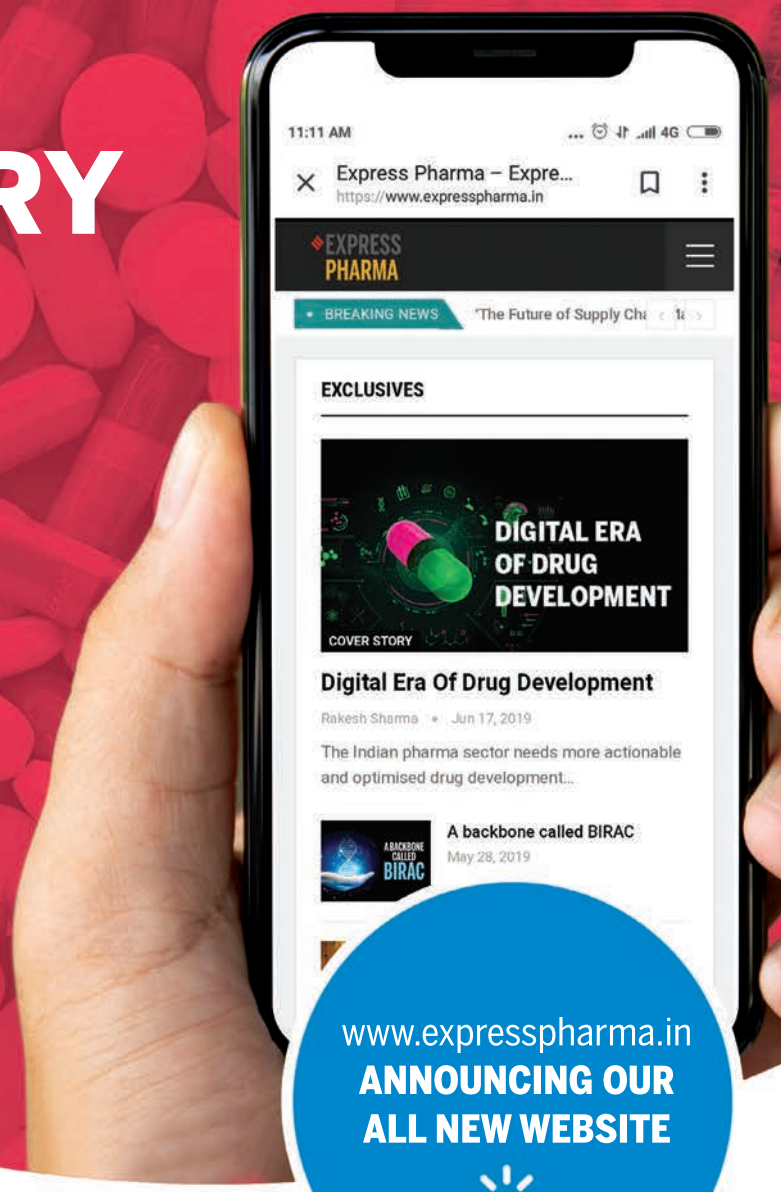

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Ending the generic prescribing stalemate

India shelved its generic-prescribing mandate because prescribers could not reliably verify the quality status of the product ultimately dispensed. Three changes using existing regulatory tools could reduce that uncertainty, explains **Dr Sowmya Josyula,** Founder, Kushala Health

In August 2023, the National Medical Commission notified the Registered Medical Practitioner (Professional Conduct) Regulations, requiring doctors to prescribe by generic name and attaching penalties of up to suspension of licence. Three weeks later, the NMC placed the regulations in abeyance. They remain in abeyance, while the 2002 Indian Medical Council regulations continue to govern professional conduct.

The objection came from both sides of the prescription. The Indian Medical Association and the Indian Pharmaceutical Alliance argued that mandatory generic prescribing was not feasible because the quality of unbranded generics could not be assured.

That was neither obstruction nor an unanswerable truth. It was an empirical claim, and it identified a real structural gap.

India's quality-assurance system is organised primarily around the factory. Revised Schedule M raised GMP standards; state licensing authorities have been directed to inspect against those standards and report monthly; and pharmacovigilance obligations now extend across manufacturers and importers. All of this operates upstream.

The prescriber and pharmacist stand downstream, at the counter, without a simple, real-time way to establish whether a specific pack, batch, or manufacturing site is linked to a current quality alert or regulatory restriction.

The contaminated cough-syrup deaths in 2025 made the consequences of that gap unmistakable. The regulatory response included licence cancellations, prosecutions, intensified inspections, and the removal of syrups from the Schedule K exemption on 9 June 2026. Those actions were important, but they came after the harm and did not change what a pharmacist can verify about the pack in hand.

The data exists. So does the identifier

CDSCO publishes monthly alerts for drugs declared Not of Standard Quality. The listings include the product name, batch number, manufacturer, dates of manufacture and expiry, nature of the failure, and testing laboratory.

The official May 2026 NSQ listing identified 157 samples. A separate spurious-drug alert listed one product. These alerts covered products across therapeutic areas, including antibiotics, antidiabetics, cardiovascular medicines, and injectables.

This is current, batch-level quality intelligence. Yet it is published in a format that is impractical to consult during routine dispensing.

Separately, Schedule H2 requires a barcode or QR code carrying a unique product-identification code; generic and brand names; manufacturer name and address; batch number; dates of manufacture and expiry; and the manufacturing-licence number. It has applied to the top 300 brands since 1 August 2023.

G.S.R. 506(E), the Drugs (Seventh Amendment) Rules, 2026, notified on 22 June after DTAB consultation, extended this requirement to four therapeutic categories: vaccines; narcotic and psychotropic medicines; anticancer drugs; and antimicrobials. The first three categories are scheduled from 1 July 2027, and antimicrobials from 1 July 2028.

Both sets of information use the same key identifiers: batch number and manufacturing-licence number. One sits on a medicine pack in a shop; the

other sits on a government website. The two are not yet connected in a way that can be used at the counter.

Three changes using existing tools

First, make the NSQ record usable. CDSCO should publish NSQ alerts as a machine-readable and searchable dataset rather than only as monthly documents, indexed by batch number and manufacturing-licence number, with an open application programming interface, or API.

A scan of a Schedule H2 code could then show whether a batch is subject to a current NSQ alert and whether its manufacturing site is under an active, publicly notified regulatory restriction. CDSCO already generates much of this information. Making it searchable is principally a data-publication and engineering task; it requires no new inspections and no additional compliance burden beyond the traceability requirements already being phased in.

The result must return in seconds at the counter—not through another portal that asks a pharmacist to search a PDF while a patient waits.

Second, put boundaries around substitution. Where a pharmacist substitutes a product against a generic prescription, the dispensed batch should not appear in a current NSQ alert. Nor should the product originate from a manufacturing site or licence subject to an active, publicly notified restriction for serious GMP non-compliance. The regulation would need to define which regulatory actions qualify, who maintains the exclusion list, how long exclusion lasts, how a manufacturer re-enters after corrective action, and what safeguards prevent exclusions from creating medicine shortages.

At present, a brand name is often the only constraint a prescriber can place on the product ultimately dispensed. A transparent substitution rule would reduce the need to use a brand as a proxy for safety.

Third, phase generic prescribing by therapeutic class. The NMC should not revive a universal mandate on a fixed date. It should follow the Schedule H2 timetable: first make product identifiers mandatory; then ensure CDSCO has made corresponding batch-level quality data publicly queryable; and only then require generic prescribing in that therapeutic class.

The mandate would follow traceability rather than precede it. That is the inversion missing from the 2023 regulation. It is worth noting that antimicrobials—the class in which prescribing quality is especially important—are scheduled last.

For patients, the benefit is not only lower prices. It is being able to accept a generic prescription without having to trust an opaque chain of substitution.

What this does not solve

This proposal governs dispensing, not prescribing. A prescription can be entirely generic and still be clinically wrong. That problem requires guideline-concordant prescribing, audit and feedback, antimicrobial stewardship, and clinician education.

The proposal would initially reach packaged formulations covered by Schedule H2, not loose dispensing. An NSQ alert is a sample-based signal: the absence of a batch from the list is weaker than its presence on it. The system would not solve counterfeit packaging, diversion, unreported failures, or a pharmacy that ignores the rule.

The legal instrument also requires proper review: whether the Drugs and Cosmetics Act and Rules are the appropriate vehicle for a substitution framework, whether enforcement should be central or state-administered, and how it would interact with existing pharmacy and dispensing regulations.

Build the answer first

The objection raised in 2023 was not that all generics are unsafe. It was that nobody at the counter could reliably tell which product the patient would ultimately receive and whether that product was subject to quality concern. Three years on, the quality data are collected monthly. The identifiers needed to retrieve them are being mandated across four therapeutic categories. The Drugs Rules amendment mechanism is actively being used. What is missing is the connection between these pieces—and building that connection is a smaller undertaking than creating each piece separately.

Generic prescribing failed in 2023 because it was imposed on the prescriber before the system could answer the prescriber's question. This time, the answer should be built first.

