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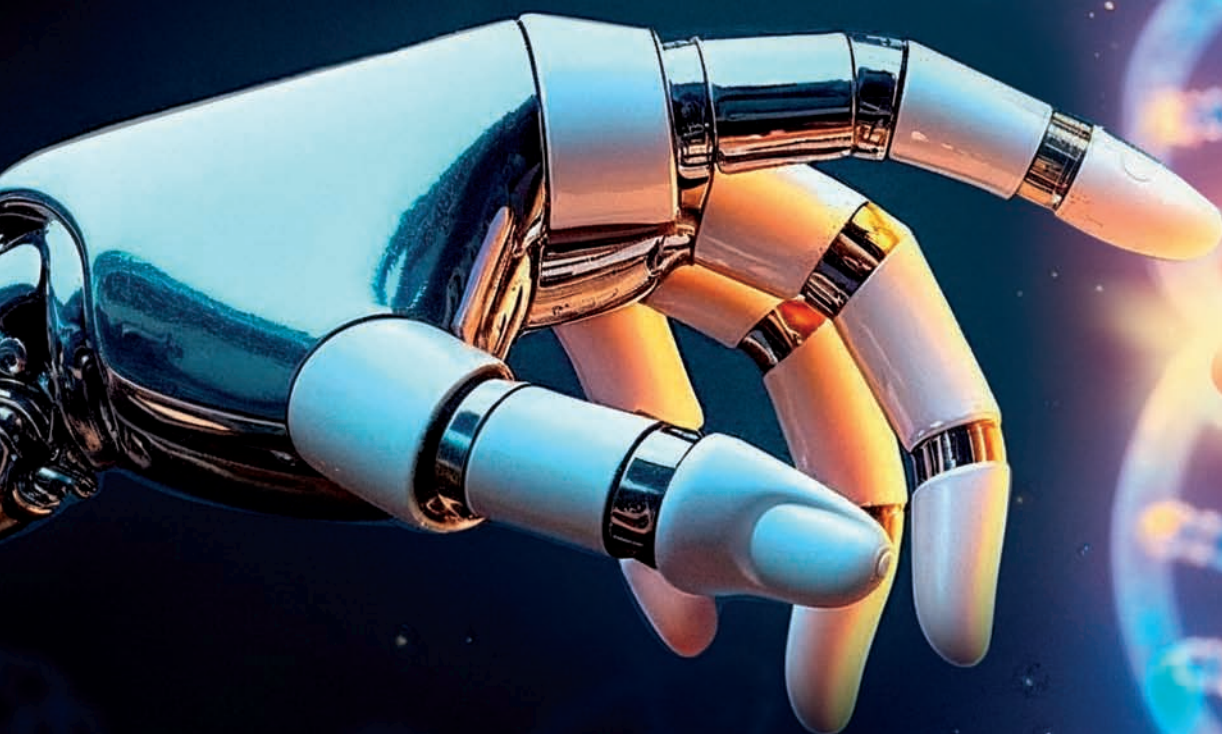


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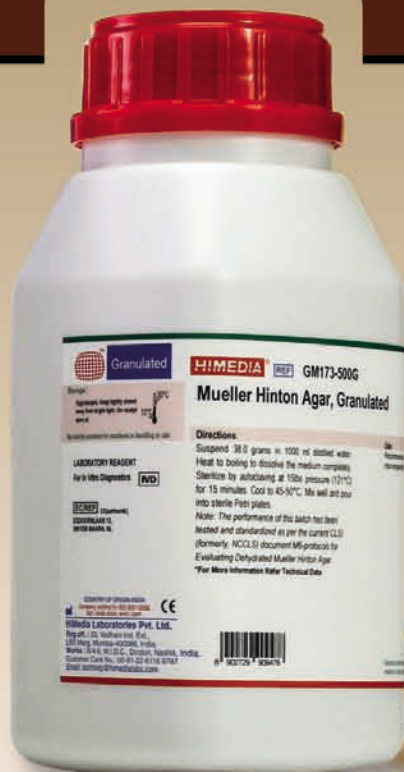
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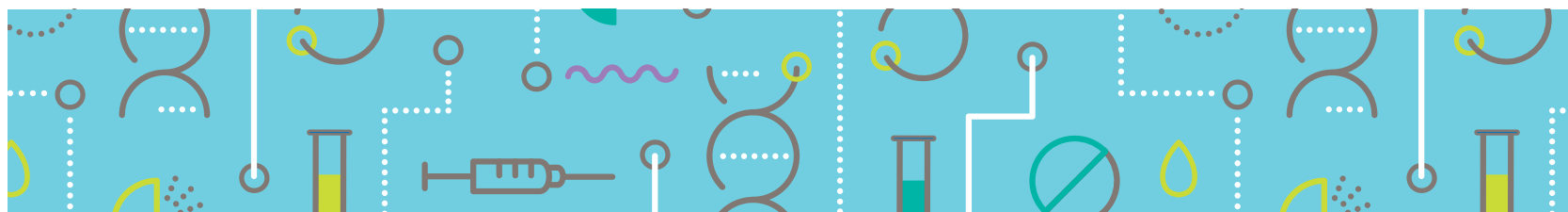
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Part of **The Dadachanji Group**, KAISHA Packaging draws on a strong legacy in pharmaceutical engineering and manufacturing excellence, combining deep technical expertise with scalable, compliance-driven execution.

Built on a thorough understanding of injectable manufacturing and Type I glass primary packaging, **KAISHA Packaging achieved an industry milestone by becoming the first company in India to manufacture aluminium seals in controlled, positive-pressure environments.** Its facilities are designed to global pharma standards, integrating GDP, controlled environments, validated HVAC systems, segregated man and material flow, and stringent EHS practices, ensuring consistent quality and audit readiness.

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Beyond aluminum seals, KAISHA Packaging offers a growing portfolio of **injection-molded products and drug delivery systems for sterile and non-sterile applications.** The range includes plastic ampoules, trays, nests and tubs, intradermal adapters, back stops, drug packaging kits, luer locks, rigid caps, vial adapters, IV and injection ports, and advanced solutions such as **Sycure AD**, a **Red Dot Award-winning** auto-disable system, and **Sycure TE**, a tamper-evident cap for pre-filled syringes. **Spray connectors** further expand the portfolio by enabling instant vial-to-spray conversion.



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The company exports to 25+ countries and demonstrated its scale and reliability during the COVID-19 pandemic by supplying over 200 million aluminum seals for critical pharmaceutical products.

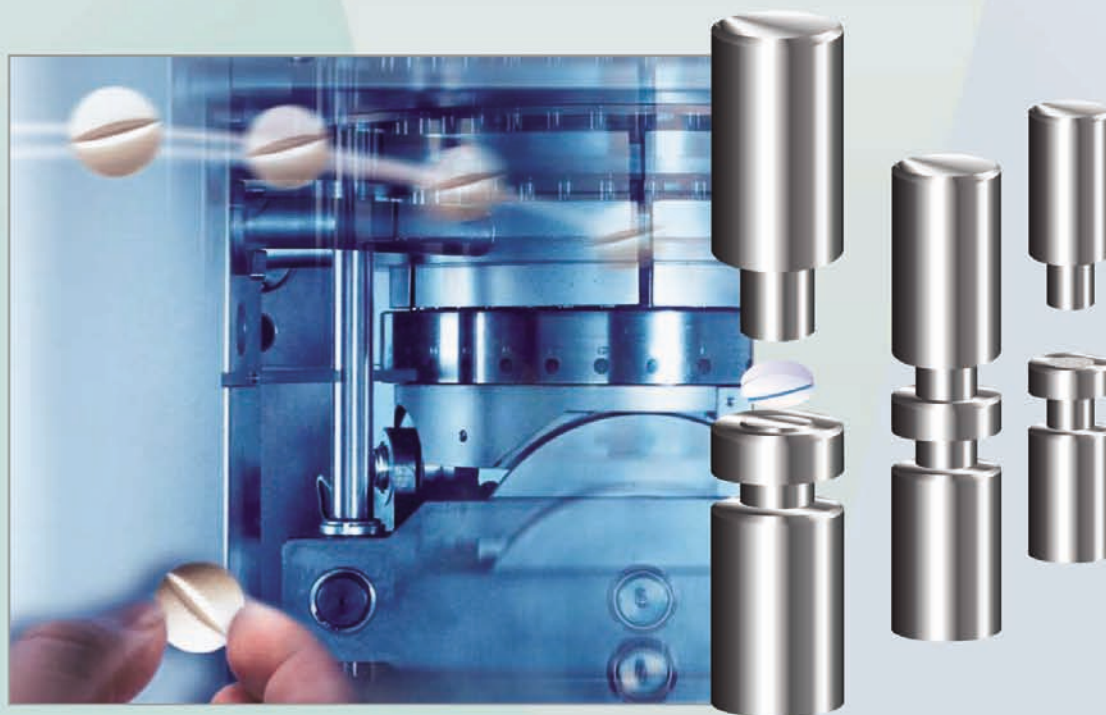


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Balancing protection and compliance

If 2025 was defined by US tariffs, predatory pricing + dumping of key ingredients, and quality concerns due to sub-standard exports and counterfeits, let's hope 2026 will see firm policy measures to balance these headwinds. Thankfully we do not need to wait for the Union Budget 2026 for such policy directives. But industry too needs to step up its efforts to comply.

For instance, India's Directorate General of Foreign Trade (DGFT), based on inputs from the Department of Pharmaceuticals (DoP), is using Minimum Import Prices (MIP) as a priority policy intervention to ensure that the early gains of the Production Linked Incentive (PLI) scheme continue to scale up, rather than be undermined by predatory pricing of key ingredients and APIs dumped by China, often at prices lower than its own production cost.

On September 18, the DGFT imposed MIP on ATS-8, a key ingredient of atorvastatin, a common cholesterol-lowering drug, at US\$111 per kg, till September 30, 2026. On December 19, DGFT imposed MIP on potassium clavulanate and related ingredients, seeking to secure India's antibiotic supply chains. Reports are that penicillin and its intermediates will also have MIPs, to incentivise pharma companies to continue to invest in fermentation-based manufacturing infrastructure.

As India moves to scale up towards self-sufficiency, MIPs and other measures will be required to safeguard progress and maintain a sustainable balance between local manufacturing and global sourcing, a key part of India's long term health security.

2026 must be the year India's pharma policy and industry align, as policy directives can only be successful if all sections of the industry step up to the challenge. For instance, consider the much delayed compliance with the revised Schedule M guidelines, which were first notified in December 2023.

Poor quality medicines due to non-compliance with Good Manufacturing Practices (GMP) have dodged India's pharma companies over the past few years. These quality concerns spurred India's authorities to release a revised Schedule M in December 2023, aimed at strengthening GMPs and pharma quality systems to assure patient safety and re-build global confidence in Made in India medicines.

While larger pharma companies have met the deadline to comply, MSME pharma companies have requested another extension beyond the December 31, 2025 deadline.

The Indian Drug Manufacturers' Association (IDMA), which represents most of the MSME pharma companies, has written to Punya Salila Srivastava, Secretary (H&FW), requesting that manufacturers who have already submitted upgradation plans and can demonstrate, through documented milestones, that execution is actively in progress, be granted extension on a case-by-case basis, commensurate with the progress demonstrated and subject to continued regulatory oversight.

IDMA's second request relates to encouraging wider MSME participation through clarificatory guidance. As per



2026 must be the year India's pharma policy and industry align, as policy directives can only be successful if all sections of the industry step up to the challenge

the letter, IDMA had earlier submitted specific suggestions and proposed clarifications on certain provisions.

Key concerns included whether the implementation would be adaptable guidelines or mandatory interpretation, the acceptance of alternate contamination-control approaches, the removal of earlier concessions for allied products like nutraceuticals, the introduction of separate, detailed requirements for hazardous substances, the uncertainty if manufacturers would alone remain accountable for pharmacovigilance compliance even when products are marketed by third parties, expectations regarding retail-level recalls, and ambiguity on additional labelling provisions beyond existing Drugs & Cosmetics Rules. IDMA reasoned that clarity on such interpretative aspects already raised in earlier submissions would increase MSME confidence, and encourage more manufacturers to submit upgradation plans in a structured manner.

IDMA's letter asks for one further conditional opportunity up to December 2026. But would another extension guarantee compliance? What can policy makers do to smooth the process for manufacturers with honest intent to upgrade, but need more clarity? One easy way would be to respond faster to queries, with clarifications.

Along with GMP compliance, India's pharma sector will also have to double down on securing their supply chain from counterfeits, as even one case can result in reputational loss, followed by a dent in revenues. In the case of vaccines, such reputational loss is even worse as it may increase vaccine hesitancy.

In the most recent example, Indian Immunologicals Limited (IIL) had to issue a clarification and refute the 'over-cautionary and misplaced' reference made to its Abhayrab anti rabies vaccine in a recent Australian health advisory, stressing that the advisory does not reflect the current situation.

As per the press note from IIL, in January 2025, the company identified one batch (Batch#KA24024, manufactured in 2023) with 'packaging different to the original.' IIL proactively notified Indian regulators and law enforcement agencies, lodged a formal complaint and worked with authorities to ensure swift action. The company had also reportedly informed health authorities in international export markets. There were no market complaints with the rest of the Abhayrab Batch#KA24024, and IIL has written to the Australian health authorities to consider revising the advisory.

The priorities for 2026 are clear: scaling up PLI-scheme production, higher compliance among MSME pharma to revised Schedule M and raising the bar against counterfeits. Or will we end 2026 with more of the same concerns?

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Pharcos Speciality's Daman plant secures WHO-GMP certification

The certification underscores Pharcos' adherence to globally recognised quality standards, safety, and regulatory compliance, strengthening its position as a trusted manufacturer of excipients

Pharcos Speciality has achieved a defining milestone in its journey of pharmaceutical excellence with its Daman manufacturing facility now certified under World Health Organization – Good Manufacturing Practices (WHO-GMP). The certification underscores Pharcos' adherence to globally recognised quality standards, safety, and regulatory compliance, strengthening its position as a trusted manufacturer of excipients.

The WHO-GMP recognition comes as Pharcos continues to expand the footprint of its flagship product, PHARCOCEL Hydroxypropyl Methylcellulose (HPMC) which has already been launched. HPMC is India's first indigenously manufactured product under the Make in India initiative.

Pharcel is widely used across pharmaceutical, nutraceutical, cosmetic, food, and specialty sectors, offering viscosity grades from 3 cps to 200,000 cps. Its versatility makes it suitable for controlled-release drug delivery, tablet and pellet coating, granulation, suspension stabilisation, and vegetarian capsule production.

The Daman campus has dedicated facility, for HPMC production, it has emerged as a benchmark for regulatory excellence. Alongside WHO-GMP, it holds an impressive suite of certifications including FDA GMP, EXCiPACT, ISO 9001, ISO 22000, Codex GMP (cGMP), Kosher, HALAL and FSSAI. Together, these certifications validate Pharcos' commitment to stringent global standards and broaden its ability to serve diverse international markets.

Vijay Doshi, Director of Pharcos Speciality, said, "Receiving WHO-GMP certification is a proud moment for all of us at Pharcos. It reflects our unwavering commitment to quality and regulatory excel-



lence. This recognition assures our partners and customers worldwide that our manufacturing practices meet the highest global standards."

He further added, "Pharcel is a product of precision and innovation and produced at plant specially designed to produce low nitrate and nitrite to mitigate risk of nitrosamine formation in drugs, a major concern globally. HPMCs are

produced with stringent process control ensuring low to absent nitrate and nitrite and reported in our certificate of analysis.

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With WHO-GMP certification backing our facility, we are better positioned to serve global markets with confidence

The certification underscores Pharcos' adherence to globally recognised quality standards, safety, and regulatory compliance, strengthening its position as a trusted manufacturer of excipients

and credibility."

With over 45 years of experience, long-standing relationships with multinational clients, and a robust R&D ecosystem supported by well-equipped laboratories and a qualified Quality Assurance team, Pharcos continues to deliver innovative and sustainable solutions.

The WHO-GMP certification is expected to further en-

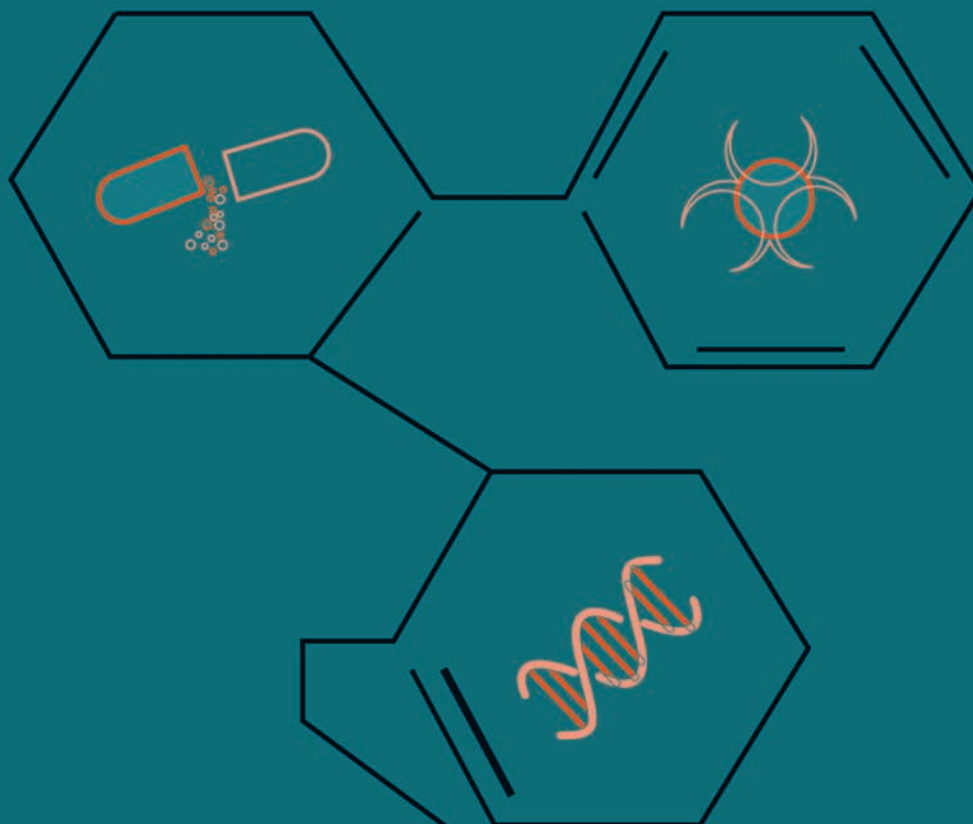
hance Pharcos' ability to participate in regulated markets across Europe, North America, and Asia, where compliance with international standards is a prerequisite for entry. Industry experts note that such certifications not only validate manufacturing practices but also instil confidence among global partners, regulators, and customers. For India, Pharcos' achievement represents another step in strengthening the country's reputation as a reliable hub for high-quality pharmaceutical excipients.

The certification also carries strategic implications for supply chain resilience. By offering a locally manufactured, globally certified product, Pharcos reduces dependency on imports and contributes to self-sufficiency in critical excipients. This aligns with India's broader vision of building a robust pharmaceutical ecosystem under the Make in India initiative.

For Pharcos, the recognition is both a validation of past efforts and a springboard for future growth. With WHO-GMP certification in place, the company is positioned to deepen collaborations with multinational pharmaceutical companies, expand its export footprint, and continue investing in innovation.

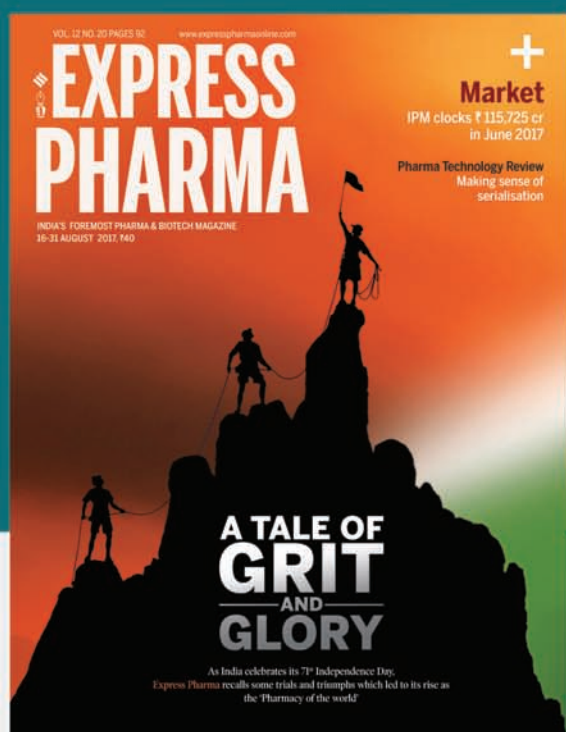
As Doshi emphasised, the achievement is not just about compliance but about setting new benchmarks for excellence: "At Pharcos, we believe innovation is driven by collaboration. WHO-GMP certification strengthens our ability to deliver solutions that are efficient, sustainable, and globally competitive."