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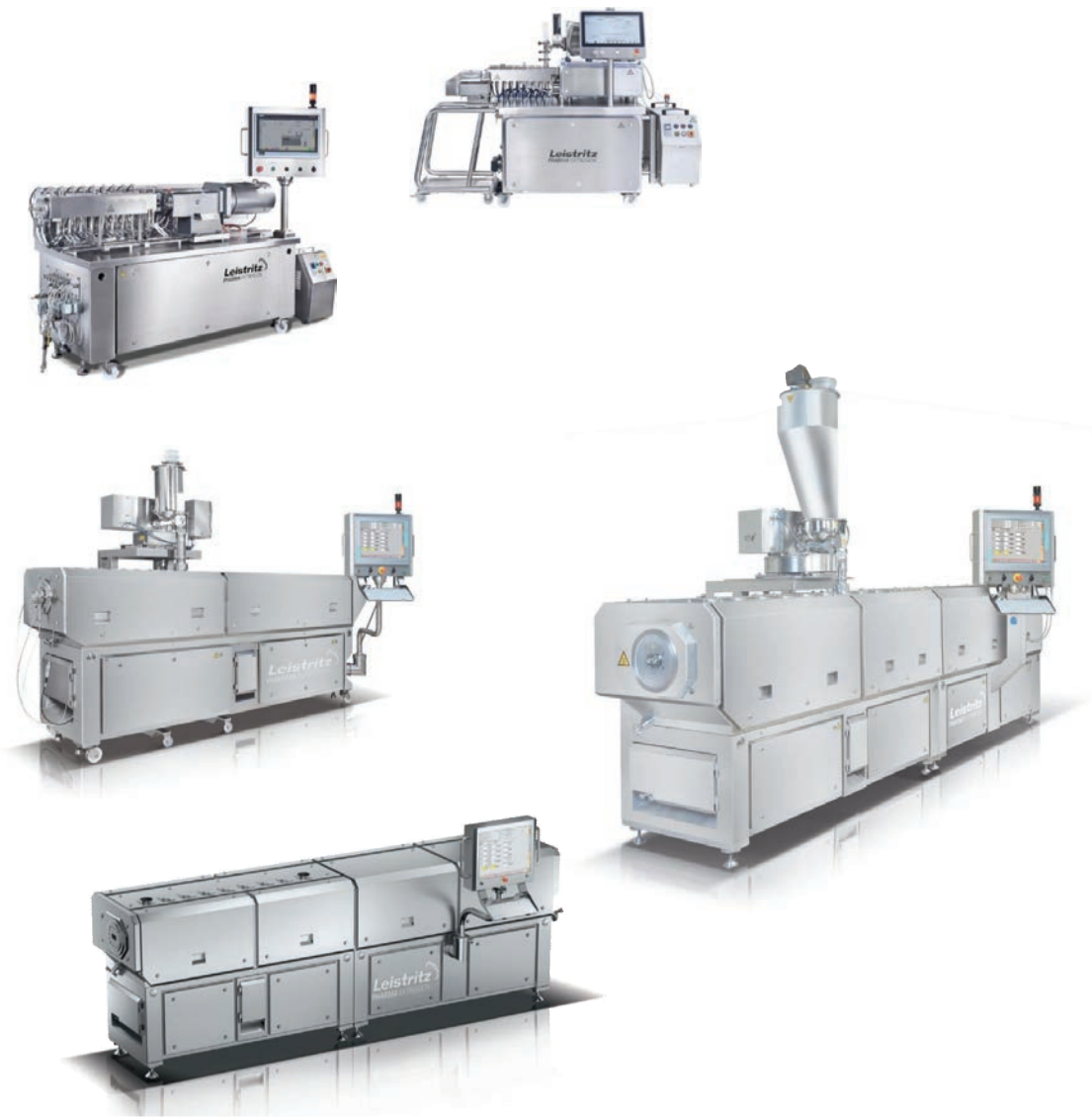

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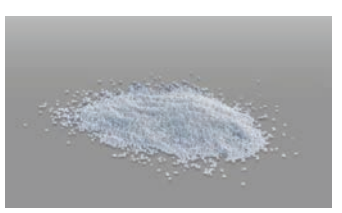

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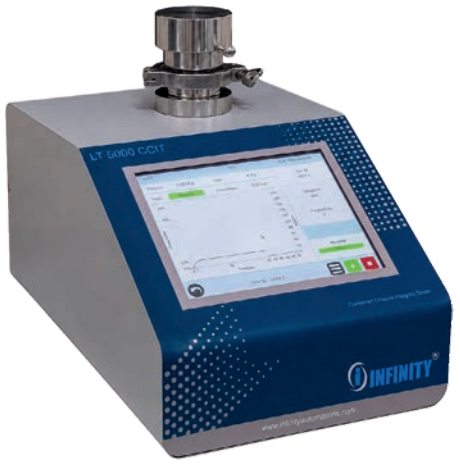

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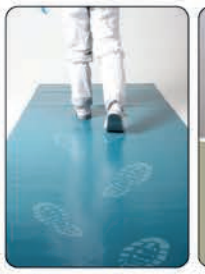
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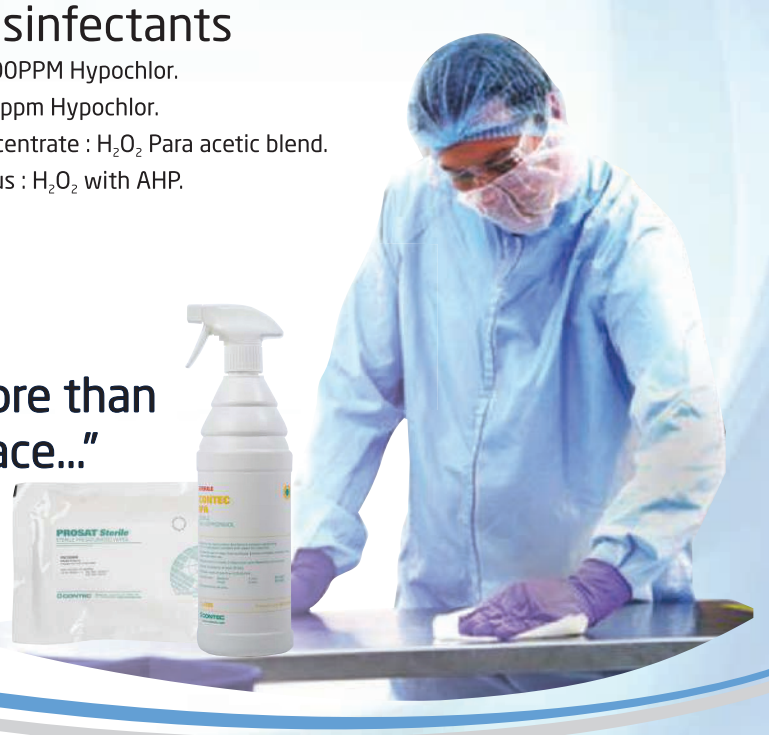

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Advancing biotherapeutic analysis with Avantor® ACE® Exclude SEC columns

Avantor® ACE® Exclude SEC columns support reproducible separation and analysis of proteins, aggregates and other biotherapeutics

In biotherapeutic development, accurate separation of protein monomers and aggregates is critical for ensuring product quality, regulatory compliance, and development efficiency. Size Exclusion Chromatography (SEC) is a widely trusted technique that separates biomolecules based on hydrodynamic size, enabling reliable assessment of protein purity and structural integrity.

The Avantor® ACE® Exclude SEC column has been specifically engineered to support modern analytical workflows by delivering reliable, high-resolution separations across a broad molecular weight range.

Challenges in conventional SEC analysis:

Despite its importance, conventional SEC methods often face limitations such as:

- Inconsistent separation between monomer and aggregates
- Variability between column batches affecting method robustness
- Limited column lifetime under high-throughput conditions
- Secondary interactions requiring high salt concentrations

These challenges can result in increased costs, delayed validation, and reduced confidence in analytical data.

Solution overview:

Avantor® ACE® Exclude SEC columns were developed with features intended to address these limitations through optimised particle and pore technology. With a selectivity range of 100–800 kDa the column demonstrated lot-to-lot reproducibility across tested manufacturing lots. The column is designed to provide consistent performance for monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), and other therapeutic proteins.

Key benefits and value proposition:

Based on internal testing, the Avantor® ACE® Exclude SEC demonstrated:

- Fewer column replacements
- Reduced downtime
- Lower cost per analysis
- Improved laboratory productivity

Technical performance:

Robust across conditions

The column demonstrated consistent chromatographic performance under both low and high salt mobile phase conditions, providing flexibility in method development.

Optimised design specifications

- Particle size: 3 ❊m
- Pore size: 250 Å
- Selectivity: 100–800 kDa
- pH stability: 2–8
- Compatible with standard phosphate buffer systems

Application example: mAb aggregate analysis:

SEC plays a critical role in:

- Protein purity assessment
- Aggregate detection
- Structural integrity monitoring
- Supporting regulatory compliance

In a demonstrated application, the ACE® Exclude SEC column successfully separated NISTmAb monomer from induced aggregates, confirming its suitability for demanding biopharmaceutical analyses.

Figures 1 shows that the Avantor ACE Exclude SEC columns provide consistent separation of protein standards across different lots.

mAb aggregate separation application

In biopharmaceutical development, SEC plays a critical role in:

- Assessing protein purity
- Detecting aggregates
- Monitoring structural integrity
- Supporting quality control and regulatory compliance

SEC is widely applied in the characterisation of monoclonal antibodies (abs), antibody–drug conjugates (ADCs), and other therapeutic proteins, supporting quality control and regulatory compliance throughout the drug development lifecycle.

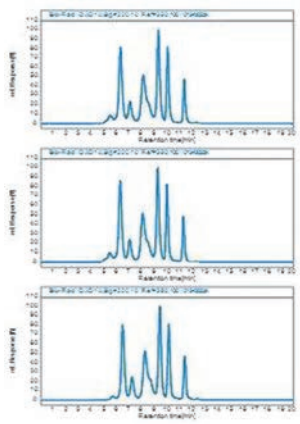

Figure 1
Test Conditions

- **Mobile phase:** 20 mM Na_2HPO_4 (pH 7.0) with NaCl
- Flow rate: 0.35 mL/min
- Temperature: 25 °C
- Injection volume: 0.5 µL

Sample:

- Thyroglobulin
- γ-Globulin
- Ovalbumin
- Myoglobin
- Vitamin B_{12}

In this example application, NISTmAb at 1 mg/mL was diluted 1:9 in mobile phase and heated to 65 °C for 30 minutes with agitation to induce aggregate formation. As shown in Figure 2, the Avantor ACE Exclude SEC column successfully separated the NISTmAb monomer from the aggregates.

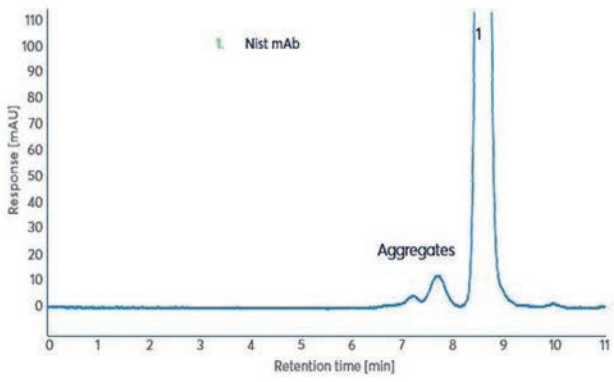

Figure 2
Test Conditions

- **Column:** Avantor ACE Exclude SEC
- **Particle size:** 3 µm
- **Dimensions:** 300 × 4.6 mm
- **Mobile phase:** 100 mM Na_2HPO_4 (pH 7.0) with 200 mM NaCl
- **Flow rate:** 0.35 mL/min
- **Temperature:** 25 °C

Injection volume: 1 µL
Detection: UV (220 nm)
Sample: 1 mg/mL NISTmAb, diluted 1:9 in mobile phase

> The Avantor® ACE® Exclude SEC column provides a reproducible SEC platform for biotherapeutic analysis. By combining high-resolution separation, excellent reproducibility, and extended column lifetime, it addresses key challenges in SEC workflows

Conclusion

The Avantor® ACE® Exclude SEC column provides a reproducible SEC platform for biotherapeutic analysis. By combining high-resolution separation, excellent reproducibility, and extended column lifetime, it addresses key challenges in SEC workflows.

Designed for modern laboratories, it enables scientists to achieve consistent, high-quality results with the potential to improve efficiency and reduce costs making it an ideal choice for mAb aggregate analysis and beyond.

Gloss with a purpose: How Ideal Cures is reimagining patient-centric film coatings

Bringing together high-gloss coating technology, enhanced patient experience, and uncompromised product performance

The moment that matters

For decades, pharmaceutical innovation has focused on better formulations, optimised drug release, improved stability, and robust manufacturing. Yet one critical part of the patient journey often receives less attention: the few seconds between placing a tablet in the mouth and swallowing it.While oral solid dosage forms remain the most widely used delivery system, patient acceptance depends on more than therapeutic performance. Tablet size, surface smoothness, mouthfeel, and ease of swallowing can significantly influence the overall dosage experience, particularly for paediatric, geriatric, and dysphagic patients.

As tablets become larger and therapies become more complex, patient-centric formulation design is gaining importance. Formulators are being challenged to look beyond traditional quality attributes and consider how a tablet is experienced by the patient.Film coatings have long been valued for protection, identification, appearance, and manufacturing efficiency.

Patients don't see dissolution profiles. They experience tablets.

What if gloss could serve a greater purpose? What if a smoother, glossier tablet surface could contribute to a more comfortable swallowing experience?

This question is redefining the role of pharmaceutical film coatings and opening new opportunities to combine aesthetics with patient-focused functionality.

Traditionally viewed as a cosmetic feature, gloss may also play a functional role in the patient experience. A smoother, glossier tablet surface has the potential to support easier swallowing, redefining film coatings as a tool not only for product differentiation, but also for patient-centric design.

Beyond appearance: A new perspective on tablet coatings

As the focus shifts toward patient-centric dosage forms, coating technologies are being challenged to deliver more than visual appeal. Today, the industry is beginning to view gloss differently: not simply as an aesthetic feature, but as a potential contributor to the patient's experience. This opens a new perspective on film coating: one system can potentially address product aesthetics, manufacturing needs, and patient experience.

To support this need, Ideal Cures developed InstaGloSS®, a next-generation HPMC-based film coating system designed to create an exceptionally smooth, glossy tablet surface while maintaining the performance expected from modern pharmaceutical products. Available for aqueous, hydroalcoholic, and organic processing, InstaGloSS® gives

formulators flexibility across diverse manufacturing requirements while delivering a distinctive high gloss finish.

What InstaGloSS® is designed to deliver

- Exceptional tablet gloss and visual differentiation
- A smooth surface with enhanced tablet slipperiness
- A patient-centric approach to the swallowing experience
- Comparable performance on selected critical tablet attributes
- Flexibility across aqueous, hydroalcoholic, and organic systems

Measuring the difference

To evaluate the impact of InstaGloSS® on tablet surface properties, comparative studies were performed using InstaGloSS®-coated and conventionally film-coated tablets. The evaluation focused on gloss, measured by light reflection at a 60° geometry, and the time required for tablets to slide through a hopper.

Set	Coating system	Gloss value (60° geometry)	Average hopper slide time (s)
1	**InstaGloSS®**	**35.43**	**5**
1	Conventional film coating	2.98	13
2	**InstaGloSS®**	**38.56**	**6**
2	Conventional film coating	5.01	12
3	**InstaGloSS®**	**44.23**	**5**
3	Conventional film coating	7.47	14

Case study 1: Evaluating gloss and tablet sliding characteristics

Three tablet sets were evaluated at a coating weight gain of 3 per cent w/w. The test tablets had dimensions of 18.5 mm × 9.05 mm.

Conclusion: In all three sets, InstaGloSS® produced markedly higher gloss values than the conventional film coating. The InstaGloSS® tablets also completed the hopper slide in 5 to 6 seconds, compared with 12 to 14 seconds for the conventional coated tablets. These results indicate a highly differentiated surface finish and reduced dry-surface sliding resistance under the study conditions.

Case study 2: Function without compromising tablet performance

A differentiated patient experience must not come at the expense of tablet quality. A second comparative study therefore evaluated paracetamol core tablets, conventional HPMC-coated tablets, conventional PVA-coated tablets and InstaGloSS®-coated tablets.

Evaluation parameter	Core tablet	HPMC coated	PVA coated	InstaGloSS®
Thickness (mm)	7.16	7.26	7.25	**7.26**
Width (mm)	11.70	11.76	11.76	**11.77**
Hardness (kg/cm^2)	14-15	14-15	14-15	**14-15**
Disintegration time (min)	1-2	2-3	2-3	**2-3**

Conclusion: The evaluated tablet dimensions, hardness, and disintegration time remained comparable across the coated systems. In the reported dissolution study, the InstaGloSS®-coated tablets also demonstrated drug-release behaviour broadly comparable with the other tablet sets.

Reported dissolution results (% drug released)

Time (min)	0	5	10	15	30
Core tablet	0	50	70	88	96
HPMC coated	0	30	55	78	88
PVA coated	0	40	64	82	90
InstaGloSS®	**0**	**40**	**68**	**87**	**95**

A new opportunity for patient-centric formulation design

For many years, coating selection has been guided primarily by protection, processability, colour and appearance. As the pharmaceutical industry continues to move toward patient-centric innovation, formulators are also looking for technologies that can improve the overall treatment experience.

The ability to create a visually elegant tablet with a smooth, highly polished surface offers a compelling approach to tablet design, especially for large tablets where swallowing experience can be an important consideration.

InstaGloSS® brings these objectives together by combining exceptional gloss, enhanced tablet slipperiness and robust coating performance in a single system. Its distinctive finish can also help differentiate a tablet visually in an increasingly competitive market.

Where gloss meets purposeGloss has traditionally been treated as a cosmetic characteristic.

By combining exceptional gloss, enhanced tablet slipperiness, and robust coating performance in a single system, InstaGloSS® gives formulators and manufacturers a practical route to differentiated, patient-focused dosage forms.

For scientists working with large tablets, challenging tablet geometries, chronic therapy products or formulations where tablet acceptability is a concern, the opportunity to improve the tablet experience may already exist within the coating itself.

The opportunity is no longer simply to make a tablet glossier. It is to use that gloss purposefully to create a better tablet experience.

Explore Instagloss® For Your Next Formulation

Request a sample or technical discussion with the Ideal Cures Formulation team. Let us explore what a functional high-gloss coating can deliver.

Editorial note: Study results are presented as comparative development observations under the stated conditions. Detailed technical information is available from Ideal Cures on request.

info@idealcures.com

Author: Tanvi Sawant, Technical Manager

Moisture Control: A Silent Factor in Pharma Manufacturing

Humidity control across pharma manufacturing, storage and packaging helps maintain product quality, consistency and compliance

Humidity is present everywhere, changing with location, season and even the time of day. In everyday life, this shift goes largely unnoticed. In pharmaceutical manufacturing, however, even small variations in moisture can have serious consequences.

> Maintaining the right temperature and relative humidity across production, filling and packaging areas helps protect product integrity at every stage

Many active pharmaceutical ingredients (APIs) and excipients are hygroscopic, meaning they absorb moisture from the surrounding air. When humidity is not controlled during processing, this moisture can affect the physical and chemical stability of a product. Tablets may soften or cap, powders may clump and lose flow, and coatings may fail to set correctly. Beyond the manufacturing floor, uncontrolled moisture during storage and packaging can shorten shelf life and compromise product quality before it ever reaches a patient.

This is why environmental control is treated as a critical part of pharma manufacturing, not an afterthought. Maintaining the right temperature and relative humidity across production, filling and packaging areas helps protect product integrity at every stage. It also supports consistency across batches, which is essential for meeting regulatory expectations and ensuring that every unit performs as intended.

As formulations become more complex and moisture-sensitive, the role of controlled environments in pharma facilities continues to grow. Getting humidity right, from raw material storage to the final pack, is no longer just good practice — it is a basic requirement for product safety, efficacy and compliance.

Ensuring clean room integrity with prime clean reset high-speed doors: Minimising air permeability and leakages

High-speed cleanroom doors help maintain pressure differentials, minimise air leakage and protect controlled environments from contamination

High-speed doors for clean rooms are specialised industrial doors essential for maintaining controlled environments. These doors are engineered to be airtight, creating a reliable barrier between different areas of a facility. Their design ensures durability and minimal maintenance, reducing the frequency of repairs and replacements.