The milestone marks a new chapter in Pharcos' journey, reinforcing its role in powering India's pharmaceutical ambitions and strengthening its position as a globally trusted manufacturer of high-quality excipients.



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INTERVIEW

Local manufacturing is not just a priority—it is a national commitment

Frehiwot Abebe, State Minister, Ministry of Health, Ethiopia, and **Bhavin Mukund Mehta**, Vice Chairman, Pharmexcil, discuss Ethiopia's evolving pharma ecosystem. They outline the country's regulatory reforms, strategies to strengthen local manufacturing, investment-friendly policies, and future plans for capacity building and vaccine development. The conversation also highlights the growing India–Ethiopia partnership, with insights from Pharmexcil on export trends, regulatory alignment, and improving the ease of doing business, in an interaction with **Kalyani Sharma**

Ethiopia is undergoing significant evolution in its pharma regulatory landscape. What are the most critical regulatory reforms underway, and how do you envision international partners contributing to this transformation?

Frehiwot Abebe: Ethiopia, with a population of over 130 million, is currently reforming its local pharmaceutical manufacturing sector. More than 85 per cent of our pharma are imported, so our visit to India had two main objectives: first, to learn from India's journey in becoming a global pharma hub, and second, to promote investment opportunities in Ethiopia.

Strengthening the regulatory framework has been essential. Over the past two to three years, we have worked continuously with the World Health Organisation to meet global regulatory benchmarks. Recently, we achieved Maturity Level 3 for pharma products, which indicates that our regulatory system is now stable, reliable, and supportive of local manufacturing and export.

To create a more responsive regulatory environment, we assessed our challenges—particularly delays in responsiveness and communication. We have now digitised the entire system, enabling companies to apply online for product registration and submit all



Frehiwot Abebe
State Minister, Ministry of Health, Ethiopia

required documentation electronically.

India accounts for more than 70 per cent of our pharma imports, so during our visit we sought feedback directly from Indian investors. Some challenges they highlighted included delays in GMP inspections. We have already begun working on improving the speed and efficiency of GMP assessments.

Overall, our approach is rooted in collaboration—learning from investors, understanding their challenges, and continuously improving our regulatory system.

Local manufacturing is a strategic priority for many African nations. What is



Bhavin Mukund Mehta
Vice Chairman, Pharmexcil

Ethiopia's long-term vision for building domestic pharma production capacity, and where do you see the strongest opportunities for collaboration with Indian companies?

Abebe: Local manufacturing is not just a priority—it is a national commitment. Our focus is on leveraging existing opportunities and learning from established manufacturing ecosystems like India.

One major challenge earlier was the availability of foreign exchange (forex) for importing raw materials. However, recent macroeconomic reforms have liberalised forex access, significantly reducing this barrier.

We also revised our procurement guidelines. Previously, these guidelines did not favour local manufacturers. Today, we provide 100 per cent procurement preference for quality-assured locally manufactured products. Only if a product is unavailable locally do we consider imports.

To encourage investment, we now offer minimum five-year and up to seven-year market guarantee frameworks for companies establishing manufacturing units in Ethiopia. Whether through joint ventures, FDI, or other models, investors are assured of a stable and predictable market.

In addition, we provide a 25 per cent price preference, duty-free exemptions, and benefit from Ethiopia's strong connectivity—our national airline can reach most global destinations within eight hours, making Ethiopia a strategic manufacturing and export hub for Africa.

Our visit to India is meant to communicate these reforms and opportunities, as many investors may not be fully aware of the advantages Ethiopia now offers.

What specific incentives or policy measures exist for foreign investments in Ethiopia's pharmaceutical sector?

Abebe: We offer a robust set of incentives:

1. Dedicated industrial parks with infrastructure

tailored for pharmaceutical manufacturing.

2. Tax-free import of raw materials, along with several other tax exemptions.

3. Procurement incentives, including a 25 per cent price preference for local manufacturers.

4. Advance payments—for instance, when procuring one million tablets of paracetamol, local manufacturers may receive up to 30 per cent advance support.

5. Long-term market guarantees of up to seven years.

6. Regulatory facilitation, including faster approvals and guidance. These measures are intended to provide certainty, reduce risk, and make Ethiopia an attractive destination for pharma investment.

Capacity building is crucial to sustaining healthcare progress. Which domains such as GMP compliance, digital health, or supply chain modernisation are Ethiopia prioritising for technology transfer and skill development from India?

Abebe: Ethiopia has a predominantly young and educated population—over 60 per cent youth. However, one gap we identified is the need for greater hands-on skills and technical expertise within the pharmaceutical workforce.

We are strengthening industry-academia linkages

to address this, but collaboration with India is vital. We hope to learn from India's experience in building skilled manpower across pharmaceutical and vaccine manufacturing.

Currently, Ethiopia has achieved Maturity Level 3 for medicines, but not yet for vaccines. India, on the other hand, has reached Maturity Level 3 in vaccine manufacturing. During our meetings with the Indian FDA in Delhi, we discussed how India built its capabilities and how Ethiopia can replicate similar systems to elevate our vaccine regulatory maturity.

We are also initiating plans to establish a vaccine manufacturing industry in Ethiopia in the coming years, and India's experience will be invaluable.

Strengthening the supply chain is essential, especially as Africa's healthcare market is projected to grow significantly. What are the key supply chain challenges for Ethiopia?

Abebe: Ethiopia is indeed a growing market, and with that comes increasing demand for efficient supply-chain systems. Our challenges include ensuring reliable distribution networks, enhancing cold-chain infrastructure, improving last-mile delivery mechanisms, and integrating digital systems for better tracking and monitoring.

Strengthening partnerships, building technical capacity, and modernising logistics are central to meeting future demands.

How have India's pharmaceutical exports to Ethiopia evolved over the past 5-7 years, and which product categories are driving the strongest growth?

Bhavin Mukund: India's pharmaceutical exports to Ethiopia have shown steady growth over the past five to seven years, increasing at a rate of around 6-8 per cent annually. The largest share of exports continues to be antibiotics, which remain Ethiopia's top priority category.

What regulatory, logistical, or market-related challenges do Indian pharma companies face in Ethiopia, and how is Pharmexcil helping them navigate these

hurdles?

Mukund: The primary challenge involves registration timelines. Indian companies exporting to Ethiopia often require fast-track registration for their products. This is where Pharmexcil plays an active role. If a company's dossier is delayed or stuck in the regulatory system, we intervene to facilitate and expedite the process. Our support ensures quicker clearances and smoother market entry for Indian pharmaceutical products.

How is Pharmexcil collaborating with Ethiopian authorities and industry stakeholders to enhance regulatory alignment, streamline approvals, and improve

ease of doing business?

Mukund: Our focus is on improving the ease of doing business and ensuring affordable access to high-quality medicines in Ethiopia. One key initiative is working toward acceptance of Indian Pharmacopoeia (IP) by Ethiopian regulators. If Ethiopian authorities recognise IP standards, it can result in a 15-20 per cent reduction in drug prices for the local market. This aligns with our objective of supporting affordable healthcare, strengthening regulatory cooperation, and making Indian pharmaceuticals more accessible in Ethiopia.

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We are cost-competitive and aligned with global ESG framework demands

From dependence on imported single-use products and containment solutions, India's biologics sector can today access domestically manufactured SUTs, which can be 20–30 per cent more cost-effective than imported counterparts. **Sachin Joshi**, Founder and MD, and **Ankush Kapoor**, CEO & Co-Founder, Pharmnxt Biotech explain to **Viveka Roychowdhury** how India is emerging as one of the fastest-growing continuous bioprocessing markets in Asia, backed by conducive policies, focus on cost containment and ESG compliance

The biologics sector is very dependent on single-use products and containment solutions. For example, the COVID pandemic exposed the vulnerability of vaccine makers to being import-dependent. Has the situation changed since then? What is the price differential for imported and Made in India single-use solutions, and how do they fare in terms of meeting global quality norms?

Joshi: The biologics industry's reliance on SUTs and containment solutions is a necessity driven by the need for flexibility, safety, and cost-effectiveness in the production of complex biological therapies. Yes, India was badly exposed during the pandemic, particularly as manufacturers were heavily reliant on imported single-use components from the US and the EU. However, since then, domestic manufacturing has surged significantly. The single-use bio-processing systems market in India jumped from \$508.9 million in 2024 and is expected to reach \$1,975.7 million by 2032, growing at a CAGR of 18.48 per cent. We see this as real progress.

While exact price differentials vary by product, anecdotal industry estimates suggest that domestically manufactured SUTs can be 20–30 per cent more cost-effective than imported counterparts, primarily due to reduced logistics costs and favorable duty structures, and the quality is aligning with global GMP standards and



Sachin Joshi
Founder and MD,
Pharmnxt Biotech

CDSO's increasingly stringent validation protocols. We're also seeing growing investment in indigenous innovation, tech-transfer partnerships with global firms and acquisitions.

What is the carbon footprint of single-use products, especially when companies will have to follow ESG norms of India as well as the countries to which they export?

Joshi: As global ESG norms tighten, both within India under frameworks like BRSR and in export destinations like the EU and US, sustainability is no longer optional. Fortunately, single-use technologies (SUTs) in biopharma are also environmentally aligned, in addition to being operationally effective.

Multiple independent life-cycle assessments (LCAs) show that single-use systems consistently outperform traditional stainless-steel



Ankush Kapoor
CEO & Co-Founder,
Pharmnxt Biotech

setups across a wide range of sustainability metrics. In one such study comparing monoclonal antibody production systems, single-use solutions delivered lower environmental impact across 18 different categories, like Carbon Footprint, Renewable Energy Adoption, Water Usage, Waste Generation, etc.

From a resource-use perspective, single-use systems consume 30 per cent less energy, 87 per cent less water, and 95 per cent fewer detergents compared to conventional cleaning and sterilisation methods. This leads to a 25 per cent reduction in carbon footprint by eliminating energy-intensive cleaning and steaming processes. This positions Indian-made single-use products strongly on the global stage. We are both cost-competitive and aligned with global ESG framework demands.

How are single-use product manufacturers ensuring that they are as sustainable as possible, without raising the prices of the final products?

Joshi: The key to cost-effective sustainability lies in strategic design, material innovation, and process optimisation.

For starters, many manufacturers are embracing sustainability-by-design, simplifying product architecture by eliminating unnecessary components like extra sampling ports or bulky connectors. Material innovation is another lever. There's a growing shift toward bio-based, recyclable, and compostable polymers, which are now being produced at scale, making them more cost-competitive. These sustainable alternatives meet the same performance standards while reducing dependency on fossil-based inputs.

In terms of operations, companies are investing in waste-to-energy (WTE) systems for safe disposal of contaminated single-use materials. Some are even exploring closed-loop water systems to further reduce energy and water consumption. Additionally, single-use systems inherently eliminate the need for steam and chemical-intensive cleaning cycles. This brings significant cost savings in validation, water, and energy which can be reinvested in sustainable improvements rather than being passed on to the buyer.

What are the global trends and focus areas in the bioprocessing space? Where

do India's bioprocessing companies fit into global bioprocessing supply chains?

Kapoor: Globally, the bioprocessing industry is moving rapidly towards trends like single-use bioprocessing systems, continuous bioprocessing, automation and digital biomanufacturing, and advanced filtration and monitoring systems. India is uniquely positioned to benefit from this transformation.

In continuous bioprocessing, for instance, India is emerging as one of the fastest-growing markets in Asia, with expected growth from a small base to nearly \$50 million by 2030. This adoption is being driven by India's strength in cost-competitive, scalable manufacturing, particularly in biologics and biosimilars.

India is also faring well in digital biomanufacturing, thanks to initiatives like Bio-E3 and dedicated biofoundries. The government is pushing for AI-enabled, automated production systems. Meanwhile, the market for single-use sensors and advanced filtration systems is booming, projected to grow over three times by 2033, aligning with international process analytical technology (PAT) standards.

Coupled with the 673 USFDA-approved manufacturing plants, the most in the world, outside the US, India is poised to capitalise on the existing trends.

What has been the uptake of government policies like the National Biopharma Mission and initiatives like Bio-E3

INTERVIEW

and Bio-RIDE? What is the timeline to see this impact?

Kapoor: National Biopharma Mission (NBM), Bio-E3, and Bio-RIDE are some of the most visionary government interventions, and they are already delivering tangible results. The National Biopharma Mission, for instance, has supported over 200 grantees across vaccines, biotherapeutics, medical devices, and diagnostics, leading to the launch of over 18 successful market-ready products. Over 450 IPR awareness campaigns have been conducted, 25+ technologies have been licensed to industry, and 300 MSMEs are actively benefiting. It's no surprise that the World Bank called the NBM a "hidden jewel" in its global portfolio.

Complementing this, newer initiatives like Bio-E3 (Empowering Enterprises in

BioEcosystem) and Bio-RIDE are working to scale innovations, create next-gen biofoundries, and drive digital and sustainable biomanufacturing. At the current pace, we can expect significant breakthroughs by 2030, making India globally competitive in biopharma. Together, these programs are laying the groundwork for India's ambitious target of a \$300 billion bioeconomy by 2047, the centenary year of our independence.

Are we hampered by a lack of a skilled workforce for biopharma, and what's being done on this front?

Kapoor: Yes, India does face a mismatch between demand and supply of niche-skilled talent in the biopharma sector. Several reports, including the GBRI, show us that sectors like R&D, manufacturing

(especially GMP-ready roles), supply chain, and customer engagement face talent shortfalls, with India ranking 17th out of 22 countries in workforce resilience in the biopharma sector. Companies struggle to attract and retain top-tier talent, especially in digital technologies and scientific roles.

However, we would not call it a crisis. With a young workforce, expanding educational infrastructure, and growing investments in training and R&D, the situation is improving. India's demographic dividend is significant: 50 per cent of its 1.3 billion population is under 25, and over 15,500 biotech graduates enter the workforce annually. The sector is also supported by a strong ecosystem, with nine DBT-supported biotech parks and 60 BIRAC-supported bio-

incubators nurturing talent. Of course, more needs to be done, but we believe as a developing country, we are getting there.

How can biopharma companies build future business strategies that are resilient to geopolitical shocks like tariffs, wars, etc?

Kapoor: Wars, tariffs, and trade disruptions are very much a part of the complex world we live in. Wars, export bans, and fluctuating tariff regimes impact everything from APIs to packaging materials. The biopharma sector, like all others, is vulnerable. But if India truly wants to fulfil its vision of becoming the "pharmacy of the world", we must etch resilience into our business strategies.

The foremost non-negotiable is to, of course, de-risk their supply chains by diversifying sourcing across

countries, vendors, and creating strategic reserves of critical components like reagents and filters. Localisation of high-value inputs is also key. Investing in domestic capabilities for single-use systems, biosimilars, and advanced biologics equipment reduces exposure to external shocks. PharmNXT is already leading this development by providing homegrown alternatives to traditionally imported components. A robust digital infrastructure can make operations more shock-absorbent.

Importantly, the Government of India is already acting on this front through PLI schemes and trade agreements like CEPA and India-UK FTA to strengthen manufacturing and innovation ecosystems.

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India at a jumping-off point in terms of commitment to global clinical studies

Paul Bridges, PhD, President, Consulting, Parexel, and **Sanjay Vyas**, President of Global Safety Services & Clinical Logistics and Country Head for India, Parexel, shortlist trends that will define 2026— from data protection uncertainty and AI governance to biosimilars' second wind, inspection readiness and India's emergence as a global clinical trials hub. Excerpts from a wide-ranging conversation with **Viveka Roychowdhury**

If you were to pick one or two trends in clinical trials and research in India in 2026, what would you be looking at? What are the trends you would track, worry about, or watch closely?

Sanjay Vyas: For me, one is the new data protection act that has just come in (the Digital Personal Data Protection Act, 2023 (DPDP Act)). There is still a lot of uncertainty. Even though the act states that if you use local patients and local vendors you need to ensure data protection, for outside vendors it may not be required. I want to see how this will be implemented.

As a CRO, I am not worried because we are already very high on compliance and data protection processes. But the skepticism remains around how data will be captured, where it will reside and how it will be reported. That is one trend I will definitely track.

The second trend that continues to keep me slightly awake is the applicability of artificial intelligence and machine learning. We are still behind in issuing clear guidelines compared to the US FDA and EMA. They have been very proactive. We have even had a seat at the table with the US FDA, where our chief data officer served as a consultant. They are asking questions like what tools are you using and where AI is being applied across clinical trial processes.

We have not reached that stage in India yet. I would like to see that progress and some clarity emerge.

The third is early phase trials, especially first-in-human studies. I hope that at some



Paul Bridges, PhD, President, Consulting, Parexel

point the doors open further and the environment becomes more conducive so that drugs can be made accessible to patients earlier, rather than waiting until phase two or phase three.

Paul Bridges: So probably the topic I would address first is Indian companies. These are well funded companies with decades, sometimes hundreds of years, of experience, now taking that knowledge and technical capability and applying it to far more innovative areas of research and development, perhaps through that biosimilar bridge to true innovation.

Some of the changes we are seeing in the US market are triggering this shift. Indian firms looking to penetrate the world's largest global market now have to commit. Questions come up around transferring manufacturing sites to the US and other related decisions. That is a significant commitment and, in my view, it

can only really be supported by true R&D investment.

So the first hot trend is conversations with very capable and credible global sponsors in India about their pipeline and their approach to conducting clinical development globally. That is what has brought me here this week, day after day of conversations with companies that have done well in generics, have had early success with biosimilars, and now want to target the next wave.

Secondly, biosimilars are seeing renewed emphasis. There is a sort of second wind behind the biosimilar opportunity because the US FDA and EMA have waived some of the phase three clinical requirements for biosimilars. A number of candidates coming off patent are becoming more attractive biosimilar targets because of this.

That said, this does not mean clinical trials are no longer required for biosimilars. Very important PK studies still



Sanjay Vyas, President of Global Safety Services & Clinical Logistics and Country Head for India, Parexel

need to be performed, along with observational studies. I would strongly advocate that sponsors maintain close dialogue with regulators around the world to understand how these new guidelines translate into operational reality.

That is where Parexel is very active right now, helping sponsors understand that they do not get a free pass on clinical studies, but that those studies can be smaller, more focused and more targeted. So this represents a second opportunity, that second wind behind biosimilars.

Finally, is the emergence of India as a potential global hub for clinical trials and clinical trial conduct. Many of the elements are falling into place. There are also areas that need more focus, including public awareness of the importance of clinical trials and greater willingness to engage in earlier phase studies. But I see India as being at a jumping-off point in terms of commitment to global

clinical studies. We have seen similar trajectories in China and other jurisdictions.

Vyas: Recently, the US FDA conducted a surprise inspection for one sponsor in Korea. That trend is increasing.

With the mandate coming from the Prime Minister's Office and the DCGI, and with new audit and inspection processes starting in 2026, there is a clear directive. The revised Schedule M also plays a role here, with a focus on getting manufacturing in India to a level of confidence aligned with US FDA and global GMP standards.

This will be a critical trend to watch in 2026. With all the attention drawn by incidents like the cough syrup cases and other situations, we recently had a symposium where a local DCGI official in Ahmedabad stated that it is now a clear mandate for every pharma manufacturer in India to operate at the highest standards. The goal is to reach a point where US FDA surprise

INTERVIEW

inspections are no longer an exception, but compliance at that level becomes the norm.

So you are inspection ready at all times?

Bridges: I am really glad you raised that. This is a massive issue. For a number of years post COVID, and then following the post election disruption in the FDA, inspection activity slowed down. Inspectors were not getting out into the field, and there was staff attrition. As a result, enforcement activity declined.