High-speed clean room doors offer a range of critical benefits essential for maintaining stringent environmental control. These doors enhance hygiene by providing an airtight seal that effectively isolates clean room environments, preventing the ingress of dust and other contaminants. This capability is especially crucial in sectors such as pharmaceuticals, biotechnology, and food production, where maintaining sterility is non-negotiable.

In the pharmaceutical and life sciences industries, compliance with rigorous regulatory standards necessitates the manufacture of products within controlled clean room environments. A high-performance clean room door is an integral component in ensuring the integrity of these spaces, safeguarding product quality and patient safety.

Beyond contamination control, these doors are engineered with advanced safety mechanisms, including automated sensors and emergency stop functions, which mitigate the risk of operational hazards. Moreover, high-speed clean room doors are designed to maintain precise overpressure or under pressure conditions within the environment. This is vital for preventing cross-contamination and ensuring that the clean room remains in a state of controlled integrity, even under varying operational demands.

Given the critical role these doors play in maintaining the purity and safety of highly specialised environments, selecting the appropriate door system is a decision of strategic importance. Prime Clean Reset, our high-speed door is designed specifically for clean rooms. This innovative solution is engineered to meet the stringent requirements of controlled environments, ensuring exceptional performance and reliability. Designed with precision to meet the stringent requirements of controlled environments, Prime Clean Reset is the epitome of performance and reliability, ensuring that your clean room operations consistently meet the highest standards of regulatory compliance and product integrity.

Prime Clean Reset is suitable for clean rooms up to ISO Class 5, offering an unparalleled air permeability rate of less than 12 m^3/m^2 h at fj 50 Pa. This ensures that even in the most sensitive environments, the door effectively maintains the critical pressure differentials required to prevent contamination, thereby safeguarding your processes and products.

Engineered with cutting-edge European technology and innovative design principles, Prime Clean Reset offers rapid cycle times for both opening and closing, making it the optimal solution for medium to large entrances in clean room applications. The door's construction is specifically tailored to minimise air leakage and particulate infiltration, ensuring that it supports the rigorous cleanliness standards necessary for applications such as pharmaceutical manufacturing, semiconductor fabrication, food processing, and other highly specialised sectors.

With its robust design and reliable performance, Prime Clean Reset seamlessly integrates into your clean room infrastructure, providing a critical barrier that preserves the integrity of controlled environments. Whether you are operating in a pharmaceutical, biotechnology, electronics, or defence industry, Prime Clean Reset offers the precision, durability, and compliance needed to maintain your competitive edge in highly regulated markets.

Key features of Gandhi Automations' High-Speed Clean Room Doors include:

- **Low Air Permeability:** Designed to maintain low air permeability in pressurised rooms with both positive and negative air pressure.
- **Compact Design:** The doors are designed to fit inside the columns, with a self-supporting construction that minimises air leakage.
- **Customisable Transparency:** They can be equipped with transparent PVC horizontal sections or vision windows for visibility.
- **Specialized Side Guides:** The special side guides ensure a tight integration of the curtain, providing high leak tightness.
- **Efficient Operation:** The doors offer high efficiency and low permeability values, compliant with EN 12426 and EN 12427 standards, ensuring < 12 m^3/m^2 h fj 50 PA.
- **Durable Control Device Enclosure:** The control device enclosure is made of Stainless-Steel SS 316, ensuring durability and resistance to corrosion.

These high-speed doors are meticulously engineered to minimise air leakage and maintain strict environmental control, making them indispensable for clean room operations. Their rapid opening and closing operation ensure that the internal facility remains isolated from external conditions, effectively upholding the cleanliness and controlled environment essential for maintaining the integrity of clean rooms.

For further information on our high-speed doors offering, contact:

Gandhi Automations Pvt Ltd
Chawda Commercial
CentreLink Road, Malad (W),
Mumbai-400064, India.
Off: +91 22 66720200 / 66720300
(200 lines)
Fax: +91 22 66720201
Email: sales@geapl.com
Website: www.geapl.com

Advanced air filtration in pharmaceutical and healthcare cleanrooms: A systems approach to contamination control

Integrated filtration, airflow management and containment solutions help pharmaceutical and healthcare facilities maintain controlled environments, support compliance and manage contamination risks shares **Chinmay Korad,** AGM and Country Head Pharma-Industrial Sales, Freudenberg Filtration Technologies India

In pharmaceutical manufacturing and healthcare environments, air quality is more than a facility parameter. It is a critical factor influencing product quality, regulatory compliance, process reliability, and patient safety. As cleanroom standards become increasingly stringent, facility operators are adopting advanced air filtration strategies that combine high-performance filters, containment solutions, and intelligent airflow management to maintain controlled environments.

Drawing on decades of global expertise, Freudenberg Filtration Technologies, through its trusted Viledon brand, supports healthcare and pharmaceutical facilities with filtration solutions engineered to meet stringent cleanroom requirements, GMP guidelines, and ISO standards.

A multi-stage approach to clean air

Effective contamination control relies on a layered filtration strategy that progressively removes airborne particles before air reaches critical production, laboratory, or healthcare spaces.

The process typically begins with Viledon pre-filters, which capture larger particulate contaminants and protect downstream filtration stages from premature loading. By reducing the burden on high-efficiency filters, pre-filters enhance overall system performance, improve energy efficiency, and help lower maintenance costs.

Further downstream, fine filters remove smaller airborne contaminants such as fine dust, pollen, and other particulates. These filters play

an important role in preserving the performance and lifespan of final-stage filtration systems while supporting consistent air quality within controlled environments.

For facilities operating under GMP requirements and stringent cleanroom classifications, HEPA filtration remains the backbone of contamination control. Freudenberg Filtration Technologies' Viledon HEPA filters are designed to support cleanroom environments ranging from ISO Class 3 to ISO Class 8, helping facilities maintain compliance while minimising the risk of cross-contamination. Their high-efficiency filtration performance makes them particularly suited for pharmaceutical production, biotechnology laboratories, research facilities, and critical healthcare applications.

Delivering clean air at the point of use

Maintaining air quality does not end within the air handling system. Final-stage filtration at the point of air delivery is equally critical.

Viledon Terminal Housing Filters provide the final filtration barrier before air enters the controlled space. Designed for reliable sealing, uniform airflow distribution, and leak-free operation, these systems help ensure that clean air reaches the cleanroom exactly as intended. Their precision-engineered designs make them a preferred choice for pharmaceutical facilities, laboratories, hospitals, and other critical environments.

In applications involving hazardous compounds or sensitive biological materials, safe filter replacement becomes equally important. Freudenberg Filtration Technologies' Safe Change Housing systems, incorporating Bag-In-Bag-Out (BIBO) technology, enable contamination-free filter replacement while protecting personnel and the surrounding environment. These systems are increasingly used in pharmaceutical manufacturing, biotechnology facilities, R&D laboratories, and high-containment applications where operational safety is paramount.

The growing importance of fan filter units

Among the most significant developments in modern cleanroom design is the increasing adoption of Fan Filter Units (FFUs). As pharmaceutical and healthcare facilities seek greater flexibility, scalability, and energy efficiency, FFUs have become a key component of next-generation contamination control strategies.

Viledon Fan Filter Units (FFUs) combine a fan, HEPA filtration system, and integrated controls within a compact, self-contained unit. Unlike traditional centralised systems that rely heavily on extensive ductwork, FFUs deliver filtered air directly into the clean space, enabling localised airflow control and streamlined cleanroom design.

Their growing adoption is driven by several advantages:

- Precise airflow and room pressurisation control
- Modular and scalable cleanroom configurations
- Simplified installation and maintenance
- Reduced infrastructure complexity
- Improved energy efficiency through optimised fan technology
- Flexibility for facility expansion and retrofit projects

For pharmaceutical manufacturers, FFUs offer the ability to create adaptable clean environments that can evolve alongside production requirements. Freudenberg Filtration Technologies' FFUs have been deployed across pharmaceutical production facilities, biotechnology applications, modular cleanrooms, process enclosures, and laboratory environments where maintaining positive pressure and reducing contamination risks are essential.

As the industry increasingly embraces modular manufacturing and flexible facility design, FFUs are expected to play an even more prominent role. Their ability to combine contamination control, operational flexibility, and energy-efficient performance aligns closely with the future needs of healthcare and pharmaceutical cleanrooms.

Looking ahead

The future of pharmaceutical and healthcare cleanrooms will depend on technologies that deliver both compliance and efficiency. From pre-filters and fine filters to HEPA systems, terminal housings, safe-change containment solutions, and advanced FFUs, each element of the filtration chain plays a critical role in maintaining a controlled environment.

Supported by its global expertise and the trusted Viledon portfolio, Freudenberg Filtration Technologies continues to contribute to cleaner, safer, and more efficient critical environments. As the demands on healthcare and pharmaceutical facilities continue to evolve, integrated air filtration strategies will remain essential for protecting product integrity, ensuring regulatory compliance, and safeguarding patient safety.

Ensuring pharma compliance with testo data measurement technology

Testo highlights how data loggers and monitoring systems can help pharma companies maintain temperature and humidity controls, support validation and ensure data compliance across production, storage and transit

Due to the crucial necessity and its direct impact on human health and welfare, Pharma is probably the most important and critical sector among others. As a consequence of which, it becomes essential to store pharmaceuticals, vaccines, laboratory samples or units of blood at the right temperatures to ensure that they remain effective and that quality is maintained. Another reason for the Pharma division to ensure safety measures & controlled environment is stringent regulations and inspection of the facilities. This elementary need for climate control can only be ensured with right data monitoring systems. Testo being a market leader in testing & measurement sector provides the best in class data loggers and data monitoring systems for the Pharma division.

Ensuring end to end climate monitoring – Testo data loggers

Pharma goods must be stored well in every situation as any deviation in the ambient temperature or humidity values may lead to deteriorated quality of the product. Testo data loggers can be used to test the optimum conditions for specific products or surroundings. Temperature & humidity data loggers are often used in Pharma industries to monitor the conditions in which drugs, medicines, vaccines are kept. Not only storage, but during the transit of goods, testo transport data loggers are useful to measure the transport conditions. The range of data loggers is very extensive. A temperature & humidity logger such as 174 T guarantees continuous monitoring in a storage or warehouse. Also, data loggers with multi channels for connecting external sensors & thermocouples, like testo 176 are available for ensuring secured work process in labs.

These data loggers are also critical for production quality assurance where the temperature has to be frequently checked at various points in production processes. Using thermocouple probes, data loggers can also record data in the kinds of extreme temperature ranges. The probe's fast response also contributes in the validation processes and quality standard optimisation in QA units & clean room applications. These instruments are the most convenient and pocket friendly solution for all Pharma application areas.

Another important and crucial application of a Pharma industry involves validation of sterilisation and freeze-drying processes. Not only that, validating cleaning and disinfecting equipment is equally necessary. In order to allow a seamless operating procedure, the validation process and the documentation work must be as efficient and smooth as possible which could be easily achieved with testo data loggers solution that has innovative data loggers for temperature & humidity, smart software and accessories.

Data compliance for audits and inspections

Testo offerings are majorly related to the data security along with comprehensive analysis & evaluation of all the recorded measurement data. Testo data loggers ensure continuous monitoring of temperature and relative humidity of pharmaceutical products during production, storage or transit of goods. Real time data monitoring is important for the quality of Pharma goods and also enables the supplier to improve the life of the goods. Transportation trucks, warehouses, cold rooms etc. can now be remotely monitored via Testo data loggers & data monitoring systems. Our data loggers are EN 12830 and 21 CFR Part 11 compliant which ensure complete documentation of parameters, be it humidity, temperature or absolute pressure. They come with professional software where the data recorded cannot be modified and the audits can be easily complied with.

Service and 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

VIVAPHARM® Alginates – Natural versatile hydrocolloids

Krishnakumar Patel highlights the properties, benefits and pharmaceutical applications of VIVAPHARM® Alginates as natural hydrocolloids

Hydrocolloids are high molecular weight hydrophilic polymers (usually Proteins and Polysaccharides chemically), which contain polar or charged functional groups, rendering them soluble in water. They are produced or extracted from various sources, such as plants (trees, seeds, tubers and pulses), animal (milk, meat, animal by-products) and microorganisms (bacteria, fungi and yeast) etc. A few examples include locust bean gum, carrageenan, pectin, starch (plant), chitosan (animal), xanthan gum (microbial fermentation), carboxymethyl cellulose, hypromellose, methylcellulose, alginates (chemical modification of natural polysaccharides) and many more. [1] [2]

Chemically, hydrocolloids generally consist many hydroxyl groups and polyelectrolytes, which make them hydrophilic in nature. They are incorporated into food formulations mainly to control rheology and structure. In aqueous environments, hydrocolloids swell, increasing their hydrodynamic volume, thereby increasing the viscosity of the system. In addition, if the hydrocolloids entrain sufficient water due to their concentration, their chains will interact, yielding a gelled network. These gels can be produced at high concentrations of polymer, or by reducing the solvent quality (i.e., alteration of pH or ionic strength). For example, addition of sufficient Calcium ions to a liquid Sodium or Potassium Alginate solution yields a gel. Due to their swelling behavior, hydrocolloids are required only in low concentrations to confer the desired effect. [1] [2]

They are used in a variety of industries to perform a number of functions, including –

- Thickening
- Gelling and binding
- Coating
- Syneresis control
- Stabilisation of foams
- Emulsions and dispersions / suspensions
- Stabilisation of pH
- Enhancement of heat resistance
- Improvement of salt tolerance
- Control release formulations and many more [3]

JRS offers a range of hydrocolloids, useful in solid, liquid, semi-solid products for pharmaceuticals, nutraceuticals and food applications, the portfolio consists of –

- VIVAPHARM® Alginates (Sodium Alginate / Calcium Alginate / Alginic acid)
- VIVAPHARM® HPMC (Hypromellose 2910)
- VIVAPHARM® Pectin (Pectins)
- VIVAPUR® MCG (Microcrystalline Cellulose Gel) [5]

VIVAPHARM® Alginates are linear Polysaccharides consisting blocks of Guluronic acid and Mannuronic acid. [5] They are derived from a rich field of brown Algae (a type of Seaweed) off the French coast. [4] As mentioned above, the range consists of –

- Sodium Alginate
- Calcium Alginate
- Alginic acid

Image 1: Manufacturing process of VIVAPHARM® Alginates [4]

TYPICAL PROPERTIES AND BENEFITS

Natural

- Extracted from sustainable harvested seaweed / No animal origin / Vegan
- During manufacturing process, no solvent or alcohol is used
- No allergens
- Clean label-friendly
- Recognised as GRAS [4]

Solubility

Solubility behavior is most important aspect for most functionalities of Hydrocolloids. Considering that, Sodium and Potassium salts are water soluble, whereas Calcium salt and acid are insoluble. [4] The table below elaborates their solubility profile in more detail –

	Sodium Alginate	Calcium Alginate	Alginic acid
Solubility in cold water	√	×	×
Solubility in hot water	√	×	×
Gel forming with Calcium	√	×	×
Swells in cold water	×	√	√

Table 1: Solubility of VIVAPHARM® Alginates [4]

Gelation via ion-exchange

In the liquid, semi-solid or textured products, Sodium Alginate helps through gelling without applying any temperature. Infusion of Calcium Chloride or other suitable Calcium ion source leads to ion-exchange between Calcium and Sodium, which results into gelation. [4] This is beneficial to products and actives where higher temperatures may prove detrimental.

Precise control on gelling

The gel setting time and its consistency can be very precisely controlled by adjusting the rate of addition and concentration of Calcium ion into the liquid system of Sodium Alginates. [4] This gives uniform batch results of viscosity, gel strength, consistency and texture to food and pharmaceutical products.

Thermostable and water insoluble gels

Gels made with Alginates exhibits improved heat and moisture stability. This results into less or no melting and no sticking of the final product in hot climatic conditions, e.g. maintains capsule integrity. [4]

Hemostasis

When Calcium alginate dressing comes into contact with wound exudate, there is an exchange between the Calcium ions in alginate and the sodium ion in blood or exudate, resulting in swelling of alginate fibers and formation of a gel. This leads to hemostasis and subsequent healing. Other properties like biodegradable, biocompatible and non-immunogenic make it useful for these applications. [4] [8]

Film formation

Alginates are excellent film-forming agents. They give instant gelling for strong, flexible, clear, glossy and consistent film-strips. [4]

Versatile

Its viscosity modifying, gelling and film-forming properties in various conditions make Alginates one of the most versatile polymer. [4]

Applications

Owing to these unique and versatile properties and benefits we can impart to various food products and pharmaceutical formulations, Alginates are widely used and generally regarded as non-toxic and non-irritant excipient. Pharmaceutical and medical applications are discussed in this section.

Medical wound dressing

Calcium alginate is useful in this application due to hemostasis properties and benefits stated in previous section. It can absorb 15-20 times of their own weight of wound exudates. Dressing with Calcium alginate provides moist environment to the affected area and is easy to remove. [4]

Dental care

Precise gelation and control over consistency makes Sodium alginate suitable for dental impression and dental gel preparations. [4]

Anti-reflux raft barrier

Alginate based anti-reflux preparations have been in use for the symptomatic treatment of heartburn for many years. Calcium alginate and Alginic acid gels are used to form protective layers in the stomach. Another element of action of these formulations is the floatation of the gel layers in the form of protective raft. When bicarbonates (Sodium and/or Calcium) and sodium alginate solution comes into contact with gastric acid, chemical reaction occurs, and Alginic acid and/or Calcium Alginate (insoluble gel layer) is generated respectively along with Carbon dioxide. Floatation is achieved by embedding Carbon dioxide bubbles in the gel layer. [4] [6] [8]

Thickener / suspending agent

Alginates modify viscosities of aqueous systems. This can be effectively applied to oral solutions and dispersions to provide structure and / or retard sedimentation of suspended particles. Alginates are widely used as a thickening and suspending agent in a variety of pastes, creams, and gels, and as a stabilising agent for oil-in-water emulsions. [5] [8]

Film-former

With Sodium Alginates, films with oil-barrier properties, anti-sticking and protective coatings can be prepared. This is quite useful when usage of conventional film-formers are restricted. [4]

Binder

Due to polymeric structure, Alginates can be

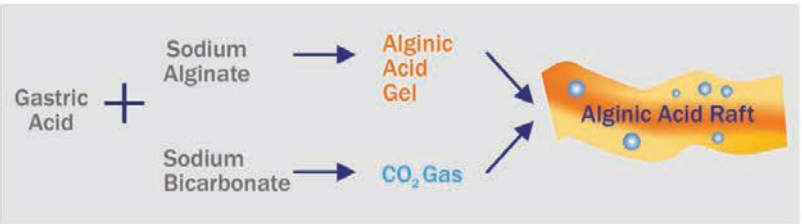

Image 2: Alginic acid raft formation [6]

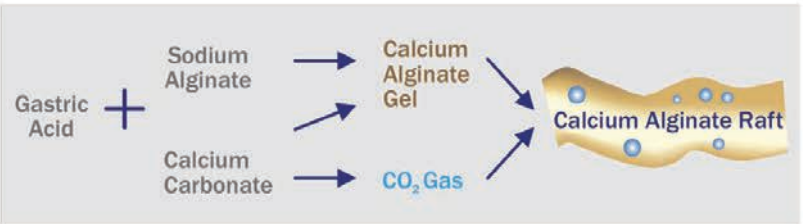

Image 3: Calcium Alginate raft formation [6]

used as a binder in granulation techniques. [5]

Controlled-release polymer

Alginate matrices are highly suited for modified/controlled release of highly acid-soluble drugs. At low pH in stomach, it forms an insoluble gel layer acts as a functional diffusion barrier, which limits the release of the API. In the intestine, it turns to sodium salt due to higher pH. It behaves as soluble viscous layer, which releases API by diffusion and erosion. [4] [7] [8]