The new US administration has been very clear that they want a leveling of the playing field between domestic US manufacturers and global sponsors. We have been telling our sponsors to be prepared, because the FDA will be coming, and inspections will now be unannounced.

Historically, Parexel would receive a call from an Indian or Korean sponsor saying they expected an inspection in a few months and needed help preparing. We would engage, identify issues and fix them. That is no longer the case.

We are also seeing an uptick in inspection activity. There are more inspectors in the field. As Sanjay mentioned, we recently heard from a sponsor who had the FDA turn up unannounced, identify issues and threaten import alerts and restrictions into the US.

This is a big deal. It would not have happened 12 months ago. We expect more of this in India as well. Framed positively, as Sanjay said, this is a great opportunity to take a leap forward in the context of the global opportunity we have been discussing today.

It is about improving

processes, strengthening data flows, using tools like AI in manufacturing, and, overall, being inspection ready. That readiness is a very important topic.

It can also be seen as a regulatory moat. Those who reach that level gain a competitive edge.

Vyas: It is no longer possible for us to sit back and remain only the generics capital of the world. We have to become the pharma manufacturing hub of the world. It does not matter whether it is generics, biosimilars or anything else, because the CDMO industry is also growing rapidly, especially in this part of the world. After what has happened, confidence levels in China have gone down a bit, so there is a clear opportunity for India to take a leap of faith and leverage that

further. There is one more point that struck me, which is the emergence of new innovative medicines coming out of India. One trend I have seen among pharma sponsors is that they are starting to look beyond biosimilars to new molecules.

Cell and gene therapy, perhaps unfortunately or fortunately, initially came from academia, with IIT being one of the first to approach it from that perspective. However, many Indian multinational pharma sponsors that I have spoken to have now, in some form or another, started exploring the development of cell and gene therapies. This has the potential to reduce the cost of these therapies by almost 60 per cent, which is a significant opportunity that India has. I see this emerging as a positive trend by 2026.

There is absolutely an

opportunity here. It is just a matter of investments and the right incentives being provided.

Bridges: Going back to manufacturing inspection readiness, it is also worth reflecting on the fact that generic and API manufacturers in India have been given some relief on tariffs for the US market. That is good news. However, what President Trump has given on one hand, he has also signalled that it could be taken away. If manufacturing standards are not at the required level, we could see punitive actions.

So I would expect that any pressure that has been absent from the tariff debate for Indian manufacturers will start to show up strongly through inspections and enforcement.

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Supriya Lifescience ramps up capacity and global readiness for next phase of growth

Recently, Supriya Lifescience expanded its manufacturing capacity at the Lote facility with the commissioning of Module E, which has enhanced operational efficiency and increased capacity utilisation from 70 per cent in FY2025 to 78 per cent in the first half of FY 2026. The company is also planning to commence commercial operations of its Ambernath formulation facility in the second half of FY 2026. **Dr Satish Wagh**, Executive Chairman and Whole Time Director, Supriya Lifescience highlights how new facility expansions, stronger regulatory capabilities, and rising capacity utilisation are positioning the company to deepen its global footprint and drive sustained growth across key therapeutic segments, in an exclusive interview with **Swati Rana**

Supriya Lifescience has built a strong global presence in Active Pharmaceutical Ingredients. What has guided this journey?

Our growth has been guided by a clear focus on niche Active Pharmaceutical Ingredients, strong backward integration and a commitment to regulatory excellence. Over the years, we have expanded into more than 128 countries, and exports today contribute between 81 per cent and 84 per cent of our revenue. Our facilities hold approvals from major regulatory agencies such as the United States Food and Drug Administration, the European Directorate for the Quality of Medicines, the World Health Organisation, the Pharmaceuticals and Medical Devices Agency, the Korea Food and Drug Administration and ANVISA. This regulatory strength, combined with consistent quality and reliable supply, has helped us build a trusted global presence.

What have been the most decisive milestones shaping Supriya's current position?

Several milestones have defined our journey. Backward integration across our product portfolio strengthened our control over quality, cost and supply reliability. The successful completion of a United States Food and Drug Administration audit conducted with only 48 hours of



notice reaffirmed our regulatory preparedness. The commissioning of Module E at our Lote Parshuram facility improved operational efficiency and stability. We also acquired three land parcels near our existing facilities to support future expansion. In addition, strengthening core functions such as production, quality assurance, quality control, regulatory affairs and engineering has helped build a robust and resilient organisation.

What are the major revenue growth drivers?

The second quarter of the financial year 2026 has already shown positive momentum with a 20 per cent and year-on-year increase in revenue.

Growth will continue to be supported by consistent demand in our key export markets across Europe, Asia and Latin America. Capacity utilisation has improved significantly, rising to 78 per cent in the first half of financial year 2026 from 70 per cent during financial year 2025, aided by the ramp-up of Module E. The commercial launch of our Ambernath formulations facility in the second half of the financial year 2026 will further strengthen our capabilities. Our continued focus on regulated markets, backward integration and product expansion will support sustained growth and profitability.

Which therapeutic categories or product lines will be the next growth drivers?

Our growth continues to be driven by segments that show steady global demand. The anaesthetic segment has been the strongest performer, contributing 54 per cent of revenue in the first half of financial year 2026 compared to 46 per cent in the previous year. The anti-histamine segment increased from 10 per cent to 12 per cent, and the vitamin segment also improved from 11 per cent to 12 per cent. These therapeutic areas remain central to our expansion and will continue driving performance in the coming quarters.

How do you balance the export-led model with the India portfolio?

Exports continue to be the core of our business, contributing more than 81 per cent of our revenue in the second quarter of financial year 2026. Our products are well aligned with the needs of regulated and semi-regulated international markets, which naturally drives our focus toward global business. While we remain committed to serving the Indian market, our growth and strategy remain centred on export demand due to the scale, consistency and long-term relationships we have built internationally.

With 81 per cent export revenue, what challenges do you face, and which markets contribute the most?

The primary challenges relate to navigating varied regulatory requirements internationally and ensuring consistent, compliant supply. Europe remains our largest contributor, with around 37 per cent to 40 per cent of revenue in the second quarter of financial year 2026. Asia contributed 34 per cent, and Latin America contributed 21 per cent, increasing from 17 per cent in the previous quarter. Both Asia and Latin America have been improving sequentially and year-on-year and continue to present strong growth opportunities.

As Supriya expands into more regulated markets, what regulatory or partnership developments do you foresee?

We maintain strong regulatory discipline, and the recent clearance of a short-notice United States Food and Drug Administration audit reflects this readiness. As Module E stabilises and the Ambernath facility becomes operational in the second half of financial year 2026, we expect increased engagement with global partners who prioritise regulatory compliance, quality and reliable supply.

How are you enhancing the Active Pharmaceutical Ingredient pipeline and do you see opportunities in Contract Development and Manufacturing?

Our focus remains on strengthening our existing Active Pharmaceutical Ingredient portfolio across anaesthetic, anti-allergic, vitamin, anti-histamine and anti-asthmatic segments. The Ambernath facility will expand our formulation capabilities and open potential avenues for future collaboration. We continue to prioritise consistency, compliance and

quality-driven manufacturing as we grow.

What technological or compliance-related improvements are being adopted in manufacturing?

Module E has contributed significantly to operational efficiency and improved capacity utilisation. Across our locations, we continue to strengthen quality systems, in-house quality control and robust engineering practices. Investments in structured operations, safety enhancements and ongoing process improvements ensure

that our facilities remain aligned with global compliance expectations.

What leadership attributes are essential as Supriya scales further?

Strong and experienced leadership across production, quality assurance, quality control, regulatory affairs, finance and engineering is essential to our progress. Our functional heads bring deep industry experience and a hands-on approach that strengthens execution, compliance and operational discipline as we expand our

capacity and market reach.

Where do you see Supriya Lifescience in the next five years?

We expect steady and sustainable growth supported by strong demand in key markets, improving capacity utilisation and the addition of new capabilities. With Module E fully operational, utilisation rising to 78 per cent and the Ambernath formulation facility scheduled to become commercially active in the second half of financial year 2026, we are well positioned for further expansion. Our focus

will continue to be on regulated markets, capacity scaling and strengthening our product mix.

What message would you offer to young professionals entering the pharma sector?

The pharma industry values commitment to quality, operational discipline and continuous learning. Young professionals who embrace these principles will find meaningful, long-term and globally relevant opportunities in the sector.

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Quality Trailblazer emphasises that leadership commitment is non-negotiable

In an exclusive interview with **Swati Rana, Ranjit Barshikar**, CEO - QbD International and author of the newly launched book *Quality Trailblazer*, shares reflections from his five-decade journey across global pharmaceutical manufacturing, quality systems, and regulatory landscapes

What motivated you to write *Quality Trailblazer*, and how does it address the most pressing quality challenges faced by the Indian and global pharma industry today?

I wrote this book to express myself—to reflect on what I did, what I learned, and how those experiences shaped me. More importantly, I hope that by documenting this path, someone somewhere—perhaps a student just stepping into the world of pharma, a young professional grappling with early challenges, or even a seasoned expert looking for perspective—may find value, insight, or even a moment of clarity.

The pharmaceutical industry has seen many waves of change (Pharma 3.0 to Pharma 4.0), and I've had the privilege of witnessing them all—from the days when 'quality' was largely about control, to the present, where 'assurance' has become the cornerstone.

Through this book, I share

not only milestones and experiences but also the core values that have consistently guided me are:

- There is no alternative to working hard and working smart
- There is no alternative to gaining knowledge
- There is no alternative to teamwork
- There is no alternative to being honest

These principles are timeless. They do not just belong to the quality sphere—they belong to life itself.

This is my first book and I sincerely hope this book serves not only as a guide but also as a source of motivation and empowerment for all who read it.

Through real experiences, case studies, and actionable frameworks, *Quality Trailblazer* provides a roadmap for adopting risk-based thinking, building a culture of ownership, strengthening systems, and aligning Indian pharma with global expectations.

Ultimately, the book is a call to



work for HIGH QUALITY with focus on Patients, from a function to a shared value, enabling organisations not only to meet global standards but to set them.

You've had a long and diverse career in the global pharmaceutical and regulatory landscape. How does your personal journey reflect in the chapters of this book?

Each chapter reflects a phase of my career: the early years where I learned the fundamentals of discipline and GMP at Pfizer; the middle years marked by global

exposure, cross-cultural experiences, regulatory expectations at Lyka Labs & Ranbaxy days; and the later years days, where consulting allowed me to see patterns, gaps, and opportunities across the industry.

This my *Quality Trailblazer* is a lived narrative—sharing principles, failures, breakthroughs, and leadership insights that shaped my thinking. The chapters are intentionally practical, mirroring the challenges, decisions, and transformations I witnessed firsthand. In essence, the book is both a professional reflection and a personal roadmap, capturing what five decades in pharma have taught me about quality, people, and purpose.

What are the top three challenges you observe in pharma quality systems, and how does *Quality Trailblazer* propose organisations to overcome them?

The top three challenges I

observe in pharma quality systems are: weak data integrity practices that stem from cultural barriers, lack of training, and pressure-driven operations; inconsistent quality culture, where quality is seen as a departmental responsibility rather than a shared organisational value; and gaps in risk-based decision-making, leading to reactive compliance instead of preventive, science-driven quality.

Which insights from your book are particularly relevant for Indian companies aiming to strengthen their regulatory standing?

Indian companies must shift from reactive problem-solving to proactive risk anticipation, embedding Quality by Design, robust Data Integrity practices, and implementing various AI technologies to speed up the Operations with additional benefit of cost savings by way of enhancing productivity, in same time with same equipment & using

saved human hours for High Patient focused Quality & Safety.

Another crucial learning is the importance of global mindset. Quality should not vary by market, and every batch must meet the highest international standard regardless of destination. Strengthening regulatory standing also requires transparent communication, strong supplier governance, continuous training, and adoption of digital tools that bring visibility and control to operations.

The book *Quality Trailblazer* emphasises that leadership commitment is non-negotiable: when leaders walk the shop floor, ask the right questions, reward ethical behaviour, and challenge shortcuts, the organisation rises to global expectations.

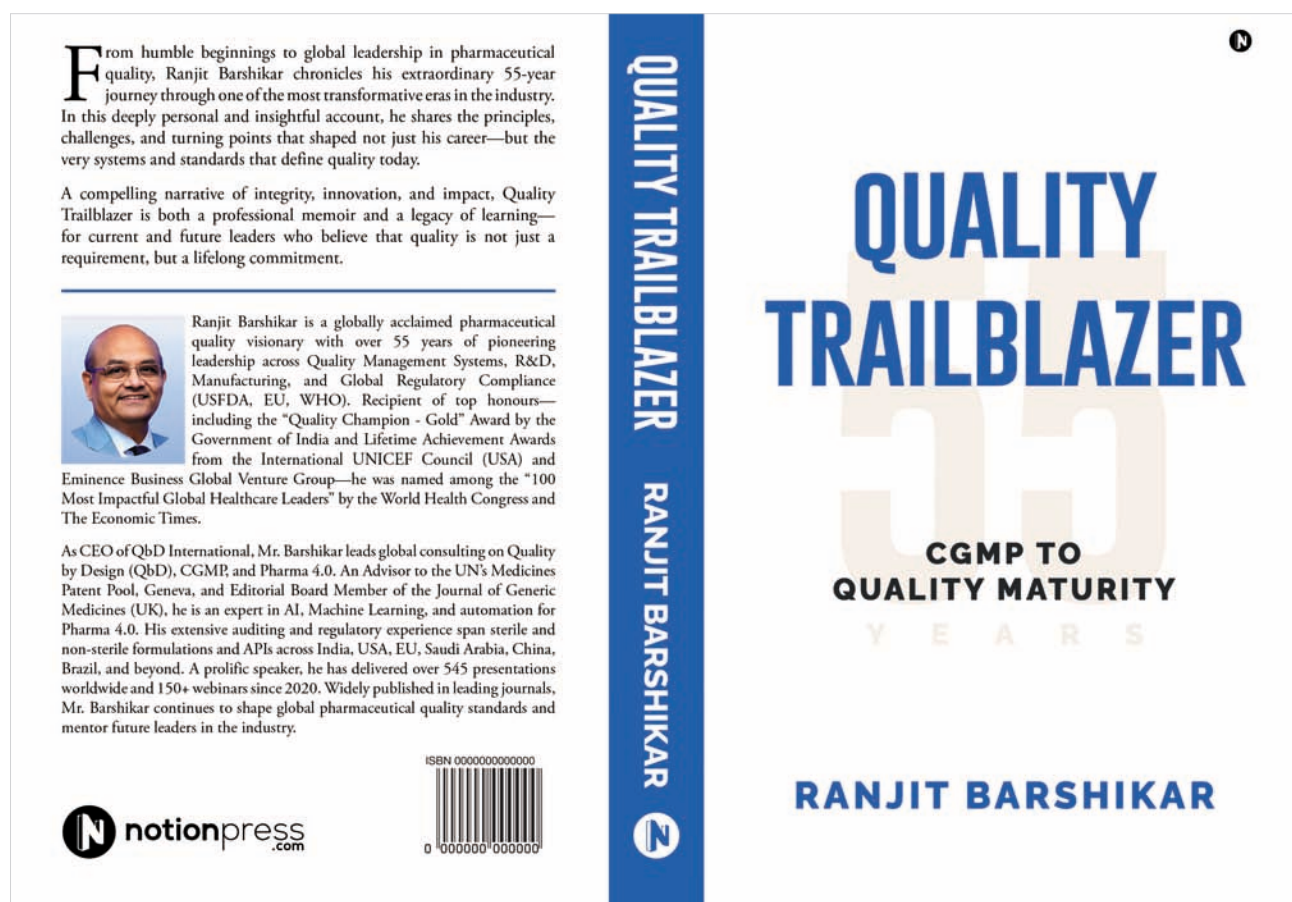
Ultimately, the message is simple yet powerful—Quality is not a cost but a competitive advantage, and companies that embed this philosophy will not only meet regulatory expectations but also build lasting trust and global respect. The cost of non-compliance is higher than quality compliance.

In the book, you highlight Quality Culture as the backbone of sustainable excellence. What practical steps can companies take to build and measure a true quality culture?

A true quality culture is built on everyday behaviours, not only policies. Companies must begin by setting a clear tone from the top leaders who visibly prioritise GMP, data integrity, and patient safety to establish the cultural baseline.

Embedding quality into daily work through simple, standardised routines, Gemba walks, open reporting, right-first-time practices, and cross-functional quality ownership creates consistency.

Capability-building is equally essential: practical training, coaching at the shop floor, and empowering teams to pause operations when



Ultimately, the message is simple yet powerful—Quality is not a cost but a competitive advantage, and companies that embed this philosophy will not only meet regulatory expectations but also build lasting trust and global respect. The cost of non-compliance is higher than quality compliance

something feels wrong. Transparent communication, learning from near-misses, and celebrating quality-positive behaviours reinforce the culture. Measurement must go beyond traditional KPIs. Companies should track leading indicators like CAPA effectiveness, right-first-time trends, audit observation recurrence, employee speak-up rates, deviation-to-batch ratio, and quality maturity assessments.

Regular cultural diagnostics—surveys, behavioural observations, and leadership engagement scores—offer deeper insight into mindsets. When

companies align values, behaviours, and accountability with the shared purpose of protecting patients, quality culture becomes self-sustaining and drives long-term excellence.

Could you share a real case or learning that significantly shaped your understanding of quality excellence?

One of the most defining learnings in my five decades came early in my career, during an investigation of a recurring contamination issue in a sterile facility. As mentioned in my book “Quality Trailblazer”, there

was an incidence of market complaints from the US Market of broken tablets, which taught us that each & every change, major or minor, must be recorded for right Root cause analysis & CAPA.

Such experiences shaped my entire philosophy of quality. It taught me that quality is never built in documents—it is built in behaviours. True excellence demands leaders who listen, who go to the real place, who respect those doing the work, and who create an environment where people feel responsible, not supervised.

Some of the most enduring

lessons I’ve learnt along this journey are to:

- Stay calm and composed in the face of challenges.
- Be patient and selflessly help others.
- Continuously adapt to new technologies and enhance your expertise.
- Embrace lifelong learning from Continuous Manufacturing to Process Analytical Technology and even exploring Artificial Intelligence in recent years.
- Without adequate knowledge, we can’t survive in this knowledge-based Pharma industry.
- Stay with the TIME.
- Effective leadership is characterised by vision, integrity, empathy, & decisiveness.

Over the years, this insight became a foundation of how I approached audits, training, culture building, and later, how I mentor leaders: systems can fail, machines can err, but a committed and informed workforce rarely does.

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Next year, resilience will bubble up as a critical business objective

As pharma R&D becomes more digital, cloud-driven and AI-enabled, cyber risk is fast emerging as a boardroom priority. **Rajnish Gupta**, MD & Country Manager, Tenable India, explains why resilience, not just prevention, will define pharma cybersecurity strategies in 2026 and beyond, in an interview with **Viveka Roychowdhury**

Can you give some examples of security breaches in the pharma R&D domain, analysing the revenue impact, the cause and the preventive actions for these breaches?

Globally, the pharma R&D sector faced increasing cyber threats, with 172 incidents recorded in the first 10 months of 2025, where 29 per cent were driven by ransomware. These attacks targeted valuable intellectual property, clinical research data and formulations, costing an average of \$5.1 million per breach due to IP loss, downtime and recovery. For instance, US-based pharma company Inotiv Inc suffered unauthorised access in August 2025 that led to exfiltration of 176 GB of data, including R&D and personnel information. Weeks of disruption caused nearly \$6 million in losses due to lawsuits and potential long-term IP risks. Exposure management can prevent such attacks with continuous assessment of the attack surface, mapping vulnerabilities, misconfigurations and identities, be it in IT, OT or IoT, to identify the riskiest exposures. This helps organisations plug exposures that pose the most risk to the business and fortify defenses in an evolving threat landscape.

As more pharma companies consider moving to cloud environments, using AI to speed up the process from bench to bedside, what are the inherent risks of such strategies?

Pharma organisations must consider what happens when the most innovative part of their cloud environments also becomes the most vulnerable. If the cloud is the operating



system for today's digital world, AI is the most critical vulnerability, as it is easy to break if organisations are not careful. For instance, Tenable Cloud Research found that 70 per cent of cloud workloads that use AI services contain at least one misconfiguration or critical vulnerability.

Cloud adoption enables scalable data processing for clinical trials and simulations but also exposes sensitive R&D data, such as trial outcomes, to breaches. Shared infrastructures amplify unauthorised access risks, with vertical setups potentially introducing Jenga®-like misconfigurations that can become the entry point for potential leaks of proprietary formulations.

AI integration compounds these risks, especially in generative models trained on internal clinical datasets. Model inversion can lead to leaks of critical IP, or data exfiltration can take place during federated learning. Data poisoning attacks can propagate errors in target identification and drug interaction predictions, potentially yielding unsafe

compounds that fail late-stage trials, ballooning R&D costs. These risks are exacerbated with deepfakes that could mimic executives to phish credentials. Hence, over-reliance on unvalidated GenAI outputs fosters the false acceleration illusion, inviting liability and reputational damage in a sector where a single error can halt innovation pipelines for years. The presence of shadow AI, where employees use generative AI tools that are not approved by the organisation, can lead to deadly blind spots, which can become portals for data leaks. Given these risks, it is very important for pharma organisations to make cybersecurity a very critical part of risk management from day one.

What are the risk mitigation strategies to protect IP, sensitive drug development/clinical trial data, etc? Protecting sensitive drug development data and intellectual property requires a holistic exposure management strategy that bridges the gap between

digital security and clinical integrity. Organisations must prioritise the encryption of data shared with third-party research partners while maintaining immutable audit trails to satisfy regulatory transparency requirements.

Tenable addresses these specific risks through its unified Exposure Management platform, Tenable One. By providing comprehensive visibility across cloud environments, traditional IT assets, and operational technology used in manufacturing, Tenable identifies the precise pathways an attacker might take to reach a critical "crown jewel" asset. This proactive stance allows pharma firms to quantify their risk in real-time, moving beyond simple vulnerability scanning to a strategic model that secures the entire research-to-market lifecycle against sophisticated industrial espionage and data breaches.

How costly would it be for pharma companies to implement such strategies, in terms of cyber insurance, etc? Implementing preventive security strategies like exposure management involves upfront and evolving expenses, depending on the organisation's size, asset count and maturity.

Cyber insurance premiums for the pharma sector are often classified as high-risk due to sensitive data. On average, premiums would cost anywhere between \$1 million and \$5 million annually. High-exposure organisations face higher premiums if cybersecurity controls are weak. Additionally, cyber insurance providers are increasingly seeking enhanced security measures.

Lax security can result in no payouts, depending on what's in the fine print. Hence, it is advisable to invest in robust preventive security solutions instead of paying high premiums and not knowing if insurance payouts will be available in case of a breach.

What are the trends in cybersecurity specific to the pharma sector for 2026?

As AI adoption accelerates, there will be no new attack vectors in 2026, per se. AI is not a magic wand; it supercharges traditional attack methods. It will drive down the cost of attack generation and increase the volume, but it's not finding novel attack techniques. At the end of the day, cybersecurity is a numbers game, and AI broadens the attackers' canvas. Basic cyber hygiene remains the best defence.

Organisations that do not prioritise and accelerate their proactive security programs to counter the speed of AI-fueled attacks are at heightened risk. The who, what, how and why of an attack do not matter because AI-fueled attacks start and end before a ticket is even created. Proactive defense makes speed obsolete.

Next year, resilience will bubble up as a critical business objective. Global-scale outages, such as major attacks on pharma giants, have highlighted just how damaging downtime is to both the bottom line and brand reputation. As a result, the focus will expand beyond avoiding an outage to include ensuring operations can be restored before it goes viral on Twitter.

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We train professionals to see quality not as a checklist but as a mindset

Prof. Dr Syed S. Abbas, Director, Institute of Good Manufacturing Practices India (IGMPI), explains how globally benchmarked programmes, hands-on learning, industry-aligned curricula, and flexible training models are preparing professionals to meet global compliance expectations and strengthen India's position as a hub for safe, high-quality pharma products, in an interaction with **Kalyani Sharma**

How does IGMPI's training ecosystem directly address the root causes of patient-safety lapses such as weak documentation, manufacturing deviations, and gaps in pharmacovigilance within India's pharma and healthcare sectors?

If we look closely, most patient-safety failures don't happen overnight. They start small, maybe a missed entry in a logbook, a deviation that isn't fully documented, or a follow-up on an adverse reaction that's delayed. At IGMPI, our programmes are designed around addressing exactly these weak points.

We train professionals to see quality not as a checklist but as a mindset. Modules on good documentation practices, data integrity, deviation handling, and CAPA make participants understand why precision matters at every step. Similarly, our pharmacovigilance courses build the skills needed to monitor drugs even after they're out in the market, ensuring that any risk is caught early. When professionals learn to connect each step of compliance with the larger picture of patient safety, they make fewer mistakes and when they do, they know how to respond effectively. That's the culture we try to build through our training ecosystem.

IGMPI's programmes are benchmarked to USFDA, EMA, WHO, and ICH guidelines. Could you elaborate on how aligning with these global standards helps Indian professionals meet international compliance expectations and

support India's export readiness?

India's pharma industry is massive; it is a global powerhouse for generic medicines. So, following international regulations is not optional. It is the only way to keep that reputation strong. That's why every IGMPI programme is structured in line with international standards like USFDA, EMA, WHO, and ICH. We want Indian professionals to be fluent in the language of global regulation. When a learner studies our GMP or QA modules, they're not just studying Schedule M from the Indian rulebook; they're also comparing it with EU Annexes or USFDA 21 CFR parts.

When professionals really dig into how different countries handle compliance, they start to see what inspectors actually want, what paperwork they need to have ready, and how audits go down in other places. That kind of awareness sticks. It gives people the confidence to face any audit, from any agency, and it helps companies stay consistent. That's how you build trust across borders.

IGMPI emphasises industry relevance. How does your curriculum spanning GMP, QA/QC, regulatory affairs, and healthcare quality ensure that learners are ready to tackle real-world challenges in pharma and healthcare environments?

We have built our curriculum backward from the real challenges people face at work. Every course, whether it's in GMP, regulatory affairs, or healthcare quality, reflects what's actually happening on



shop floors, in audit rooms, or during product recalls. For example, GMP and QA/QC learners work through case studies that mirror real deviation reports or CAPA investigations. Those studying regulatory affairs also learn formats like CTD and eCTD for submission, exactly what they'll need to handle in their jobs. In healthcare quality, we explore process improvement, patient-safety indicators, and documentation systems used in modern hospitals.

This approach keeps learning practical. By the time participants finish their programme, they're not just aware of regulations; they've already practiced applying them. That's what helps them walk into the workplace ready to solve problems, not just identify them.

How does IGMPI integrate practical exposure through case studies, lab sessions, and tools like QbD, Process Analytical Technology, and Computer System Validation into its programmes to create

job-ready professionals?

The truth is, you can't just read a textbook and expect to handle the real-life challenges of pharma manufacturing or compliance. That's why our training is hands-on. In the lab, participants get their hands dirty with the basics of QA and QC; calibration, validation, sampling, and analytical methods. We bring in sessions on Quality by Design and Process Analytical Technology, so people can see first-hand how these tools cut down on process hiccups and keep everything running smoothly.

Inclusive of Computer System Validation, the digital systems and automation are taking over. People learn to validate manufacturing and documentation software, ensuring every record is accurate and traceable. By mixing real-world case studies, technical skills, and digital knowledge, we are building professionals who can manage both the traditional and the emerging sides of pharma. That is the kind of talent the industry needs right now.

With professionals often unable to take career breaks, how does IGMPI's flexible learning model (online, part-time, and corporate training) help in continuous workforce development without disrupting existing roles?

Most people we train are already working and that's a good thing because it means they can apply what they learn immediately. We've made flexibility a core part of how we teach. Our online and part-time courses let people learn without quitting their day jobs. Classes are hands-on, and the

assignments tackle real problems, not just things you memorize and forget. We also bring training straight to companies, shaping it around whatever compliance headaches or audit surprises they're facing. This kind of setup helps companies build stronger teams without missing a beat. Employees develop new skills, and the whole system gets sharper. Upskilling happens right on the job, blended into the workplace instead of just pulling people away from it.

Looking ahead, how do you see IGMPI's training model contributing to India's long-term goal of becoming a global hub for safe, high-quality, and compliant pharma products?

The big shift now is that everyone expects higher standards for quality and compliance and that's where solid training comes in. Our aim is to create professionals who don't just follow global standards, but actually get why they're important. With programmes aligned to USFDA, EMA, WHO, and ICH, and new focus areas like automation, ESG, and digital validation, we're preparing the workforce for the next phase of global manufacturing.

If India wants to be recognised as a hub for safe and high-quality pharma products, compliance has to become a habit; something that's embedded in everyday practice. That's what we're working toward at IGMPI: a workforce that treats quality as culture, not as a requirement.

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Results win customers. Leadership discipline keeps them

Drawing themes from his new book *The Dual Mandate in B2B – Driving Results. Shaping Culture*, **Mohan Joshi** – Global C-Suite Partner & Former President, SCHOTT India, discusses leadership systems, alignment, and execution in conversation with **Neha Aathavale**.

What inspired you to write *The Dual Mandate in B2B*, and how is it different from your earlier book?

My inspiration came from a consistent observation across B2B ecosystems: organisations rarely struggle because of technical capability — they struggle because of inconsistent leadership actions. I saw high expertise but weak alignment, unclear assumptions, delayed communication and uneven ownership. These gaps silently weaken quality, documentation, supply reliability and customer confidence.

My first book, *Real Time Growth with Customers*, focused on the customer-facing side of the DIG 3×3 Framework. But the deeper challenge lies inside organisations — in how leaders think, communicate and act every day. That realisation shaped *The Dual Mandate in B2B*, which brings results and culture together through nine leadership drivers.

As I write in the book: “Results win customers. Leadership discipline keeps them.”

My perspective comes from working closely with global suppliers to pharma companies — the organisations responsible for quality, compliance, supply assurance and customer trust. This experience deepened my understanding of how pharma stakeholders operate and why alignment between partners strengthens long-term credibility.

The first book built the



In pharma ecosystems, culture is not expressed in words — it is revealed through leadership precision and response discipline

foundation through the customer lens. *The Dual Mandate in B2B* builds the leadership system behind it.

Where do organisations struggle more in B2B — driving performance or building culture?

Leaders often assume performance is the problem. In reality, challenges begin when leadership discipline becomes inconsistent.

You see this in patterns like:

- high activity but low clarity

- high communication but low alignment
- high reporting but low movement

These gaps reduce predictability, increase friction, and frustrate customers.

As I write: “Leaders rarely fail by moving slowly — they fail by moving blindly.”

The DIG 3×3 Framework brings clarity to this. From the Diagnose pillar, Clarity (supported by Focus & Awareness) immediately sharpens direction, often

more effectively than adding processes or dashboards.

In pharma ecosystems, culture is not expressed in words — it is revealed through leadership precision and response discipline.

Which global insights matter most for India’s pharma ecosystem?

Three insights apply universally across global pharma partnerships:

- 1. Transparency reduces anxiety**

A supplier once informed a customer of a deviation before completing the investigation. The response was: “Your transparency reduced our anxiety.” In pharma, early communication is leadership.

- 2. Alignment beats capability**

Customers trust suppliers when QA, SCM, Production and Commercial present one aligned narrative. Parallel truths erode confidence.

- 3. Predictability builds long-term partnerships**

Customers do not expect perfection — they expect visibility, clarity and early signals.

India’s pharma ecosystem already has strong capability. Strengthening leadership actions makes this capability more predictable, scalable and audit-ready.

How can leaders build clarity, trust and ownership — inside teams and with customers?

By converting values into visible leadership actions.

A practical way to do this is by applying one core driver

from each DIG 3×3 pillar:

Clarity – Diagnose

(supported by *Focus & Awareness*) Clarity becomes visible when leaders:

- define success in one sentence
- surface assumptions before acting
- close meetings with one outcome, one owner and one next step

“Clarity is the first act of leadership — without it, every solution risks solving the wrong problem.”

Trust – Influence

(supported by *Intent & Collaboration*) Trust increases when teams:

- communicate deviations early
- maintain one version of truth
- share facts transparently

In global pharma: “The speed of trust determines the speed of collaboration.”

Ownership – Grow

(supported by *Outcomes & Agility*) Ownership becomes visible when teams:

- move decisions without reminders
- escalate risks before customers feel the impact
- focus on outcomes, not activity

“Ownership is not about doing more — it’s about caring more.”

These leadership actions shape customer experience far more than capability alone.

How can senior pharma leaders use your book during planning, reviews and team discussions?

The Dual Mandate in B2B is built as a leadership operating system, not a conceptual

INTERVIEW

model.

One driver per pillar for real-world meetings

- Clarity strengthens QBRs and RCA discussions
- Trust aligns cross-functional communication
- Ownership ensures momentum without reminders

Ten sharp leadership questions

One example: "What has changed for this customer in the last 90 days?" This question alone improves forecasting, decision-making and audit readiness.

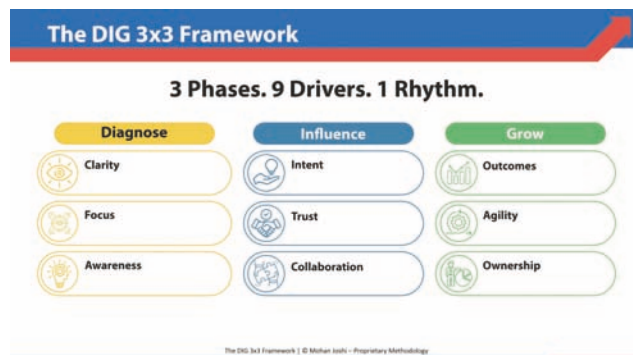
Direct pharma applicability

The framework works across:

- deviation and escalation handling
- risk and documentation reviews
- supply assurance communication
- customer visits
- internal alignment before major audits

Its power lies in simplicity — and simplicity scales.

Culture is difficult to measure. How can leaders



convert values into everyday actions?

Culture becomes measurable when leadership actions become consistent.

As I write: "Culture grows when values become verbs."

Trust becomes visible when:

- early visibility is given
- functions speak one aligned narrative
- no parallel truths exist

Ownership becomes visible when:

- loops close proactively
- escalations happen early
- reminders are unnecessary

Clarity becomes visible when:

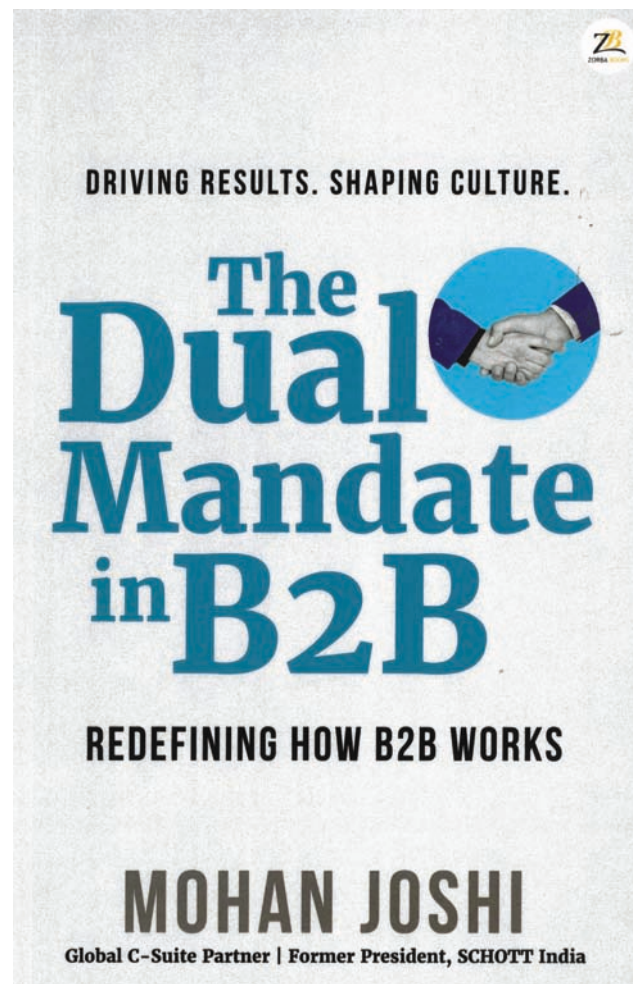
- assumptions are surfaced
- outcomes are defined
- decisions lead to movement

These actions quietly shape how customers perceive reliability and create the predictability that global pharma depends on.

The future of pharma partnerships will be shaped less by capability and more by leadership discipline and alignment. Organisations that strengthen clarity, trust and ownership will build predictable, transparent and resilient ecosystems — creating long-term confidence across global supply chains.

"Leadership isn't proven by ideas — it's remembered by impact."

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Leadership imperative shaping India's healthcare and pharma landscape in 2026

India's rapidly growing healthcare sector now needs a new kind of leadership—one that blends scientific expertise with strategic, ethical, and digital capabilities to remain globally competitive, explains **Sai Gandhi**, Partner, Positive Moves. He argues that the future will be shaped by hybrid, diverse, and ethically grounded leaders who can connect science, business, and purpose to guide the industry through its next stage of transformation

India's healthcare and pharmaceutical industries stand at an inflection point. The sector grew at a remarkable 17.5 per cent CAGR over the past decade—primarily driven by large-scale innovation in hospitals, pharmaceuticals, and diagnostics—and is projected to surpass USD 1.5 trillion by 2030. As scientific discovery, digital transformation, and global expansion continue to accelerate, the most critical question is no longer about growth anymore. It is whether leadership at the helm can match the pace of this growth and sustain it in the long run.

As the healthcare ecosystem transforms through digitalisation, AI-driven research, global ESG mandates, and patient-centric models, it is becoming clear that scientific excellence alone cannot sustain global competitiveness. As we enter 2026, the next era of healthcare leadership will be defined by how leaders connect science, business, and purpose.

From specialists to synthesists

Amidst global disruption, expectations from healthcare and pharma leaders—by boards, investors, and markets—are evolving from narrow specialisation to integrated synthesis, combining scientific mastery with strategic insight, commercial acumen, and organisational foresight. This shift in expectations is prompting global organisations to rethink leadership design. In the US and Europe, high-potential executives are being rotated across business functions and geographies to build cross-cultural and com-

mercial fluency. Scientists are being encouraged to take on P&L responsibilities, while business leaders are being exposed to R&D environments to strengthen empathy for innovation cycles. This fusion of science and strategy is cultivating a generation of hybrid leaders who understand both molecules and markets.

Indian organisations must also recognise and prepare for this shift at scale to support domestic growth, global expansion, and rapid digital transformation. Leadership pipelines now need to be designed for complexity—including cross-border operations and technology adoption—not just regulatory compliance. To guide globally integrated, digitally intelligent enterprises, India's healthcare leaders must pair op-



models, how to balance automation with empathy, and how to ensure that the pursuit of efficiency does not compromise patient trust.

This is where leadership becomes both art and responsibility. The leaders shaping the future of healthcare will be those who can integrate ethics into business strategy, and scale innovation without losing sight of humanity. In this era, boards and C-suites must elevate their oversight to match the dual imperatives of technological growth and ethical accountability.

Reimagining leadership for healthcare's next decade

The future of India's healthcare and pharmaceutical industries demands boards to go beyond traditional succession planning

them as optional considerations.

Women currently occupy less than one-fifth of leadership roles in India's healthcare ecosystem and earn 34 per cent less than their male counterparts. This is not merely a social imbalance—it's a strategic blind spot. Studies consistently show that diverse leadership drives superior decision-making, richer innovation, and stronger financial performance. India's healthcare growth trajectory over the next decade will hinge on how inclusively its leaders are developed and deployed.

The leadership challenge for boards today is no longer about filling senior roles—it is about reimagining what effective leadership looks like in an industry being reshaped by GenAI and global integration. By 2026, this challenge will become even more pronounced, as organisations face a sharper need for leaders who can seamlessly connect science, business, and purpose, with strategic clarity, operational depth, and global agility. This isn't just an evolution of roles; it's a redefinition of the very capabilities that will determine which organisations lead the next phase of healthcare transformation.