Disintegrant

The solubility profile of Calcium alginate and Alginic acid shows that they do not get dissolved but swell in cold water. This property makes them suitable to be used as disintegrants in oral solid formulations. [4] [8]

Enteric polymer

Being anionic in nature and exhibiting pH dependent solubility profile, Sodium alginate can be explored as an enteric polymer for tablets and capsules. [4] [8]

Chemistry	Grade	Viscosity (mPaS)	Application(s)
Alginic acid	VIVAPHARM® Alginic Acid PH 060	NA	Disintegrant
Calcium Alginate	VIVAPHARM® Alginate PH 460	NA	Disintegrant
	VIVAPHARM® Alginate PH 470 S2	NA	Disintegrant
Sodium Alginate	VIVAPHARM® Alginate PHU R5	300 – 700 at 10 %	Suspending agent, Anti-reflux raft former
	VIVAPHARM® Alginate PHU 170 S1	100 – 300 at 2 %	Controlled-release polymer
	VIVAPHARM® Alginate PHU 175	350 – 550 at 1 %	Controlled-release polymer

Table 2: Various grades of VIVAPHARM® Alginates and related applications

JRS OFFERINGS OF GRADES UNDER VIVAPHARM® ALGINATES

Multiple grades are available under VIVAPHARM® Alginates umbrella, which consist of Alginic acid, Calcium Alginate and Sodium Alginates. A short summary is given in Table 2 –

Summary

VIVAPHARM® Alginates consist of Alginic acid, Calcium Alginate and Sodium Alginates. They are of natural origin extracted from brown seaweed. Their different solubility profiles make them suitable for various applications in food, medical and pharmaceuticals.

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[5] JRS Hydrocolloids - Innovations based on renewable resources (jrspharma.com) (https://www.jrspharma.com/pharma-wAssets/docs/brochures/brochure-hydrocolloid-gb-210216-web.pdf)

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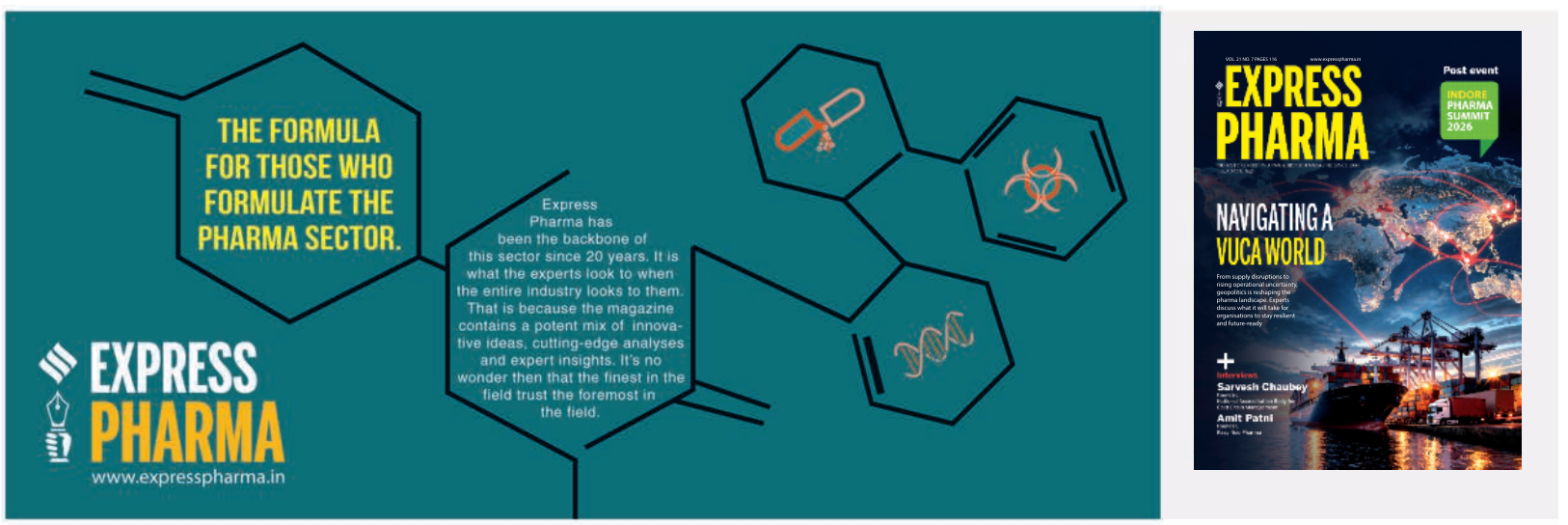
AUTHOR
Krishnakumar Patel
Technical Services – Pharma, JRS India
Krishna.Patel@jrsindia.com



Environmental monitoring reimagined : Automating Petri dish handling under GMP Annex 1

Automated Petri dish handling reduces routine interventions in environmental monitoring while maintaining established culture-based methods under GMP Annex 1

Environmental monitoring is a fundamental element of contamination control in aseptic pharmaceutical manufacturing. Culture plate-based monitoring using Petri dishes has long been an established and widely accepted method for assessing microbiological conditions within cleanrooms and isolator systems.

With the implementation of EU GMP Annex 1, increased attention has been placed on minimising interventions within critical aseptic environments. While conventional monitoring methods remain unchanged, manufacturers are increasingly evaluating technologies that reduce manual handling activities associated with routine monitoring operations.

One area attracting growing interest is the automation of environmental monitoring workflows. These systems enable manufacturers maintaining established monitoring principles while reducing operator involvement inside the isolator.

The role of conventional plate-based monitoring

Traditional environmental monitoring relies on active and passive sampling using Petri dishes. During active sampling, air is drawn across the culture medium, while passive plates collect microorganisms through natural sedimentation. Following exposure, the plates are incubated and evaluated according to microbiological procedures.

These methods remain a cornerstone of pharmaceutical quality systems and are supported by extensive operational experience. Depending on the facility's risk-based Contamination Control Strategy, active microorganism samplers may need to be closed after 10 to 40 minutes. During active sampling, the medium dries relatively quickly and may lose its ability to collect microorganisms. Plates must therefore be changed frequently, particularly at the beginning and end of a batch. Over the course of a batch, this can result in a considerable number of glove interventions.

This does not call the established method into question. Rather, Annex 1 has increased the focus on technologies that automate recurring handling steps while preserving the underlying microbiological monitoring principle.

Automating the monitoring workflow

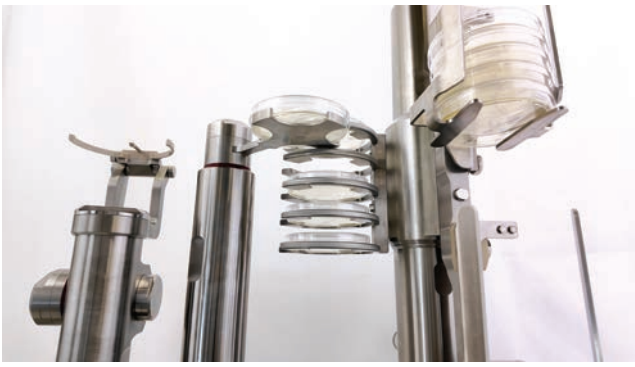
Automated environmental monitoring systems based on conventional Petri dishes represent one such approach.

In these systems, culture plates are stored within a dedicated buffer area inside the isolator. A mechanical handling system automatically retrieves a plate from storage and transports it to the designated monitoring location.

Once positioned, the system opens the plate, initiating the sampling process. The plate is simultaneously scanned and digitally documented.

After completion of the defined exposure period, the plate is automatically closed and transferred to a separate storage position. A new plate can then be introduced into service without direct operator involvement. The sequence is performed automatically and follows predefined procedures designed to ensure reproducibility.

With this system, glove interventions are required only during large batches when the buffer must be replenished with new Petri dishes. This means that monitoring can continue throughout extended production campaigns with minimal operator involvement, while the established plate-based method remains unchanged.



Automated handling transfers each Petri dish from the internal buffer to the monitoring position, where it is opened, scanned and documented. After the defined exposure period, the dish is automatically closed and moved to a separate storage position

The same microbiological culture media are used, the same incubation procedures are applied, and the same microbiological assessment is performed after sampling. The innovation lies in automating plate handling rather than changing the underlying detection method.

Benefits beyond intervention reduction

Although intervention reduction is often the primary motivation for considering automated monitoring systems, automation can also provide advantages in documentation and process consistency.

Each plate can be associated with a unique scan and timestamp when activated. This creates a documented link between a specific monitoring plate and a defined period within the production process. After incubation and microbiological evaluation, the resulting data can therefore be correlated with individual manufacturing intervals.

Such traceability can support investigations in the event of contamination findings. Rather than relying solely on manual documentation, manufacturers have access to automatically generated records that help reconstruct environmental monitoring activities throughout the batch.

Automation may also contribute to greater standardisation. Because plate positioning, opening and closing are performed according to predefined mechanical sequences, variability associated with repetitive handling activities can be reduced. From a contamination-control perspective, this consistency aligns with broader industry efforts to improve process robustness and reproducibility.

Position within the future Monitoring Landscape

The automation of conventional Petri dish handling should be viewed within the broader context of environmental monitoring innovation.

Alongside automated plate systems, real-time monitoring technologies are also receiving considerable attention. These systems aim to detect contamination through optical and fluorescence-based methods, potentially providing immediate information on particles and viable microorganisms within the critical environment.

However, many manufacturers continue to value the familiarity and established regulatory acceptance of culture-based methods. Automated plate handling therefore occupies an interesting position between traditional manual monitoring and emerging real-time solutions. It combines proven microbiological techniques with modern automation technologies while avoiding fundamental changes to the monitoring principle itself.