For the first time, the conversation around healthcare's future is not just about science, markets, or systems. It is about mindsets that drive culture, ethical decision-making, and sustainable impact. The organisations that will define the next decade will be those that understand that in the business of healing, leadership itself must evolve as the ultimate catalyst for change.

The leadership challenge for boards today is no longer about filling senior roles—it is about reimagining what effective leadership looks like in an industry being reshaped by GenAI and global integration. By 2026, this challenge will become even more pronounced, as organisations face a sharper need for leaders who can seamlessly connect science, business, and purpose

erational discipline with visionary agility.

The ethics and empathy imperative

As technology increasingly permeates healthcare, leadership in this sector warrants a heightened moral dimension. The

adoption of GenAI, for instance, is transforming every layer of the healthcare value chain—from discovery to diagnostics to patient interaction. While this acceleration drives efficiency and scale, it comes with profound ethical questions: how to manage bias in data-driven

and cultivate a leadership philosophy that integrates diversity, purpose, ethics, and patient outcomes alongside cost, compliance, and operational efficiency. Boards must proactively build systems and processes that embed these values into leadership pipelines rather than treating

INDIA'S INNOVATION JOURNEY FROM PROMISE TO PROOF

India's pharma ecosystem is ready to embrace stronger science and bolder ideas. Turning early breakthroughs into scalable, sustainable innovation remains the challenge

By Lakshmipriya Nair



India's pharma industry's global reputation has been built on scale. Affordable generics, dependable vaccines, and world-class manufacturing. That foundation remains strong. But as India aspires to become a \$30–35 trillion economy by 2047, the expectations from pharma are changing.

Scale alone will no longer be enough. The next phase must be driven by innovation, value creation and science-led leadership. (Read: <https://www.expresspharma.in/innovation-made-in-india/>).

While India has many of the ingredients required for innovation, several structural bottlenecks continue to slow progress.

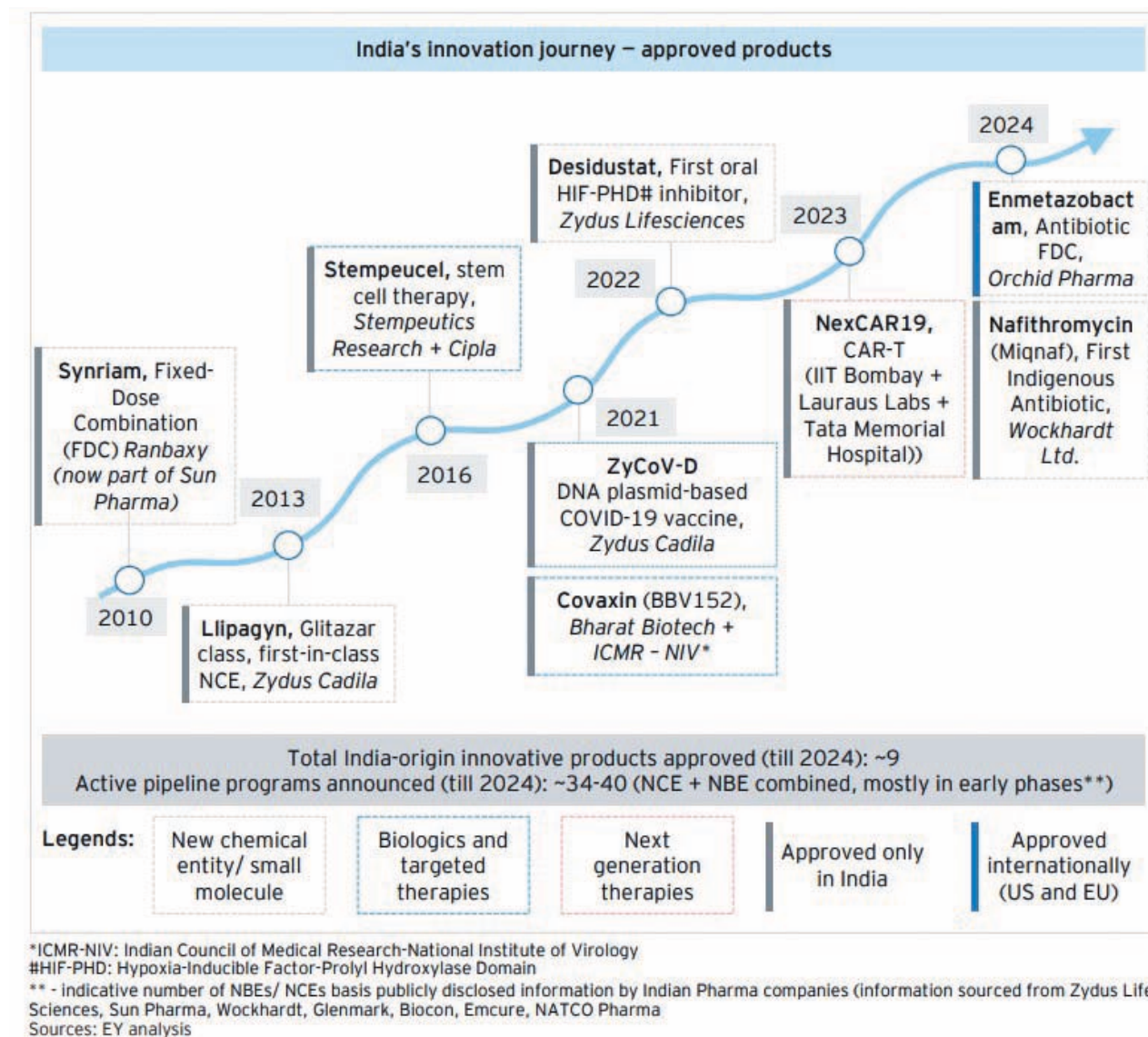
This article, Part II of our series on India's innovation journey, focuses on those bottlenecks. The next part will explore the strategies that could help India move from promise to proof. However, before examining what is holding India back, it is important to recognise how far the ecosystem has already come.

The promise

India's bottom of the innovation pyramid is well built. Startups are emerging. Academic science is strong. Incubators and early grants are more accessible than before.

In a recent report titled, 'The innovation imperative: Indian pharma's road to global leadership by 2047', Suresh Subramanian, National Life Sciences Leader, EY-Parthenon highlights, "Multinational innovators are increasingly outsourcing early research, development, analytics and manufacturing. Indian CRDMOs are moving up the value chain by investing in advanced modalities, digital QA/QC and integrated development pathways. This shift positions India not just as a manufacturing destination but as a strategic partner in complex, science-led innovation, underlining the momentum behind CRDMO/CDMO sector's growth in India."

He also points out, "Nearly



Source: EY-Parthenon report - The innovation imperative: Indian pharma's road to global leadership by 2047

half of the world's leading life sciences companies now run GCCs in India, capitalising on deep scientific talent and strong digital capabilities. These centers have evolved from efficiency-focused units into global innovation hubs that support drug discovery, trial optimisation, digital therapeutics, safety analytics, regulatory operations and enterprise-wide transformation. These trends reinforce the growing maturity of India's life sciences ecosystem."

Dr Priya Kapoor G Hingorani, MD, Miltenyi India and VP- South East Asia, also notes, "India is known globally for its talent. With over 80 incubators, ATAL Innovation Cen-

tres, DBT-BIRAC supported bio foundries, and strong academic hubs, the country produces high-quality science at scale."

The paradox

Clearly, India's innovation ecosystem has matured over the past decade.

The country has a deep pool of scientific talent, a growing network of incubators, public funding platforms and academic institutions that are increasingly open to translational research.

Early-stage innovation is no longer the weak link. Support from institutions such as BIRAC, C-CAMP and THSTI has created a strong foundation

for startups and translational research and improved access to funding, laboratories and mentorship.

And yet, innovation outcomes remain uneven. Breakthrough ideas emerge, but too few make it all the way to scalable, globally competitive therapies.

As Dr Sundaram Acharya, JSPS Postdoctoral Fellow, University of Tokyo, puts it, "India doesn't suffer from a talent deficit. It suffers from a risk-capital and risk-appetite deficit."

His work, enFnCas9, country's first indigenously developed CRISPR genome editing platform with a granted US patent, received the

DHR-ICMR Health Research Excellence Award 2025 (Gold). The team developed engineered, kinetically enhanced, high-precision FnCas9 (enFnCas9) variants which were conceived, built and validated entirely in India.

This is the paradox at the heart of Indian pharma innovation. India can generate ideas, but struggles to consistently scale them into globally competitive therapies. While Indian pharma companies have steadily improved R&D capabilities, spending levels remain well below global peers. Especially in high-risk areas such as biologics and cell and gene therapies.

The country has science and

ambition, yet hesitation and risk-aversion still prevents it from backing bold, long-term bets.

That hesitation, however, is not without reason. Innovation-led drug development demands long timelines, high upfront investment, and acceptance that not every programme will succeed.

In contrast, India's pharma success has historically been built on efficiency, predictability and speed to market. Bridging this mindset gap will be one of the industry's most difficult transitions.

Taking bigger innovation bets

Industry conversations increasingly point to one underlying issue. India's innovation challenge is no longer about intent, but about environment.

There are positive policy changes, and innovation features prominently in strategic discussions. But the ecosystem is still not fully designed to support risk-taking at scale. Funding cycles remain short, regulatory pathways lack clarity, and there are access gaps to advanced infrastructure.

Dr Acharya explains this gap clearly, and says, "To take bigger innovation bets, we now need three shifts. He elaborates:

Non-dilutive early capital for deep-tech: Grants in India are too small and too fragmented. A young team can't build a genome editing platform or a new therapeutic modality on ₹50-75 lakh. We need at least ₹1million equivalent catalytic grants that let teams pursue bold ideas without immediately optimising for revenue.

Technical infrastructure that doesn't require reinventing the wheel: Shared core facilities, GMP-adjacent pilot labs, and rapid regulatory pathways would cut development cycles by years.

A culture that rewards originality rather than incrementalism: Too many young scientists are trained to avoid failure. Bigger bets require institutional protection for people who push

INDIA'S PROGRESS IN PHARMA INNOVATION

- In April 2025, ISB 2001—a first-in-class trispecific antibody from Ichnos Glenmark Innovation (JV of Ichnos Sciences and Glenmark Pharmaceuticals)—received US FDA Fast Track designation for relapsed/refractory multiple myeloma. In mid-2025, IGI signed a global licensing and commercialisation deal with AbbVie.
- Cipla invested €3 million in German biotech Ethris in 2022 (and another €3 million in 2024) to co-develop mRNA therapies, and set up CiplaRNA GmbH in Germany in May 2025 to accelerate mRNA development.
- Cellogen Therapeutics secured patent approval for an indigenously developed bi-specific third-generation CAR-T therapy, with trials at CMC Vellore and backing from CSIR, RCB and IGIB.
- Miltenyi Biotec India partnered with Biotechnology Industry Research Assistance Council (BIRAC) to strengthen India's C> capabilities via training, translational research and point-of-care CAR-T manufacturing.
- Bugworks Research, supported by C-CAMP, is advancing next-gen antibiotics and collaborating with GARDP on IV and oral formulations to address antimicrobial resistance.
- Wockhardt recently received US FDA Qualified Infectious Disease Product designation for WCK 6777, a once-a-day β-lactam enhancer class antibiotic

Sources: EY-Parthenon report, Media reports

boundaries and occasionally break things.

Thus, it is clear that innovation at scale demands patience. It also demands systems that allow failure, long development timelines, and uncertainty without reputational or commercial penalties. These conditions are still evolving across India's pharma ecosystem.

Collaboration matters

Building such an environment is not the responsibility of any single stakeholder. This is where collaboration becomes central to India's innovation journey.

As the EY-Parthenon report highlights, "Achieving the value-driven transformation will require more than isolated corporate initiatives; it demands the creation of a robust ecosystem that nurtures research, rewards risk-taking and synergistically connects all elements of the ecosystem."

It adds, "The ability to realise India's vision of becoming a global pharma powerhouse hinges on collaborative efforts across all stakeholders in the ecosystem: global and domestic pharma companies, CRDMOs,

GCCs, government, regulators, academia, hospitals, private investors and start-ups. Each segment is evolving to excel in its domain, but now is the time to converge, align priorities and act cohesively to achieve the nation's ambition of emerging as a global leader in pharma and healthcare innovation."

Dr Hingorani also underlines the importance of stronger PPPs and says, "Public-private collaboration enables global players such as Miltenyi Biotec to bring end-to-end CGT workflows, helping Indian innovators de-risk development, accelerate timelines, and deliver patient-centric therapies that can meet both Indian and global regulatory expectations."

India already has several government-led initiatives that support early-stage innovation. What is needed now is deeper engagement from industry and global players. We need to bring translational expertise, operational excellence, and global benchmarks into the ecosystem.

Public and private players should work together to make innovation faster, manage risks

better, and ensure predictable outcomes.

Regulatory clarity: A key imperative

India's regulatory environment has matured, but predictability remains uneven, particularly for early-phase innovation. Industry experts stress that partnerships depend on clarity. Early-stage research flows to ecosystems where regulatory pathways are transparent and timelines predictable.

Innovation does not need diluted standards. It needs agile, science-led regulation that enables early experimentation without compromising safety.

The hardest challenge: Integration

Advanced therapies introduce a new level of complexity that the ecosystem is still learning to manage.

According to Dr Hingorani, "The harder challenge lies in building an integrated cell and gene therapy (CGT) ecosystem, especially across various elements in the value chain while keeping patient outcomes at the centre."

Cell and gene therapies de-

mand early coordination across manufacturing, quality systems, supply chains, clinical design, and access planning. Unlike traditional development models, these elements cannot be layered in sequentially.

In India, however, these components often come together too late. This makes scale-up slower, riskier and more expensive.

The missing middle

A persistent bottleneck in India's innovation journey is the gap between discovery and scale, the so-called missing middle. The ecosystem falters at the stage where science must be translated into scalable, regulatory-ready products.

This stage demands manufacturing discipline, efficient quality systems, robust supply chains, and strong clinical intent. When these considerations are not built in early, projects face delays, redesigns and rising costs later.

Experts explain why this transition is so fragile and point out Translating promising science into therapies that are scalable, reproducible, consistent, reliable, affordable, and regulatory-ready requires early alignment of manufacturing discipline, quality systems, supply chain robustness, clinical intent and access models.

The issue here is not scientific capability. It is systemic gaps.

Risk and predictability

Funding and laboratory access in India have improved significantly over the years. Yet founders working on deep-science innovation still face uncertainty, particularly as projects move into longer, capital-intensive phases.

For Acharya, predictability is as critical as capital. He asserts, "To accelerate the upward curve, founders need predictability and patience, clear regulatory pathways, continuity of support, and encouragement to build for global markets from India, not just local ones."

Dr Hingorani views are similar, "India has successfully built

the foundation through sustained public funding, regulatory strengthening, and infrastructure creation. To accelerate the upward curve, founders need predictability and patience, clear regulatory pathways, continuity of support, and encouragement to build for global markets from India, not just local ones. Miltenyi Biotec sees its role as supporting this transition by working with institutions such as BIRAC and THSTI, and by contributing technical experience to the evolving regulatory and manufacturing landscape for cell and gene therapies in India.”

Predictability across policy, regulation and funding gives innovators the confidence to build ambitious platforms rather than incremental solutions. Without it, even the most promising science struggles to survive the long journey to market.

Why these challenges matter

These bottlenecks come at a moment of real opportunity for Indian pharma.

Global pharma value chains are being reconfigured. Companies are actively seeking reliable, innovation-capable partners. Advanced manufacturing, digital tools and data-driven discovery are reshaping how medicines are developed.

At this stage, industry leaders argue that incremental change will not be enough.

LESSONS FROM CHINA

China serves as a strong example of how to build an innovation-led pharmaceutical ecosystem. Once viewed as a “me-too” producer, China has significantly expanded its innovation capabilities over the past decade and has emerged as a major competitor in the international pharma landscape.

Some key lessons include:

1. Regulatory reforms: In the last ten years, the Chinese government has implemented numerous regulatory initiatives, such as the 2015 “Opinions on Deepening the Reform of the Review and Approval Processes to Encourage Innovation of Drugs and Medical Devices.” This initiative acted as a catalyst for change, leading to the establishment of various regulatory frameworks designed to promote domestic innovation, expedite drug approvals, and enhance China’s presence on the global pharmaceutical stage. GlobalData’s report, “China’s Evolution in Global Drug Development and Clinical Trials,” indicates that such changes have advanced the development of novel targeted therapies, optimised clinical trials, and increased international collaboration.

2. Reforming pricing and reimbursement policies: China has reformed its pricing and reimbursement policies to facilitate the inclusion of innovative products on the reimbursement list, thereby improving the attractiveness of the local market.

3. High-quality innovation infrastructure: China has developed clusters across the country to strengthen its innovation capacity, accelerate the commercialisation of research, and integrate more deeply with global value chains.

Source: Prashant Khadayate, Director – Lifesciences Consulting & Research, GlobalData

“The sector must move beyond short-term volume gains and cost efficiencies to invest in next-gen therapies, digital transformation, regulatory agility and a robust talent pipeline. To sustain and accelerate this journey, every stakeholder—industry, government, academia, investors and start-ups—must converge and act cohesively. Strong public-private alliances, purposeful digital integration and ecosystem-wide investment in R&D are essential to building a future-ready

healthcare sector that serves India and the world,” opines Anil Matai, Director General, OPPI, in the EY-Parthenon report.

As Suresh Subramaniam also notes, “The shift from volume to value marks a profound transition that demands bold thinking, sustained investment and collective ambition. As the boundaries between science and technology blur, India’s success will depend on how effectively the ecosystem converges – linking academia and

industry, global and local partners, established players and emerging innovations, and deep science and digital technology.”

India has scale, talent and a growing digital backbone. What it still needs is alignment between capital and science, regulation and risk, ambition and execution.

If these gaps are not addressed now, India risks remaining just a secondary player in innovation-led value creation.

As Subramaniam from EY-

Parthenon asserts in the report, “The time to act is now. India’s aspiration to become the world’s innovation engine is within reach – but it will take courage to invest, trust to collaborate and vision to lead collectively.”

What comes next

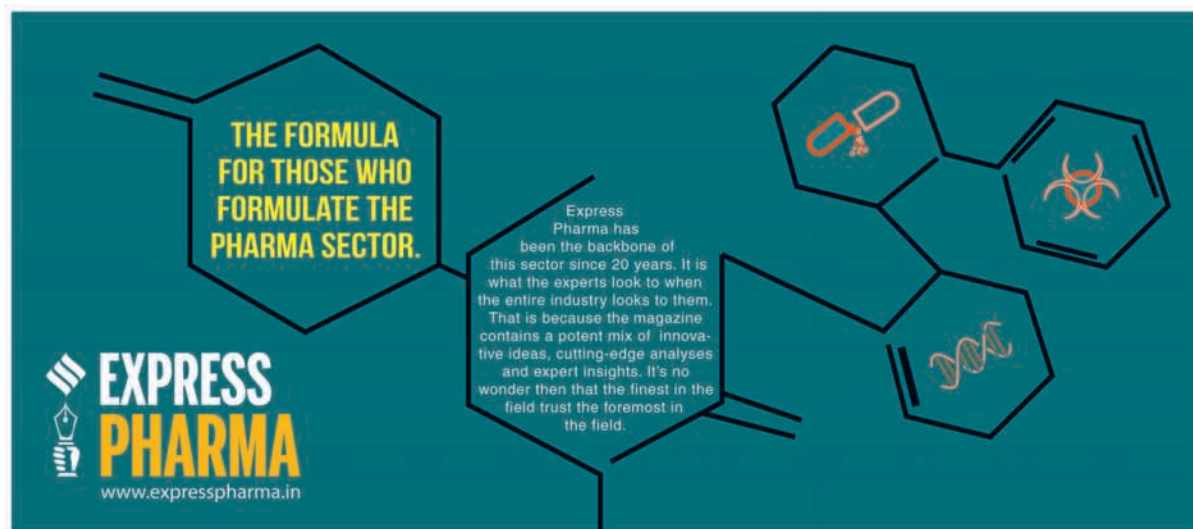
What is holding India back are limited risk appetite, underinvestment in scale-up, weak integration across the value chain, and a lack of predictability for founders.

India’s pharma ecosystem is no longer asking whether it can innovate. The real question is whether it can build the systems needed to scale innovation consistently and sustainably.