Conclusion

The pharmaceutical industry is adapting its operations to meet the expectations of Annex 1 without abandoning proven practices. Environmental monitoring is one area where innovation is being achieved through the further development of established methods. Automated environmental monitoring systems based on conventional Petri dishes preserve the underlying microbiological principles long used in aseptic processing while automating plate handling, documentation and replacement activities. As a result, manufacturers gain an additional tool for reducing routine interventions and increasing process consistency while maintaining familiar monitoring practices.

Rather than replacing conventional environmental monitoring, automated EMS solutions demonstrate how established methods can evolve to support the next generation of contamination control strategies in aseptic fill-and-finish operations.

Resilient Vaccine Supply Chains: Building Manufacturing Security, Sustainability, and Global Preparedness in a Post-Pandemic Era

The COVID-19 pandemic changed the way the world thinks about vaccine supply chains. Before 2020, supply chains were largely evaluated through familiar measures—cost, efficiency, inventory turns, lead time and delivery performance. The pandemic exposed the limitations of that model. Manufacturing capacity could not be created overnight, demand forecasts became unreliable, logistics networks were disrupted, and governments became major procurement agencies almost overnight.

More importantly, the pandemic demonstrated that a vaccine supply chain is not a linear sequence from raw material to manufacturer to patient. It is a highly interconnected network involving suppliers, manufacturers, regulators, governments, logistics providers, donors and healthcare systems. Failure at one critical node can affect the entire network. The experience of COVID-19 therefore leaves an important message for the next pandemic: resilience must be designed before the crisis, not improvised during it.

The vaccine supply chain must now be viewed as an essential component of national and global health security. The challenge is not simply to manufacture more vaccines. It is to build a system capable of anticipating disruption, absorbing shocks, recovering quickly and adapting continuously.

Moving Beyond Traditional Demand Forecasting

One of the clearest lessons from the pandemic was the inadequacy of conventional annual forecasting. Vaccine demand can change rapidly in response to disease surveillance, epidemiological developments, government policy, procurement decisions and public-health priorities.

The COVID-19 Vaccine Collaborative Supply Planning initiative demonstrated the value of bringing governments, manufacturers and partners together to improve visibility of supply and demand. Collaborative planning enabled better understanding of stock positions, products at risk of expiry and consumption patterns, while allowing forecasts to be adjusted as new information emerged.

Future forecasting therefore needs to become dynamic. Disease surveillance, inventory visibility, procurement commitments, manufacturing capacity and consumption data should feed a common planning process. Artificial intelligence, predictive analytics and digital twins can further support scenario modelling, but technology will only be effective when reliable data are shared across the ecosystem.

This is particularly important because vaccine shelf life creates a difficult balancing act. Procurement systems may seek large quantities and long lead times, while manufacturers need flexibility to respond to changing demand. If tender timelines and minimum remaining shelf-life requirements are poorly aligned, products can be rejected or expire before they are administered. The result is simultaneously higher wastage and lower availability.

The objective should be adaptive replenishment rather than fixed annual forecasting.

Manufacturing Security Begins Before the Factory

Vaccine manufacturing security is often discussed in terms of vaccine production capacity. Yet the pandemic showed that manufacturing depends on a much broader ecosystem.

Glass vials, elastomeric stoppers, filters, cell-culture media, adjuvants, syringes, vaccine vial monitors, single-use bags and assemblies, specialised lipids and other inputs can become critical bottlenecks. A shortage of one material can constrain production even when vaccine manufacturing capacity itself is available.

This makes supply assurance a strategic manufacturing issue.

Single sourcing may appear economically attractive during normal conditions, but the apparent savings can disappear rapidly when a single supplier experiences a quality problem, capacity constraint, geopolitical disruption or transportation failure. Strategic multi-sourcing should therefore become part of vaccine preparedness. A resilient architecture may include a primary supplier, a qualified secondary supplier, regional backup capacity, technology-transfer arrangements and strategically managed inventories.

Redundancy should no longer automatically be regarded as inefficiency. In critical healthcare supply chains, redundancy is an investment in continuity.

The same principle applies to manufacturing geography. The concentration of critical capabilities in a small number of countries creates systemic risk. Regional manufacturing hubs can reduce dependency, shorten response times, support regional stockpiles and enable technology transfer. The argument is not for every country to become completely self-sufficient, which would be neither practical nor economically efficient. Rather, regions should develop sufficient strategic manufacturing and component capability to avoid catastrophic dependence during a global emergency.

Public–Private Partnerships Must Become Operational

No single organisation can build a resilient vaccine ecosystem alone.

Governments determine policy and procurement; manufacturers provide production capability; suppliers provide critical materials; regulators provide oversight; universities contribute science and talent; logistics companies provide physical connectivity; and organisations such as WHO and Gavi support global coordination.

The next generation of preparedness therefore requires public–private partnerships that extend beyond emergency purchasing. Governments can provide long-term demand signals and strategic procurement commitments, while industry can invest in capacity, technology and workforce development. Regulators can support science-based pathways for rapid qualification of alternative suppliers without compromising quality.

Modular manufacturing could also become an important element of preparedness. Flexible facilities and coordinated investments can allow capacity to be deployed or repurposed more rapidly when demand changes. Earlier work on resilient vaccine supply chains has highlighted modular manufacturing and coordinated investment as potential enablers of preparedness.

For emerging manufacturing economies, this model offers an opportunity to combine public health security with industrial development.

India: From Vaccine Manufacturer to Resilience Hub

India is uniquely positioned to contribute to the next phase of global vaccine supply-chain resilience. The country already possesses substantial vaccine manufacturing capability, a large pharmaceutical ecosystem, engineering expertise and a growing base of suppliers supporting biopharmaceutical manufacturing.

The opportunity extends beyond finished-dose vaccines.

Localising critical inputs—such as single-use bioprocessing components, filters, assemblies, specialised packaging, monitoring systems and other manufacturing consumables—can reduce dependence on distant supply networks. Developing these capabilities to internationally recognised quality standards would strengthen both Indian manufacturing and the global vaccine ecosystem.

India could therefore evolve from being primarily a high-volume vaccine manufacturer into a global resilience hub, combining manufacturing, component production, technology development, supply-chain services and regional distribution.

Such a transformation requires sustained investment in quality systems, technology, workforce capability, R&D and

supplier qualification. It also requires closer collaboration between industry, government and academia.

Digital Visibility: From Knowing to Anticipating

Resilience depends on visibility.

During a crisis, knowing where inventory is, how much is available, what is being consumed and which shipment is at risk can be as important as knowing how much manufacturing capacity exists.

Digital supply-chain technologies can connect previously fragmented information. IoT devices can provide real-time temperature and location data. Digital inventory systems can provide visibility across facilities. Predictive analytics can identify emerging shortages. Digital twins can model alternative scenarios, while blockchain-based architectures can strengthen traceability and data integrity.

Recent research has proposed federated blockchain frameworks combining blockchain, smart contracts, federated learning and edge computing to improve traceability, cold-chain monitoring and real-time decision-making.

However, digitalisation should not become an exercise in technology for its own sake. The real objective is better decision-making. A digital supply chain should answer practical questions: Where is the risk? Which material is becoming constrained? Which shipment is likely to expire? Which supplier can provide qualified alternative capacity? How quickly can inventory or production be redirected?

The future belongs to supply chains that can sense, interpret and respond, rather than simply report what has already happened.

Rethinking the Cold Chain

Cold-chain infrastructure remains one of the most vulnerable components of vaccine distribution. Temperature excursions, inadequate storage infrastructure, unreliable electricity and poor monitoring can compromise vaccine quality and create avoidable losses. Research has consistently identified cold-chain infrastructure, storage practices and skilled personnel as important determinants of resilient vaccine delivery.

The answer is not simply to build more conventional refrigeration capacity.

Passive cooling technologies, solar refrigeration, continuous temperature monitoring, reusable shippers, IoT sensors, drone delivery and thermostable vaccine formulations can collectively reduce dependence on conventional cold-chain infrastructure. Solar-powered refrigeration has already demonstrated potential in settings where reliable electricity is unavailable or expensive.

The most resilient cold chain may ultimately be the one that requires less cold-chain infrastructure.

Resilience Must Also Be Sustainable

Preparedness cannot be built by ignoring environmental consequences. Vaccine programmes involve plastics, packaging, dry ice, refrigeration, transportation, energy consumption and waste treatment. At global scale, these impacts become significant.

Research assessing the environmental footprint of COVID-19 vaccination estimated that the cold supply chain could account for a substantial proportion of vaccination-related energy consumption, depending on transportation distance.

Sustainability must therefore become part of supply-chain design rather than a separate corporate initiative. Sustainable packaging, reusable transport solutions where appropriate, renewable energy for cold storage, optimised transportation and better waste management can reduce environmental impact while potentially improving resilience.

The goal is to optimise three objectives simultaneously: security of supply, economic efficiency and environmental sustainability.

Measuring the Journey to Resilience

Resilience should also become measurable.

A useful maturity model begins with a reactive organisation focused on recovering from stock-outs. The next stage is preparedness through supplier qualification, multi-sourcing, safety stock and business continuity planning. A more advanced organisation achieves end-to-end visibility through digital inventory and connected cold-chain systems. The next stage becomes predictive, using AI, risk sensing and digital twins. Ultimately, an adaptive supply chain can dynamically allocate capacity, replenish inventory and coordinate stakeholders in near real time.

The relevant metrics consequently evolve—from stock-outs and inventory levels to supplier readiness, visibility, forecast accuracy and ultimately time-to-recover.

This shift is fundamental. A resilient supply chain is not one that never experiences disruption. It is one that can absorb disruption without losing its ability to protect patients.

Preparing Before the Next Crisis

The pandemic has receded, but the structural vulnerabilities it exposed have not disappeared. Demand has normalised, yet concentrated sourcing, fragmented information, fragile logistics and dependence on specialised inputs remain.

The next five years should therefore focus on ten practical priorities: collaborative demand forecasting; multi-sourcing of critical materials; regional manufacturing hubs; digital supply-chain visibility; intelligent inventory policies; modern cold-chain infrastructure; sustainable packaging; workforce capability; public–private partnerships; and national resilience metrics.