That answer will shape not just the future of Indian pharma, but India’s role in global healthcare over the coming decades.

As Dr Acharya puts it, “Ultimately, India’s global leadership will come from recognising a simple truth. More people means more problems but also more brains, more perspectives, and more original ideas. If we align capital, institutions, and risk appetite to harness this collective intelligence, India will not just participate in the global innovation ecosystem, it will reshape how innovation itself is done.

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Odisha's pharma pitch

The inaugural Odisha Pharma Summit 2025 delivered strong early signals of intent, positioning the state as an upcoming destination for PLI-triggered expansions, to complement existing pharma hubs. As **Hemant Sharma**, ACS Industry Dept and I&PR Dept, Govt of Odisha puts it, the aim is to “become a good, viable second option.” How fast can the eastern newcomer catch up and become India's next life sciences hub, asks **Viveka Roychowdhury**

The recently held Odisha Pharma Summit 2025, the state's first dedicated summit focused on pharmaceuticals, medical devices, and life sciences manufacturing, is by all accounts a success. (<https://www.expresspharma.in/odisha-pharma-summit-2025-positions-odisha-as-eastern-indias-emerging-life-sciences-hub-odisha-cm/>)

The December 16 summit reportedly attracted strong investor response, with a total of 69 Memoranda of Understanding (MoUs) signed across pharmaceuticals, medical technologies, and industrial infrastructure. These MoUs represent an investment commitment of Rs 7,043 crore, with an estimated employment generation potential of 44,646 jobs.

Pharmaceuticals bagged the lion's share (32 MoUs with proposed investments of Rs 2,681 crore, generating over 6,528 employment opportunities) followed by Medical Technology & Devices (12 MoUs, Rs 582 crore in committed investments, to create over 1,878 jobs). An MoU was also signed to set up an industrial park, with an investment of Rs 3,000 crore, expected to generate nearly 30,000 jobs.

The Odisha government's pharma foray is part of the government's overall Viksit Bharat @2047 vision, and specifically to boost investment and development of Eastern India under the Purvodaya (look east) policy push.

The state has charted its own policy, Samruddha Odisha 2036, for becoming a developed, future-ready state by 2036, Odisha's centenary year of statehood.

Summing up the intent, Hon'ble Chief Minister Shri Mohan Charan Majhi while



We are not saying that in the next two years or three years or five years, we will become the largest pharma hub or medtech hub in India, but we will become a good, viable second option

Hemant Sharma

ACS Industry Dept and I&PR Dept, Govt of Odisha

addressing the Odisha Pharma Summit 2025 on December 16, 2025 said, “Odisha will be a leading destination for pharmaceutical and medical-device investments – the most competitive hub for innovation and jobs. Yahi samay hai.”

But will Odisha catch up with more established pharma/medtech hubs in the country? After all, what does the “new kid on the block” offer to attract investments?

PLI plus policy

The state is in fact positioning its late entry as an advantage. As Hemant Sharma, ACS Industry Dept and I&PR Dept, Govt of Odisha explains, “The PLI scheme is a trigger for expansion of capacities in the pharma sector.” Odisha is positioning itself as a new geography, for companies which have exhausted all expansion avenues at their existing locations and are looking to reduce their cost of operations.

He points out that the pharma industry, like any industry which competes in global markets or even in domestic markets, “this is a very thin margin game. This is also a game which is dependent on a lot of inputs, dependencies on many chemicals to be imported from outside. Therefore, these cost advantages will certainly work (to Odisha's advantage).”

Agreeing that this will take some time to materialise, he reasons, “We are not saying that in the next two years or three years or five years, we will become the largest pharma hub or medtech hub in India, but we will become a good, viable second option.”

He points out that companies who set up manufacturing plants and warehouses in older hubs like in Maharashtra,

Gujarat, Hyderabad or Vishakhapatnam, now feel that the cost of operations are going up. So Odisha's first proposition for the pharma industry is that any company in expansion mode will be able to compare Odisha favorably with existing locations.

A key highlight of the December 16 summit was the launch of the Odisha Pharmaceutical and Medical Devices Policy 2025, which the media release describes as "a forward-looking policy aimed at building a globally competitive, innovation-led, and employment-oriented life sciences ecosystem in the State." The policy reportedly offers a comprehensive framework covering infrastructure development, investment facilitation, research and development, skill development, and targeted incentives for pharmaceuticals and medical devices manufacturing.

Gateway to the East + ASEAN

Odisha's second trump card is its coastal location, with existing ports like Paradip, Dhamra, and Gopalpur ports, which have already served Odisha's fairly large chemical processing and export firms. Therefore Sharma reasons that they can be the right locations for large-scale bulk drug and API manufacturing plants.

Sharma points out that large chemical companies like Deepak Nitrite, SRF and UPL, chose port cities like Gopalpur or Paradeep as one of their second locations, after they had exhausted all growth expansion in their western India locations.

Their move to Odisha also brought them closer to newer markets in Southeast Asia, Far East and others, which are closer to ports on the eastern coastline. Ports in Mumbai, Navasheva, JNPT, Mundra, Kandla and others on the western coastline are closer to the EU and US markets.

Early success stories

For instance, Sharma mentions that the state's pharma policy today prescribes up to 40 per cent capital investment subsidy in plant and machinery with a



KEY ANNOUNCEMENTS AT THE ODISHA PHARMA SUMMIT 2025

- **For pharmaceuticals:** 32 MoUs with proposed investments of Rs 2,681 crore, generating over 6,528 employment opportunities.
- **For medical technology and devices:** 12 MoUs with Rs 582 crore in committed investments, creating over 1,878 jobs.
- **For a landmark industrial park proposal:** 1 MoU with an investment of Rs 3,000 crore, expected to generate nearly 30,000 jobs.
- **Investment intent of:** Rs 780 crore and generating of employment potential of 6240 received during the event

particular limit and 30 per cent capital investment subsidy in plant and machinery without any upper limit. The policy has remodeled the definition of plant and machinery to make it more suitable to the pharma and medtech devices sectors so that the majority of their investment components are included.

"We were guided in this by

one of the early players here, the Bharat Biotech Park, set up at Bhubaneswar, which is a very successful venture of the Bharat Biotech Group. And therefore, we feel that our policy should be able to drive the initial flow of investments in Odisha," opines Sharma.

A lot of homework has gone into Odisha's choice of locations for pharma/medtech parks.

"We studied at least four such parks initially before we zeroed down on these two investment regions."

All this background work culminated with the Hon'ble Chief Minister Majhi unveiling two new industrial parks, one dedicated to pharmaceuticals at Khordha-Nayagarh and the second to medical devices at Khordha. These parks report-

edly come equipped with industrial infrastructure, common utilities, testing and certification facilities, and compliance-ready ecosystems to enable faster project implementation and ease of operations.

Listing the benefits of these locations, Sharma explains that the 250 acre pharma park and the 150 acre medtech devices park, are located very close to Bhubaneswar, about 45 minutes drive from the Bhubaneswar International Airport. The medtech devices park is part of the larger electronic city providing access to the talent from nearby technical and professional institutions.

The locations have been chosen in anticipation of future growth. According to Sharma, "The pharma park is located in such a manner that it can grow further, from today's 250 acres to 1000 acres." Besides being close to Bhubaneswar, the location is also accessible to National Highway 16, which connects Kolkata with Chennai as well as National Highway 55, which connects Bhubaneswar with Sambalpur.

In addition at Gopalpur, Sharma refers to another bulk drug park launched, which is 500 acres of land in a special economic zone, very close to the Gopalpur port, with ready to move in infrastructure with plots, built-up plots, a deep sea discharge facility as well as a CETP and doorstep availability of water and power. The Odisha state government is obviously hoping that the presence of leading companies including Bharat Biotech, Infunex, Hetero Pharma, and Granules Lifescience, combined with aggressively competitive policies will attract more pharma and medtech companies to consider investing in the state. As the Odisha Chief Minister put it, the first Odisha Pharma Summit positioned Odisha as eastern India's emerging life sciences hub. Now, the state will have to live up to its intent, with strong and speedy implementation.

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Pharma trends that will shape 2026: Building a future-ready, patient-centric industry

Anil Matai, Director General, OPPI, outlines the major pharmaceutical trends expected to shape 2026, detailing how digital health, AI-driven drug development, precision medicine and resilient supply chains will influence the industry's shift towards a future-ready, patient-centric ecosystem

As we move closer to 2026, the pharmaceutical ecosystem is undergoing a profound transformation driven by digital innovation, scientific advances, and a strengthened focus on patient-centricity. The last few years have set the stage for accelerated disruption—whether through AI-enabled drug discovery, genomics-driven precision medicine, or the rise of advanced digital health platforms. India's position in this global transition is particularly noteworthy. With the country emerging as a strategic hub for R&D, digital innovation, and quality manufacturing, 2026 promises to be a defining year for the sector.

Digital health roles become the new mainstream

The momentum around digital health is reshaping workforce needs and operating models across the industry. Telemedicine, digital therapeutics, virtual clinical trials, and AI-powered health apps are no longer peripheral innovations—they are central to patient engagement and real-time care delivery.

This shift is reflected in workforce trends as well. According to industry reports, jobs in India's healthcare and pharma sector grew 62 per cent year-on-year in March 2025, driven largely by roles in digital health, AI, and informatics. Companies are aggressively hiring professionals who can manage digital platforms, integrate technology with clinical workflows, and interpret digital health data for actionable insights.

In 2026, this trend will deepen further. We will see a significant rise in hybrid roles—digital medical advisors, AI-clinical analysts, virtual trial coordinators, data-driven phar-

macovigilance specialists, and patient-experience technologists. These roles will bridge the gap between science and technology, enabling more personalised, accessible, and continuous healthcare for patients.

Genomics, precision medicine and companion diagnostics take center stage

Globally, precision medicine has moved from a niche concept to one of the most influential drivers of therapeutic innovation. Between 2019 and 2023, more than 10,000 oncology trials were initiated worldwide, with nearly 30 per cent focused on precision-oncology approaches. This remarkable shift toward biomarker-driven research is reshaping pharma's talent landscape.

Companies increasingly require expertise in genomics, molecular biology, bioinformatics, data modeling, companion diagnostics development, biomarker validation, and precision-oncology trial design. With the rise of genomic profiling and targeted therapies, India has an opportunity to position itself as a global

innovation hub. Strengthening genomic research infrastructure and digital biology capabilities will be critical to sustaining this growth.

As we enter 2026, we can expect rapid advancements in multi-omics research, cell and gene therapies, and diagnostics-led treatment pathways. The future of medicine will be increasingly customised—not just to a disease profile but to the unique genetic makeup of each patient.

AI-driven pharmacovigilance and drug safety analytics scale up

With a significant increase in global clinical trials and marketed products, the volume of safety data is expanding at an unprecedented pace. Traditional pharmacovigilance processes—which rely heavily on manual efforts—are evolving to incorporate automation and advanced analytics.

AI is now enhancing automated case processing, signal detection, risk prediction, adverse event classification through natural language pro-

cessing, and real-time safety monitoring. In 2026, AI-powered pharmacovigilance will become foundational to regulatory submissions, safety updates, and post-marketing surveillance. This shift will enable drug safety teams to identify risks more rapidly, improve accuracy, and deliver more timely interventions.

AI-accelerated drug discovery becomes standard practice

Artificial intelligence has proven its potential to compress discovery timelines, enable novel molecule identification, and simulate clinical outcomes with remarkable precision. In 2026, AI adoption will deepen across the entire value chain—target identification, lead optimisation, toxicity prediction, and the use of digital twins in clinical trial design.

This evolution will help pharmaceutical companies reduce R&D costs, accelerate innovation cycles, and deliver life-changing therapies more efficiently. India, with its dynamic startup ecosystem, expanding pool of computational biologists, and diverse patient datasets, is well-positioned to lead this next phase of AI-driven drug innovation.

Sustainable and resilient supply chains rise in priority

Geopolitical shifts, environmental disruptions, and the urgent need for supply chain independence are pushing pharma companies to build more sustainable, resilient, and technologically integrated systems. In 2026, predictive analytics for supply chain risk assessment, digitised manufacturing, and eco-friendly production processes will become increasingly important.

For India, this means contin-

ued investment in advanced manufacturing capabilities, the expansion of critical API production, and strengthening quality infrastructure to enhance global competitiveness.

Conclusion: A future built on innovation, trust & patient-centricity

The pharma industry in 2026 will be defined by scientific precision, digital acceleration, and a deepened commitment to patient well-being. For India, this moment presents a unique opportunity. The country is rapidly emerging as a global healthcare powerhouse—not only because of its strong manufacturing capabilities but also due to its expanding digital infrastructure, vibrant scientific talent pool, and commitment to innovation-driven growth. To fully harness this potential, the sector must continue investing in next-generation research, nurturing specialised talent in fields like bioinformatics and digital health, and fostering strong public-private collaboration.

Equally important is the need to maintain and reinforce regulatory excellence. As therapies become more complex and data volumes grow, robust, agile, and science-led regulatory frameworks will be essential to ensuring patient safety and accelerating access to cutting-edge treatments. We commend the Government for taking an Innovation-First approach. We see an improvement in IP protection with the on-going discussions on Regulatory Data Protection. Strengthening trust between stakeholders—patients, policymakers, healthcare providers, and industry—will be foundational to building a resilient and future-ready healthcare ecosystem.



Can Indian biosimilars and generics restate accessibility in global underserved markets?

Hari Kiran Chereddi, MD & CEO – HRV Pharma & NHG Pharma highlights that India's success in generics is no longer enough, as the world now demands advanced biologics, biosimilars, and personalised medicines. He further emphasises on the need for stronger regulation, innovation, and investment so India can lead in next-generation therapies and expand global access to cutting-edge healthcare

Pharmacy of the world, a name that India has earned through the provision of low-cost, quality generics to patients geographically.

India now produces close to 20 per cent of the world's generic medicines and more than 60 per cent of the demand for vaccines worldwide. The global healthcare landscape is evolving with patients no longer asking for affordable drugs alone, but are seeking innovative biologics, biosimilars, and personalized medicines.

The conversation is no longer about India retaining the position as one of the world's largest generics suppliers; it is about establishing leadership with next-generation therapies and redefining access to underserved therapeutic categories.

Generics: The bedrock of access

Generic medicines have revolutionized the affordability of healthcare globally. India's scale of production, regulatory capacity, and low-cost supply chains supported the global spread of ARVs for HIV/AIDS in Africa, oncology medicines in Latin America, and critical antibiotics in Asia as a few examples.

But the generics business is coming of age. Price erosion, patent cliffs levelling out, and increasing regulatory pressures are compressing margins. India needs to approach generics not as the end game but as the springboard for innovation to continue playing its role as the pharmacy of the world.

Biosimilars: The next frontier of access

Treatments using biologics for oncology, autoimmune disorders,

and orphan diseases amount to almost half of the worldwide pharmaceutical market in value. At these prices most low- and middle-income nations get excluded. Biosimilars, the generics equivalent for biologics, do provide a great opportunity to expand access across the board. India is already a strong player in this sector; it already has over 100 approved biosimilars and has established global supply capacity with players such as Biocon, Dr.



providing affordable precision treatments—not only to high-income markets, but also to nations where personalized medicine has been regarded as a luxury.

What India needs to do to lead

To lead the pack as one of the world's largest generics players and go up the value chain, India needs to adopt a multi-pronged strategy:

The manufacture of biosimilars requires advanced biologics manufacturing, clinical comparability trials, and credibility with regulators in the US and EU. To lead the way here, India will need to invest in advanced biologics facilities, develop scientific sophistication in cell line development, and align regulatory norms with the most stringent global norms

Reddy's, Intas, etc., With cost savings of 20–40 per cent relative to innovator biologics, Indian biosimilars have the potential to repeat the generics revolution on an even larger scale. But there are challenges. The manufacture of biosimilars requires advanced biologics manufacturing, clinical comparability trials, and credibility with regulators in the US and EU. To lead the way here, India will need to invest in advanced biologics facilities, develop scientific sophistication in cell line development, and align regulatory norms with the most stringent global norms.

Precision medicine: Beyond "one-size-fits-all"

The future of medicine is in

personalizing treatments to the patient profile—genomics, proteomics, and AI-driven information. Precision medicine is no longer limited to academic laboratories; it's about bringing commercial pipelines and treatment guidelines globally to India, thereby presenting this as both a challenge and an opportunity.

The task is obvious: advanced R&D capacities, large-scale biobanking, and assured data governance remain embryonic. The potential is larger; India has unparalleled genetic diversity, an accelerant in its digitizing healthcare environment, and computational science cost advantages. With the combination of AI and biopharma production and clinical studies, India can bypass into

parties like universities, startups, and the pharma industry work together on biosimilars, monoclonal antibodies, and even on gene therapy.

4. Leverage AI and digital health - Utilize AI for predictive compliance, supply-chain optimization, and precision medicine R&D. India's IT backbone naturally enhances its digital bio-pharma integration capabilities.

5. Develop global market access - In addition to the US and the EU, we need to look at Africa, Southeast Asia, and Latin America. Countries where demand for affordable biosimilars and precision therapies is escalating. It will be important to partner with local distributors, regulators, and governments.

6. Maintain talent development - Specialised programmes in manufacturing of biologics, regulatory affairs and bioinformatics need to be introduced in universities and also scaled up to ensure the workforce is future ready.

A new definition of accessibility

While the early writings in the story of India's pharmaceutical journey was that of making generics affordable, the next chapter should be the one to make innovative medicines available. We don't just need low priced medicines, we need access to therapies that can alter the course of autoimmune conditions, rare diseases & cancer.

By building on its established strengths India can redefine medicine access for billions. It will not only solidify our position as the pharmacy of the world, but also advance our position to become a global health innovator.

The next wave of growth will belong not to the fastest manufacturers but to the most innovative problem-solvers

As India moves into 2026, industry experts state that the next phase of growth in pharmaceuticals will depend on strengthening formulation R&D, building a skilled and adaptable workforce, and closing gaps between academic research and industry needs. The discussion highlights the role of translational research, aligned industry-academia frameworks, continuous upskilling, digital and regulatory capability, and sustained private investment in shifting India from volume-led manufacturing to a value-led innovation ecosystem, reports **Neha Aathavale**

Industry must provide real-world problem statements to align academic research with market needs

The biggest gap between academic research and industry application lies in the lack of strong translational capability. While universities excel in cutting-edge research, there is a significant shortfall in the resources and guidance needed to move innovations from the bench to the bedside.

One effective solution is to establish dedicated nodal centres that provide end-to-end support, including technical expertise, scaling capabilities, regulatory navigation and access to specialised infrastructure that individual institutions may not be able to afford. These centres could operate as shared national or regional resources, making advanced capabilities more accessible and cost-effective. To make these centres successful, academia, government bodies, and industry must collaborate to build platforms that offer both strategic direction and hands-on execution support. Involving senior industry experts as core contributors would ensure that research aligns with real-world



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needs and market pathways.

At the academic level, students should be taught the fundamentals of intellectual property, technology transfer, and

legal frameworks, so they understand how to translate their ideas into impactful, patentable innovations. Lack of awareness in these areas often discour-

Industry can contribute by providing real-world problem statements, funding infrastructure, and mentorship to align academic research with market needs

ages young researchers from pursuing high-stakes development projects. Equipping them with this knowledge can empower them to think creatively and ambitiously. Career advancement should be tied not only to research papers but also to patents filed, prototypes developed and industry collaborations. Institutions can also share revenue from patent commercialisation and licensed technologies with faculty and students, motivating them to pursue further research.

Industry can contribute by providing real-world problem

statements, funding infrastructure, and mentorship to align academic research with market needs. By offering collaboration, internships, and support for commercialisation, companies can help accelerate the journey from lab innovation to practical, scalable products.

Fostering interdisciplinary teams can promote cross-pollination of ideas, resulting in more robust and market-ready solutions. This integrated approach can significantly accelerate the journey of innovation from the lab to the market.

India must move from a volume-led trajectory to a value-led innovation arc

India's pharmaceutical sector has long been admired for its manufacturing strength and its ANDA approvals. But the landscape ahead demands more than past achievements. Global price pressures, declining new chemical entities and the rising burden of chronic and age-related diseases are redefining what it takes to stay competitive. The next wave of growth will belong not to the fastest manufacturers but to the most innovative problem-solvers.

This is where India has a compelling opportunity. By deepening its FR&D capabilities, the country can move from a "volume-led" trajectory to a "value-led" innovation arc. As regulatory expectations tighten and innovation cycles accelerate, the true differentiator will be a workforce that is agile, interdisciplinary, digitally fluent and future-ready.

Strategies to build and continuously upskill the FR&D workforce

A transformative leap will require a deliberate and sustained talent strategy:

1. Establish competency academies for future skills:



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Strengthening India's FR&D Workforce for Global Competitiveness

mies for future skills:

Companies can institutionalise advanced academies dedicated to formulation sciences,

analytical innovation, regulatory sciences, nano-formulations, targeted delivery, biosimilars and long-acting injectables. Blending

rigorous classroom learning with real laboratory immersion can accelerate practical mastery.

2. Build industry – Academia research clusters:

Collaborative R&D clusters can align academic curricula with real-world formulation challenges. Early exposure to quality frameworks, regulatory pathways and translational science prepares young researchers to work with global expectations.

3. Embed digital and AI fluency across roles:

AI/ML-driven formulation prediction, data modelling, automation and digital quality systems are rapidly transforming FR&D. Integrating these tools into training ensures scientists are equipped to innovate in increasingly technology-augmented environments.

4. Create rotational & cross-functional career pathways:

Exposure to manufacturing science, clinical development, intellectual property and regulatory affairs cultivates holistic problem-solving. These rota-

tional programs help build scientific leaders who understand the full value chain and can drive end-to-end innovation.

A workforce nurtured on continuous learning, interdisciplinary thinking and digital competence will form the bedrock of India's evolution into a global FR&D innovation hub.

The rise of CRDMOs and CDMOs, combined with regulatory agility, innovation financing and talent development highlights the urgent need to elevate India's knowledge capital. A recurring insight across industry dialogue is that "partnerships follow predictability." Strengthening intellectual property protection, ensuring regulatory clarity and fostering trust in early-phase research environments will be essential to attract high-value innovation work.

India stands at a promising inflection point. By committing to capability-building and scientific excellence, the industry can help create a world-class R&D ecosystem, one that not only keeps pace with global formulation needs but helps shape the future of healthcare innovation.

A future-ready FR&D workforce is essential for India's pharma sector to evolve beyond cost leadership

What strategies can industry adopt to build and continuously upskill a workforce to keep pace with evolving formulation research needs?

India's pharmaceutical sector is globally recognised for its manufacturing capabilities and supply of affordable generics. However, to sustain global competitiveness and transition into an innovation-driven ecosystem, the industry must strengthen its Formulation Research & Development (FR&D)

capabilities — with workforce development as a key pillar. To build and continuously upskill a workforce that can keep pace with evolving formulation research needs, industry can adopt the following strategies:

1. Establish industry-academia collaborations

● **Joint centres of excellence:** Create integrated research hubs in partnership with leading academic institutions to foster innovation and hands-on training.

● **Curriculum alignment:** Work with universities to align pharmaceutical science curricula with current and emerging industry needs, including advanced formulation technologies and regulatory science.

2. Invest in continuous learning and upskilling

● **Modular training programs:** Offer short-term certifications and micro-credentials in areas like complex generics, novel drug delivery systems, and QbD (Quality by Design).

● **Digital learning platforms:** Leverage e-learning, AR/VR simulations, and AI-driven personalised learning to make training scalable and engaging. Use AI-driven personalised learning platforms to assess skill gaps and recommend targeted learning paths.

● **Mentorship and knowledge transfer:** Encourage senior scientists to mentor junior staff, ensuring tacit knowledge is passed on effectively.

3. Build specialised talent

pipelines

● **Talent incubation programs:** Identify and nurture high-potential candidates through internships, fellowships, and rotational R&D programs.

● **Global exposure:** Facilitate international collaborations and exchange programs to expose Indian researchers to global best practices and regulatory expectations.

4. Foster a culture of innovation

● **Intrapreneurship initia-**

tives: Encourage employees to propose and lead formulation innovation projects within the organisation.

● **Recognition and incentives:** Reward scientific contributions, patent filings, and successful product development to motivate continuous learning and innovation.

5. Use cross-functional learning

● Promote interdisciplinary collaboration (e.g., chemists working with data scientists or engineers) to build holistic skillsets.

● Rotate staff across departments or projects to expose them to a wider range of formulation challenges.

6. Enhance regulatory and compliance readiness

● Set up regulatory intelligence teams to monitor global standards.

● Conduct mock audits and workshops to ensure audit



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preparedness.

7. Leverage public-private partnerships

● Collaborate with government skill development missions (e.g., Skill India)

● Making use of government schemes like BIRAC and Promotion of Research and Innovation in Pharma-MedTech sector (PRIP)

● Utilise shared infrastructure for hands-on training in advanced formulation techniques.

8. Monitor and adapt to emerging trends

● Regularly assess skill needs based on technology trends (e.g., AI in formulation, sustainable materials).

● Use workforce planning tools to forecast future competencies and address gaps proactively.

9. Adopt agile workforce models

● Use contract researchers, consultants, or academic collaborations to supplement in-house ex-

pertise as needed.

● Build flexible teams that can be rapidly upskilled or reconfigured in response to project demands.

10. Bridging the funding gap

● India's R&D spending is only 0.65 per cent of GDP, with just 36.4 per cent coming from the private sector—far below global leaders like the US (3.5 per cent) and Israel (5.4 per cent). Sustained private investment can fill this gap, especially in industrial R&D

Conclusion

A future-ready FR&D workforce is essential for India's pharma sector to evolve beyond cost leadership. By investing in integrated learning ecosystems, regulatory alignment, and innovation culture, the industry can position itself as a trusted global source of high-quality, competitive formulation.

India must reward translational focus differently to accelerate pharma innovation

Bridging academia and industry: Accelerating innovation in India's pharma R&D

India's pharmaceutical sector is globally recognised for manufacturing strength and affordability. To evolve into an innovation powerhouse, we must tighten the bridge between academic research and industry needs—especially the mismatch of pace/speed of development, key responsibility areas (KRAs), key performance indicators (KPIs). Industry scientists work to time-bound deliverables and market continuity, while academic teams pursue longer-horizon, curiosity-driven goals. Their primary responsibility (KRA) remains delivery of skilled manpower to industry and KPIs are often focused on numbers of research publications, PhD supervised, grants etc. Not that these are not relevant indicators but this divergence surely slows translation from lab to market.

Policy momentum by the



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government is definitely encouraging; the PRIP scheme funds industry-academia col-

laborations from ideation to commercialisation and backs CoEs at NIPERs, while the

ANRF provides strategic direction for national research; PLI programs further incentivise complex products and biosimilars. Yet impact will depend on rewarding translational focus differently—grant architectures must provide autonomy in fund use with transparent accountability to prevent misuse.

Following structural reforms can close the gap:

a) Lab incubators inside universities, organised like Section 8 companies, to build self-sustaining funds and nurture startups.

b) Tech transfer offices with business-development teams fluent in market dynamics and translational value.

c) Internships not only for students but also for faculty, immersing professors in industrial workflows and regulatory expectations.

d) Joint KRAs, KPIs for translation or high-impact innovation and shared infrastructure to align timelines

across academia/Industry partners.

e) Challenge complacency in permanent academic posts, linking progression to measurable innovation outcomes critically reviewed by global panels to ensure competitiveness.

f) Curriculum reform and regulatory science training. India's digital health backbone (ABHA, eSanjeevani) can enable adaptive trials and real-world evidence for formulations.

These are the levers, I believe, to close skill and translation gaps. If India implements bold structural reforms with autonomy and accountability in academia, industry/venture funds shall pour in capital and partnerships will be sustained. It can move from being the 'pharmacy of the world' to the world's formulation innovation hub.

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Clinical research careers: India's next big opportunity

Dr Seema Pai, President, Indian Society for Clinical Research highlights that India's clinical research sector is rapidly growing, and this growth is creating global opportunities, fostering collaboration, and opening promising career pathways for young professionals while positioning India as a future leader in clinical research

With the global healthcare and life sciences sector set to cross USD 4.28 billion by 2033, India has emerged as one of the fastest-growing economies in the world when it comes to clinical research. This growth has not only been a driver but also an outcome of the professional scientific innovation and has opened new avenues for career opportunities for young professionals.

India offers a large and genetically diverse population set that is both cost-effective and offers unique advantages for clinical research trials when compared to established hubs like the US and China. NexCAR19 is an extremely powerful representation of this unique capability. NexCAR19 is India's very first CAR-T cell therapy that is self-developed. India's ability to create advanced complex solutions towards medical breakthroughs that are both high in complexity and high in cost demonstrates the revolutionary side of India.

Patient centricity and technology driving change

India has a high prevalence of diseases and a diverse patient pool, which, combined with cost-effectiveness, makes the country an attractive destination for global pharmaceutical and biotechnology research. At the same time, clinical trials in India are evolving to become more patient centric.

Indian start-ups are leading this change with decentralised trials, direct-to-patient models, remote monitoring through wearables, and telehealth services. These advances make research more inclusive by reaching underrepresented



A clinical research career is successful only when it is paired with research skills.

Understanding the steps in designing clinical trials, clinical practice standards, and the workings of certain programming software such as SAS, R, Python, and SPSS are a few of the vital skills

populations, while also giving patients more value and researchers more representative data enabling equity and representation of real-world populations in research.

New technologies such as Artificial Intelligence, data science, and personalised medicine are redefining how trials are conducted and analysed. Digitised regulatory reforms and platforms

are also aiding in quick approvals leading towards faster, more streamlined, and more transparent processes. Together, these developments are creating a dynamic, globally competitive ecosystem. Importantly, they are also opening up new career pathways for young scientists making India an exciting place to shape the future of medical research.

Collaboration and ecosystem growth

Clinical research is no different for India than for any other part of the world. It involves defining a 'local market' where activities of the government, global capability centers, academia, and the global clinical research industry work together within a common framework to drive innovation and long-term growth. The collaborative Global Centers of Clinical Research Relations Partnership model is opening new centers of employment and establishing new skill sets. Gradually, industry-academia coupled research initiatives with the Indian Council of Medical Research (ICMR) and other universities and research institutes are driving innovation and knowledge exchange in the world.

The clinical research sector in India is the primary beneficiary of these factors. The positive growth trend is a result of strong and prudent sector-specific policies, increasing digital adoption in the economy, and positive demographic factors such as a growing young population.

Talent and career opportunities

With the growth of the industry comes the growth of the industry's specialised talent. Positions including clinical research associates, data managers, biostatisticians, medical writers, and professionals in regulatory affairs, for instance, are quite lucrative, financially rewarding, and work with clear career advancement opportunities. The span of opportunities is remarkable as it cuts across fields including clinical science, pharmacovigilance, operations, data management, quality assur-

ance, and many others.

A clinical research career is successful only when it is paired with research skills. Understanding the steps in designing clinical trials, clinical practice standards, and the workings of certain programming software such as SAS, R, Python, and SPSS are a few of the vital skills. Other skills such as being a leader, working in a team, resolving disputes, and critical thinking are also vital. This captivating blend of skills will ensure that the professionals are able to manage the intricate and complex data and processes of research, as well as the human side of research.

In India, clinical research for young scientists comes as a gift considering the way it combines real-world application with the improvement of medicine.

India as a global hub

India's clinical research sector is more than an investment opportunity; it is an opportunity to provide expansion solutions that are relevant, accessible, and ethical on a global scale. With sustained focus on investment, technology, and talent, along with policy and regulatory enablement, India is poised to claim global leadership in clinical research. This is a time of opportunity unlike any other. With a focus on patient care, India can sculpt the future of global healthcare with approaches that are robust in the cross-border collaborations and homegrown talent weaved around a patient-focused ecosystem.

At the end of it all, clinical research is more than finding novel therapeutics; it is ultimately about achieving health impact at scale.

India's Pharma 2047: How academia can drive innovation and self-reliance

Dr Supriya Shidhaye, Principal, Vivekanand Education Society College of Pharmacy (Autonomous), asserts that pharmacy institutions must become catalysts of discovery, translational research, and high-value skill development. The future demands not just graduates, but innovators and leaders capable of shaping global healthcare

As India marches toward its 2047 vision of becoming an innovation-led, self-reliant pharmaceutical powerhouse, the role of academia becomes central and transformative. The nation's remarkable rise in the Global Innovation Index—from the 80s to the 40s range in a decade—signals progress, but sustaining this momentum requires a strategic reset. Pharmacy institutions must become catalysts of discovery, translational research, and high-value skill development. The future demands not just graduates, but innovators and leaders capable of shaping global healthcare.

To drive Pharma 2047, academia must evolve through strategic planning across curriculum, research capabilities, industry collaboration, and national alignment. The following pillars outline how various stakeholders—academia, industry, and government—can jointly accelerate India's journey.

1. Redesigning academic curricula for a multidisciplinary, innovation-driven workforce

◆ **Stakeholder:** Academic Institutions & Regulatory Bodies (PCI, University, HEIs)

Pharmacy education can no longer operate in disciplinary silos. To meet the expectations of an innovation-centric pharma sector, institutions must build interdisciplinary learning pathways integrating:

- Pharmacology and systems biology
- Pharmaceutics and biotechnology
- AI, big data analytics, and computational modelling
- Regulatory sciences and market access
- Pharmacoeconomics and patient-centric design

Outcome-based education must replace content-heavy teaching. Students should graduate with the ability to connect molecular understanding to for-

mulation design, regulatory intelligence to development strategy, and analytics to clinical decision-making.

The curriculum must embed 21st-century competencies—critical thinking, communication, entrepreneurship, and ethics—ensuring India produces future-ready scientific leaders and not just degree holders.

2. Building a strong research culture to enable discovery and translation

◆ **Stakeholder:** Academic research centres, faculty, ANRF

One of the biggest gaps in Indian academia is the limited pipeline of translational research—solutions that move from conceptual science to deployable products. Academic institutions must invest in:

- Advanced formulation, analytical, and bioprocessing laboratories
- Preclinical modelling facilities
- IP generation and technology-transfer frameworks
- Incubation centres for student-led deep-tech ventures

The launch of the Anusandhan National Research Foundation (ANRF) is a watershed opportunity. Pharmacy institutes must aggressively compete for multi-disciplinary, problem-driven national grants while aligning research towards national health priorities such as antimicrobial resistance (AMR), chronic disease management, rare diseases, biosimilars, precision medicine and advanced therapeutics.

To achieve this, faculty development becomes critical—upskilling in frontier technologies like CRISPR, biologics development, automation, green chemistry, and AI-assisted discovery.

3. Making academia-industry collaboration outcome-oriented and accountable

◆ **Stakeholder:** Pharma and MedTech industry, academic in-



stitutions, sector skill councils

For India to move from volume to value in exports, academia-industry collaboration must shift from ceremonial MoUs to co-owned, co-delivered, and co-evaluated models. Strategic actions include:

- Establishing collaborative research centres for biologics, advanced drug delivery systems, novel excipients, AI-enabled manufacturing, and sustainability solutions
- Co-developing micro-credentials in regulatory compliance, quality systems, clinical operations, supply chain, and digital manufacturing
- Embedding mandatory internships and apprenticeships
- Creating shared research platforms to solve industry-defined problems
- Encouraging contract research and CDMO-linked academia innovation

Structured collaboration will ensure students become job-ready from Day 1 while also generating prototypes, patents, and scalable solutions for industry.

4. Aligning academia with India's Pharma 2047 priorities and the QuRATE framework

◆ **Stakeholder:** Government, industry bodies (Pharmexcil, IDMA), academia

The national vision for Pharma 2047 is guided by the QuRATE pillars—quality, regulation, access to global market,

talent, and entrepreneurial innovation. Academia must play a complementary role in enabling these.

Key priorities aligned to national goals

- **Quality and regulation:** Train students in QbD, cGMP, data integrity, and international regulatory pathways.
- **Access:** Promote innovations that are affordable, scalable, and patient-centric.
- **Talent:** Build a scientifically and ethically strong research workforce.
- **Entrepreneurship:** Support student startups through incubators and innovation funds.
- **Supply chain resilience:** Encourage research on indigenous APIs, green chemistry, and sustainable manufacturing.

Institutions should embed case studies on global compliance, recalls, and quality failures to inculcate scientific integrity and accountability.

5. Leveraging NEP 2020 for a new academic paradigm

◆ **Stakeholder:** Government, PCI, higher education institutions, students, university

The National Education Policy (NEP) 2020 provides a powerful blueprint for reimagining pharmaceutical education.

- Academic opportunities under NEP 2020:
- Multidisciplinary Education and Research Universities (MERUs) as national models
- Four-year degrees with research tracks
- Multiple entry and exit options supporting workforce flexibility
- Vocational and skill development integration
- Innovation councils, incubation centres, and industry-designed credit courses
- International and national collaborative research frameworks (SPARC, GIAN)

These reforms will allow pharmacy graduates to become globally competitive while

deeply rooted in India's healthcare priorities.

6. Creating India's future research leaders and thought architects by 2047

◆ **Stakeholder:** Academia, research agencies, industry mentors

For India to lead in biosimilars, vaccines, medtech, novel therapeutics, and AI-driven healthcare, academia must focus on developing:

- Young innovators through specialised talent tracks
- Industry-academia doctoral and postdoctoral pathways
- Leaders trained in global quality systems, ethics, and compliance
- Professionals who combine innovation with responsibility

By 2047, India must possess a research ecosystem where ideas mature into technologies, students become innovators, and academic research generates global impact.

Academia as the strongest pillar of India's pharma future

India's aspirations for 2047 are ambitious and achievable. The transformation of academia—from knowledge dissemination to innovation leadership—will determine whether India merely catches up or truly leads. Pharmacy institutions must deliver the curriculum redesigned by PCI effectively, to strengthen research, to forge purposeful industry partnerships, and to align with national strategic frameworks.

If academia embraces this responsibility with imagination, rigour, and collaboration, India will not only achieve self-reliance but emerge as a global leader in affordable, high-quality, accessible healthcare innovation. The story of Pharma 2047 will indeed be written in our classrooms, laboratories, and incubation spaces.

Beyond the ladder: Why sustainable growth needs to be T-shaped and self-driven

As the landscape of work grows more dynamic and interconnected, the way we think about career growth must evolve with it. Today, sustainable success hinges on professionals who can deepen their expertise while widening their perspective, outlines **Suneela Thatte**, VP & Head, Merck Healthcare R&D India

If one looks at the organisations that have excelled in their core operating areas and also considered as employers of choice, one will find that employee growth and development are deep rooted in the ethos of such organisations and act as strategic drivers for professional and organisational success. While for individuals, it is the path to relevance, fulfilment, and creating impact, for organisations, it is the engine that sustains innovation, resilience, and long-term performance. Yet, the way we define and pursue growth has changed over time.

Not too long ago, professional success was often seen as a straightforward climb, progressing through structured roles within well-defined functions. This approach worked well in stable environments, where responsibilities were clear and change was an exception rather than the norm. Today, the business context is very different. Organisations need to thrive in the VUCA world, team are more fluid, challenges are cross-functional, and the pace of transformation demands more than just technical expertise.

This shift calls for a broader definition of growth, one that is no longer only vertical. It is layered, multidimensional, and shaped as much by perspective as by proficiency. One can imagine such growth curve to be T-shaped rather than linear, a growth framework that embraces both depth and breadth, and reflects the kind of agility and adaptability the modern world demands.

What is a T-shaped growth curve?

At its core, the T-shaped growth



As decisions are increasingly influenced by a multitude of dynamic variables, the capacity to integrate knowledge across disciplines has become a critical differentiator in how organisations adapt, evolve, and deliver impact in an agile manner

combines deep expertise in a core discipline (the vertical bar of the "T") with the ability to en-

gage across adjacent areas (the horizontal stroke). The horizontal dimension varies by role, but

its purpose is consistent: to enable collaboration, build contextual understanding, and foster more informed decision-making. For example, a regulatory affairs professional may enhance his effectiveness by developing fluency in data tools, while a clinical trials expert might broaden her insight by exploring digital health or patient engagement. When professionals understand how their work fits into a larger system, they ask sharper questions, anticipate downstream impact, and become better partners in decision-making.

Why does this matter now?