The central lesson is straightforward. Vaccine resilience begins long before a vaccine enters a vial. It begins with the availability of raw materials, diversified suppliers, qualified manufacturing capacity, reliable information, robust logistics, effective regulation and coordinated decision-making.

The post-pandemic objective should not be to return to the supply chains that existed before COVID-19. It should be to build something better—a vaccine ecosystem that is secure enough to withstand disruption, agile enough to adapt to uncertainty, sustainable enough for the future, and globally connected enough to protect populations wherever the next health emergency emerges.

For India and other emerging manufacturing economies, this is more than a preparedness agenda. It is an opportunity to become indispensable partners in the architecture of global health security.

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Written By:
Priyabrata Pattnaik
Chief Executive Officer (CEO)
Mail Id:
pattnaik.p@amipolymer.com

Breaking Import Dependency: Building Local Reliability Through Innovation & Quality

Lactose India Limited is strengthening its pharmaceutical-grade lactose portfolio and domestic manufacturing capabilities to support evolving formulation needs, quality expectations and supply-chain requirements

Supporting Pharmaceutical Manufacturing with Consistent, Application-Focused Lactose Solutions

The pharmaceutical industry is moving through a period of significant change. Across India and global markets, manufacturers are working with stricter quality expectations, evolving regulatory requirements, increasing formulation complexity and greater focus on supply-chain reliability. In this environment, the choice of an excipient supplier has become an important part of maintaining consistent manufacturing and product quality.

Pharmaceutical Manufacturing: A Changing Landscape

In India, pharmaceutical manufacturers are adapting to stronger expectations around Good Manufacturing Practices, quality systems, documentation, risk management, facilities and equipment. The revised Schedule M has added further focus on these areas, making quality and compliance an ongoing responsibility across the manufacturing and supply chain.

At the same time, manufacturers are managing cost pressures and the need for dependable availability of critical raw materials. Developing reliable domestic sourcing options and maintaining qualified suppliers can therefore become an important part of building a resilient supply chain.

Global Markets, Evolving Requirements

For companies supplying international markets, the challenge becomes more complex. Different countries and regions have their own regulatory frameworks, Pharmacopeial requirements and expectations for quality documentation and supplier qualification. Regulatory guidelines continue to evolve, requiring manufacturers and their suppliers to keep pace with changing expectations.

Technical requirements are evolving as well. Formulations and manufacturing processes such as direct compression, dry granulation, roll compaction, orally disintegrating tablets and inhalation delivery can require excipients with specific physical and functional characteristics. Particle size, flow, compressibility and other material properties can influence processing and formulation performance.

This makes excipient selection more than a purchasing decision. It is a quality, technical and supply decision.

What Manufacturers Need from an Excipient Partner

Today's pharmaceutical manufacturers need suppliers who can provide more than a product that meets the specifications. They need consistent manufacturing, appropriate quality and regulatory documentations, application-specific grades, technical understanding and the ability to support changing requirements.

Supply capability is equally important. A dependable partner should have the manufacturing infrastructure and capacity to support customers as their requirements develop, while providing sourcing options that contribute to supply-chain resilience.

LIL: Building Capabilities Around Customer Requirements

Lactose India Limited (LIL) has been developing its pharmaceutical grade lactose capabilities with these requirements in mind. Through its FORMULAC® portfolio, LIL offers pharmaceutical grade Lactose Monohydrate along with specialised Spray Dried, Anhydrous, Inhalation and Low Endotoxin Lactose grades.

The portfolio includes different grades and particle-size ranges designed for a variety of pharmaceutical applications. Lactose Monohydrate grades support applications including wet and dry granulation, direct blending, tablets, capsules, sachets and lyophilization. Specialised grades extend into direct compression, effervescent tablets, ODTs, roll compaction and inhalation applications.

The focus is not simply on offering different products, but on providing pharmaceutical grade lactose grades suited to different formulation and processing requirements.

Technical Capability for Different Applications

FORMULAC® SDL Spray Dried Lactose is produced through spray drying and offers spherical agglomerates with approximately 10–20% amorphous content. Different particle-size distributions are available for applications including direct compression, effervescent tablets, ODTs, capsules and sachets.

FORMULAC® ANH Anhydrous Lactose consists of crystalline β- and α-lactose and is available in different particle-size distributions. It is used across applications including direct compression, effervescent tablets, ODTs, capsules and sachets, and is specifically identified for roll-compaction applications.

For specialised drug-delivery requirements, LIL also offers FORMULAC® INH Inhalation Grade Lactose, supported by dedicated processing capabilities including sieving, milling and Micronization with stringent facility requirement in-terms of Controlled area.

Together, these capabilities allow LIL to address a wider range of formulation requirements rather than relying on a single standard lactose grade.

Strengthening India's Domestic Supply Capability

A strong domestic manufac-

turing base can provide pharmaceutical companies with additional sourcing options and support greater supply-chain resilience.

LIL's Vadodara facility has a current lactose capacity of 10,000 MT per annum, while an additional facility at Surat is being developed with another 10,000 MT per annum capacity. This expansion reflects LIL's continued focus on strengthening its pharmaceutical grade lactose manufacturing capabilities in India.

For customers, the objective is to provide access to a reliable Indian manufacturing source while continuing to develop capabilities for specialised pharmaceutical applications.

Quality That Supports Global Requirements

Quality remains at the centre of pharmaceutical manufacturing, particularly for customers operating across regulated markets. LIL's being a publicly listed entity, the major accreditations that includes WHO-GMP, GMP, ISO 9001, EXCiPACT, FSSC 22000, USDMF, CEP (EDQM) and HALAL.

These systems and certifications form part of LIL's commitment towards quality, manufacturing control and serving customers across domestic and international markets.

Indian Manufacturing. International Outlook.

LIL's experience extends beyond the domestic market, with international business, export activities and documented experience in supporting overseas projects. Its market reach includes Europe, LATAM-Latin America, Southeast Asia-Pacific, the Middle East and North Africa.

This combination of Indian manufacturing capabilities and international market exposure allows LIL to understand the requirements of customers operating in different pharmaceutical markets across the globe.

Building for What Comes Next

Pharmaceutical manufacturing will continue to evolve. Regulatory expectations will change, formulation technologies will develop and customers will continue to look for greater consistency, technical support and supply reliability from their partners.

LIL is responding through continued investment in upgrade and upskilling for the manufacturing capacity & Capabilities, technical capabilities, quality systems and dynamics across international markets.

The objective is simple: to provide consistent pharmaceutical-grade lactose today while building the capabilities needed to support the requirements of tomorrow.

Strengthening India's Pharmaceutical Supply Chain

With global supply chains facing uncertainty due to geopolitical developments and disruptions across regions, strengthening domestic manufacturing has become increasingly important for the pharmaceutical industry. At Lactose India Limited, we believe in Vocal for Local

and the vision of Aatmanirbhar Bharat, the major focus shifts on developing Indian capabilities to eliminate the dependency of domestic pharmaceutical manufacturer on Imported specialized grades of Lactose, that largely depend up on Import from other regions.

Our portfolio includes Pharma Grade Lactose Monohydrate, Spray Dried Lactose, Anhydrous Lactose, Inhalation Grade Lactose and Low Endotoxin Lactose, catering to a range of specialized formulation requirements for domestic markets. LIL also has capabilities in Lactulose API and pharmaceutical formulations, further expanding the areas we can serve. With our manufacturing facilities and capacity expansion plans, we aim to provide quality Indian alternatives, dependable supply and specialized solutions to pharmaceutical customers in India as well for the international markets.

A Partner Beyond the Product

For pharmaceutical manufacturers, an excipient is part of a much larger process. Its quality and consistency can contribute to formulation performance, manufacturing efficiency and overall product quality.

That is why the right excipient partner needs to bring together product capability, technical understanding, quality systems and supply strength.

At Lactose India Limited, the focus is on bringing these capabilities together to support pharmaceutical manufacturers.

LACTOSE INDIA LIMITED
Quality | Innovation | Technical Excellence | Customer-Centricity

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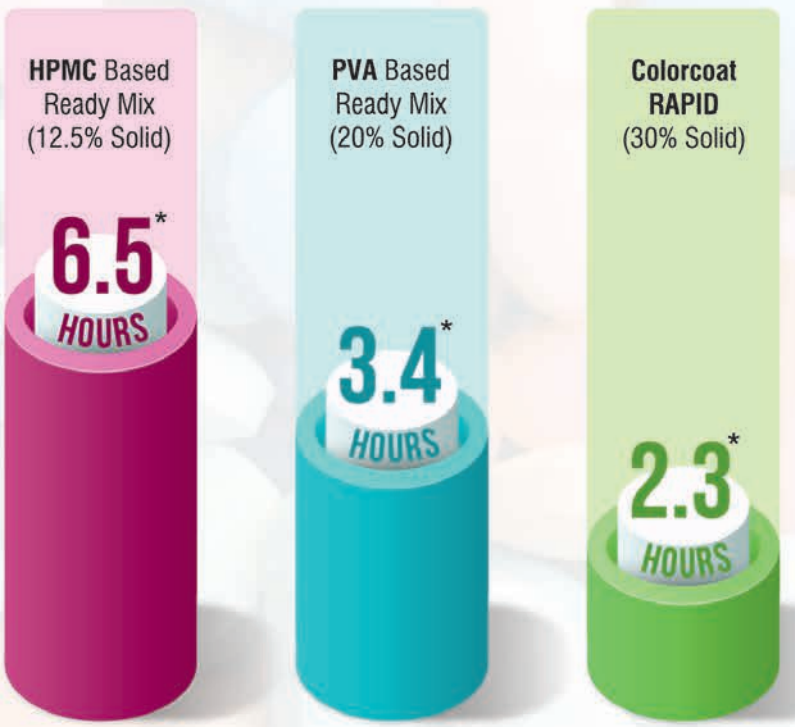
- Regulatory support



*Performed on 150 kg batch in 48" pan

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