In today's complex and fast-paced environment, the challenge for most organisations isn't a lack of expertise, it's the inability to connect that expertise to broader context, strategy, and outcomes. As decisions are increasingly influenced by a multitude of dynamic variables, the capacity to integrate knowledge across disciplines has become a critical differentiator in how organisations adapt, evolve, and deliver impact in an agile manner.

According to the World Economic Forum's 2025 Skills Outlook, 63 per cent of employers identify skill gaps as a critical barrier to transformation. Yet, in many cases, the challenge lies not in a lack of depth, but in a lack of perspective. Professionals may excel within their domains, but often struggle to operate confidently across the broader system.

Those who combine deep expertise with cross-functional insight are inherently more adaptive. They grasp how upstream decisions influence downstream impact, collaborate effectively

across boundaries, and bring clarity in times of ambiguity. Their strength doesn't stem from having all the answers—but from understanding the system well enough to ask the right questions and navigate complexity with confidence.

Role of individual ownership

T-shaped growth is not confined to informal or accidental learning. It can take shape through both self-driven curiosity and planned cross-functional assignments that intentionally broaden exposure. What matters is the willingness to stretch beyond the familiar. Professionals who grow in this way make conscious choices—to engage in conversations beyond their immediate remit, contribute to cross-functional initiatives, and invest time in understanding how success is defined across the broader organisation. Over time, these choices expand not just capability, but perspective—enabling deeper impact.

At mid and senior career stages, this often requires a mindset shift. Once expertise is well established, it becomes easy to remain anchored in familiar roles and routines, which in most cases acts like a barrier to sustainable growth. Self-driven professionals defy these boundaries. They deliberately step outside their comfort zones, taking on unfamiliar challenges, seeking diverse experiences, and embracing ambiguity. This willingness to go beyond the safe zone or routine is what unlocks the breadth of T-shaped growth. They continue to learn not out of necessity, but because expanding their perspective sharpens their judgment and enhances

the value they bring to complex decisions.

How mentorship expand strategic range

While T-shaped growth often begins with self-driven curiosity, it accelerates through structured planning and purposeful mentorship. Cross-disciplinary mentorship—especially from fields seemingly unrelated to one's own—can profoundly reshape how professionals think, solve problems, and connect ideas. When a healthcare strategist learns from an expert in behavioural economics, or a regulatory professional is mentored by a commercial strategist, the outcome is more than cross-functional awareness. The mentees begin to think in systems: understanding how priorities evolve across domains, how constraints shape decisions, and how long-term impact is often determined

far upstream.

This kind of contrast fosters more than growth, it builds diverse skillsets. It challenges professionals to look beyond their own assumptions and to lead with a broader, more integrated perspective. In fact, according to an article 'A Better Approach to Mentorship' published in Harvard Business Review, 75 per cent of executives credit their success to mentors, and 90 per cent of employees with a career mentor report being happy at work.

Making T-shaped growth sustainable

Self-driven growth is often framed as an individual pursuit. But its long-term impact depends on whether the organisational environment supports it. Professionals may be willing to expand their perspective, but they also need to see that such growth is viable, visible

and valued.

According to Deloitte's 2025 Global Human Capital Trends report, while 72 per cent of organisations acknowledge the need for agility, only 39 per cent have made progress in enabling it. The gap is not only strategic, it is cultural. Especially in specialised fields like technology and research, early career paths are typically deep and narrow. In the absence of cross-functional exposure, professionals may not recognise where broader understanding is needed, or how their expertise contributes to larger outcomes. This is where organisational culture matters. When teams engage across disciplines, context becomes visible, and growth becomes more intentional.

Leaders play a pivotal role in enabling this shift. Recognition must move beyond outcomes alone to include the behaviours

that foster cross-functional insight and collaboration. Growth should be measured not just by progression in title, but by expansion in perspective and influence. Ultimately, sustainable T-shaped growth lies at the intersection of individual intent and organisation's strategy—and hence both must take ownership for it to take root and thrive. Leaders who have themselves experienced T-shaped growth are uniquely positioned to guide others in this journey. Having balanced deep expertise with cross-functional perspective, they are better equipped to navigate complex realities, make informed decisions across domains, and model behaviours that encourage broader collaboration and adaptability. Their example helps embed a culture where growth is not only possible, but also more valued and visible.

Redefining growth beyond role and rank

Some of the most effective professionals aren't defined by how quickly they rise, but by how fully they evolve. They may stay anchored in their domain, yet they operate with a deep understanding of the broader system. They lead through influence rather than hierarchy, and their value lies not just in execution, but in their ability to connect ideas, people, and purpose.

T-shaped growth personifies such contribution and reflects a reality that not all leadership comes with a title, and not all growth is linear. In today's complex world, the most future-ready professionals won't just climb—they'll connect. Their strength lies in integration, not direction. Because the most resilient careers are shaped across dimensions, not along a single path.




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Strategic procurement in clinical trials: A digital transformation imperative

Gourab Ray, Global Category Buyer, Sanofi outlines key value levers, describes an operating model that integrates procurement with clinical and supply-chain functions, and proposes a pragmatic roadmap for sponsors and CROs seeking to modernise their approach

Clinical trial procurement is moving from a narrow, transactional "buying" function to a strategic capability that shapes speed, cost, quality and patient access. Rising protocol complexity, decentralised and hybrid trial models, supply-chain shocks and intensifying regulatory expectations mean sponsors can no longer treat procurement as a back-office activity. At the same time, digital technologies -- advanced analytics, AI/ML, RPA, digital twins, and integrated e-procurement platforms -- are creating new ways to plan, source and manage critical services and supplies.

This article argues that strategic, digitally enabled procurement has become a core differentiator in clinical development. It outlines key value levers, describes an operating model that integrates procurement with clinical and supply-chain functions, and proposes a pragmatic roadmap for sponsors and CROs seeking to modernise their approach.

The changing economics of clinical trials

Across geographies and phases, the economics of clinical trials are dominated by a small set of cost drivers. Analyses of US trial budgets consistently show that clinical procedure costs, administrative staff, and site monitoring together account for a large share of total spend, often in the range of 35-60 per cent depending on phase and design^{[1][2]}. Figure 1 illustrates the major cost categories that dominate clinical trial budgets.

These cost drivers are heavily influenced by decisions that procurement can shape:



- Which CROs and vendors are selected, and on what commercial model.

- How comparator drugs, ancillaries, devices and logistics services are sourced and contracted.

- How risk is shared (or not) across multi-country, multi-year studies.

At the same time, global sponsors are grappling with:

- More complex and adaptive protocols.

- Growth in decentralised and hybrid trial models.

- Increased focus on diversity, equity and inclusion in recruitment.

- Heightened regulatory scrutiny of data integrity, temperature control, and supply continuity.

In markets like South Asia and India, industry observers expect 2026-2027 and beyond to bring a further surge in

early-phase research, more decentralised trials and deeper reliance on digital tools for patient recruitment and operational oversight^[15]. Against this backdrop, a purely transactional approach to procurement -- focused on unit price and contract execution -- is no longer sufficient.

From transactional buying to strategic clinical procurement

Historically, clinical trial procurement was often fragmented:

- Study teams ran one-off RFQs via email and spreadsheets.

- Category strategies for CROs, labs, depots, packaging or home-healthcare were weak or absent.

- Data on supplier performance, change orders and pass-through costs was scattered across systems.

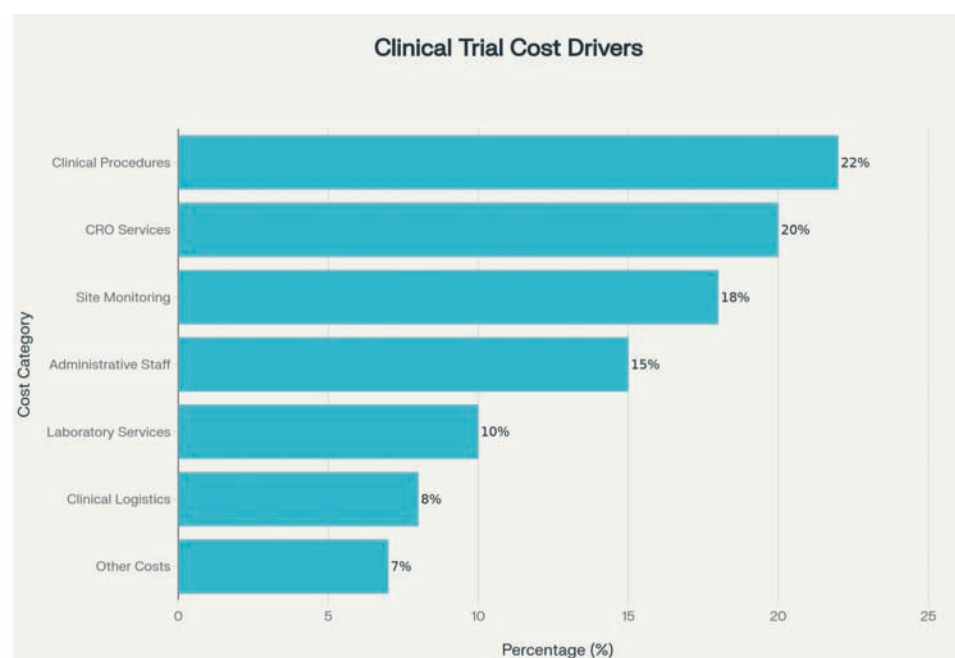
Strategic procurement in clinical development looks very different. It is characterised by:

1. Category management and supplier segmentation:

Dedicated category strategies for CRO services, central labs, eCOA/ePRO, clinical logistics, packaging and labelling, home-care vendors, technology platforms and specialist consulting^{[13][14]}. Key suppliers are treated as long-term partners, not just bidders in episodic tenders.

2. Value-driven relationships instead of pure price competition:

Commercial models increasingly combine base fees with performance-linked elements tied to start-up timelines, recruitment, data quality or audit outcomes^[11]. Structured business reviews and joint improvement roadmaps



[FIGURE 1: Major cost drivers in clinical trials]

replace purely transactional interactions.

3. Integrated quality and compliance thinking: ICH-GCP, data integrity and GDP requirements are built into category strategies and contracts rather than addressed ad hoc at the site or study level. Procurement works with QA, pharmacovigilance and regulatory teams to ensure vendors can withstand inspection and scale with the portfolio.

4. Early involvement in protocol and operational design: When procurement is brought into discussions before protocols are finalised, it can surface feasibility, comparator access, depot strategy and packaging concerns that materially influence timelines and cost of goods^[12].

This shift mirrors developments in purchasing and supply-management more broadly, where AI/ML, data and integrated platforms are turning procurement into a strategic business partner^{[13][14]}.

The digital imperative: new tools for an old problem

Digital transformation in clinical trial procurement is not about adopting "shiny" tools; it is about creating better, faster and more resilient decisions across the study lifecycle. Chart 1 presents the strategic positioning of key technologies based on implementation ease and strategic value. Several technology layers are now maturing:

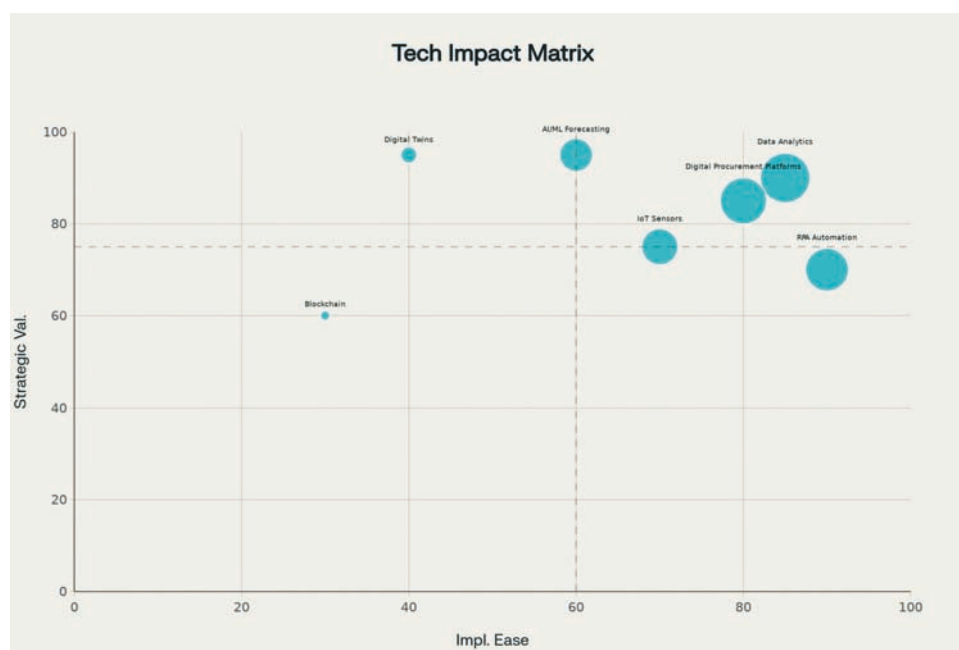
Data foundations and analytics

Many sponsors still struggle with basic questions:

- What is our true spend on CROs, labs, depots and logistics across the portfolio?
- How often do we trigger costly urgent resupplies or protocol-driven rework?
- Which suppliers consistently hit or miss key milestones?

Modern analytics platforms, fed from CTMS, eTMF, ERP, e-sourcing tools and AP systems, allow procurement to build an integrated view of:

- Study-level and category-level spend.
- Change orders and scope



[CHART 1: Technology Impact Matrix - Implementation vs Strategic Value]

creep.

- Cycle times (e.g. start-up, contract execution, site activation).
- Supplier performance and quality signals.

In parallel, biopharma companies are starting to use AI and ML to predict site performance, enrollment trajectories and operational risks, enabling earlier interventions and more realistic supply plans^{[3][4]}.

AI/ML for forecasting and scenario planning

AI/ML techniques are increasingly used in clinical development to:

- Predict enrollment based on historical data and real-world evidence.
- Optimise site selection and country mix.
- Flag potential bottlenecks in monitoring, data cleaning or logistics.

For procurement, this translates into better demand signals for comparators, IMP and ancillaries, as well as more robust scenarios for:

- Depot placement and capacity.
- Packaging batch sizes and overage levels.
- Safety stock thresholds for temperature-sensitive supplies.

This is where digital twin concepts become powerful^{[6][7]}. A clinical supply digi-

tal twin creates a virtual model of the trial supply chain, allowing teams to simulate and compare different sourcing and logistics strategies before implementing them in the real world.

RPA and workflow automation

While AI tackles complex prediction problems, robotic process automation (RPA) is quietly attacking the "paperwork mountain" that surrounds clinical procurement:

- Automating invoice capture and matching for high-volume vendors.
- Creating and routing purchase orders from approved budgets.
- Extracting key data from contracts and amendments into structured fields.
- Updating status dashboards and alerts.

RPA has already shown value in pharma finance and R&D operations, reducing manual effort and error rates while improving process consistency^{[9][10]}. Applied to procure-to-pay, it frees specialists to focus on negotiations, risk management and stakeholder engagement rather than data entry.

Digital procurement platforms and SRM

E-sourcing, e-contracting and

supplier relationship management (SRM) tools are mainstream in many industries, and adoption in pharma is accelerating^[13]. For clinical procurement, these platforms enable:

- Structured, transparent RFX processes with standard templates.
- Centralised storage of contracts with version control and audit trails.
- Systematic supplier onboarding, qualification and risk scoring.
- A shared view of obligations, rebates and performance metrics.

External industry commentary increasingly emphasises the role of procurement as a driver of digital innovation in pharma, particularly in building digital supplier ecosystems and using data to manage risk and foster co-innovation^[14].

Emerging technologies: digital twins, IoT and blockchain

IoT-enabled sensors and control towers now provide near real-time visibility of temperature, location and dwell time across depots and lanes, improving compliance and reducing write-offs^[6].

Digital twin approaches are being piloted not only for manufacturing but also for end-to-end supply-chain design,

stress-testing networks against disruptions and policy changes^[7].

Blockchain-based solutions for drug traceability and anti-counterfeiting are under active exploration; while not mandated by regulators, they can complement existing serialisation and data-integrity controls.

Operating model: making digital and strategic stick

Tools alone do not transform procurement. Organisations that get this right typically rethink their operating model along four dimensions.

Centre-led, hybrid structures

Global surveys show that many mature organisations gravitate towards centre-led or hybrid procurement models, blending a small central team responsible for strategy and standards with empowered local teams closer to studies and sites^{[11][12]}.

In clinical procurement, this often means:

- A central category team for CROs, labs, logistics, packaging and DCT vendors.
- Regional or BU-level teams embedded with clinical operations, accountable for tactical execution within global frameworks.
- Governance forums that include clinical, medical, quality and finance stakeholders, not just procurement.

This structure allows sponsors to leverage scale and standardisation where it matters, without losing the agility needed for country-specific requirements and investigator relationships.

Integrated governance with R&D and quality

Strategic clinical procurement is tightly connected to:

- R&D portfolio governance -- to align sourcing strategies with pipeline priorities.
- Clinical operations -- to ensure vendor choices support recruitment, diversity and patient-centric design^[5]
- Quality and pharmacovigilance -- to embed inspection readiness and data-integrity concerns from the outset.

Joint steering committees,

shared KPIs and integrated risk registers help prevent the "hand-offs" that have historically plagued complex programmes.

Skills and culture

Digital and strategic procurement require a different skill mix from traditional buying:

- Data-literate category managers able to interpret analytics, scenario outputs and AI insights.
- People comfortable leading cross-functional negotiations on risk-sharing, innovation and performance metrics.
- Familiarity with regulatory expectations specific to clinical trials and GxP environments.

Research on AI in purchasing and operations emphasises that benefits are realised only when organisations invest in skills and change management, not just tooling[8].

Supplier collaboration and innovation

Finally, strategic procurement builds collaborative innovation networks with CROs and niche providers:

- Shared dashboards on performance, risk and improvement initiatives.
- Co-designed pilots on decentralised models, remote monitoring or novel logistics solutions.
- Carefully structured agreements for co-development and data sharing where appropriate.

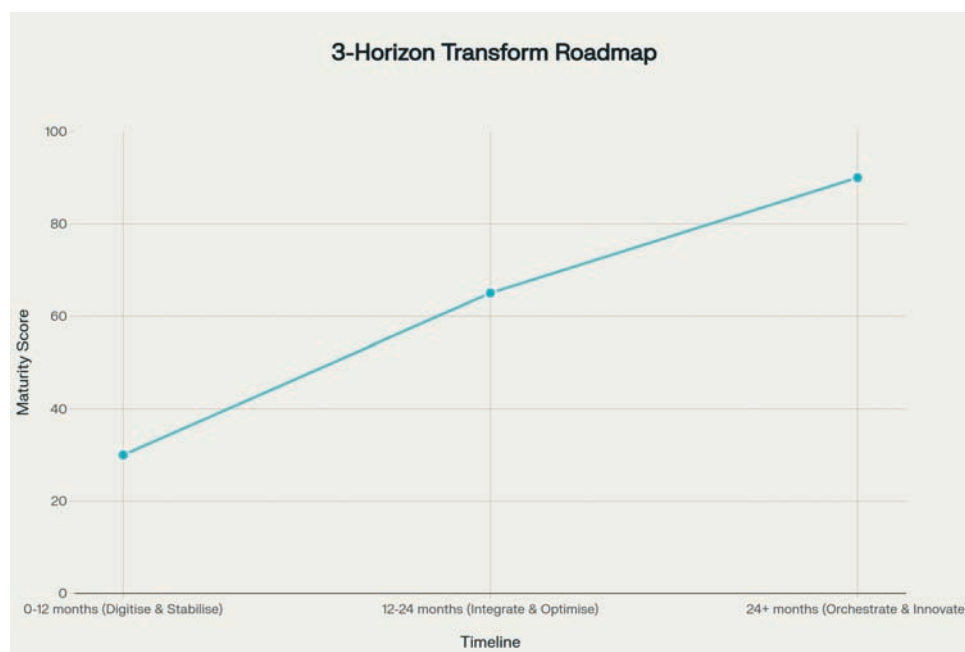
The goal is not to outsource responsibility, but to co-create better ways of running trials^[4].

A practical roadmap for sponsors and CROs

Every organisation starts from a different baseline, but a simple three-horizon roadmap can help. Chart 2 illustrates the progressive maturity trajectory across these horizons.

Horizon 1 (0-12 months): Digitise and stabilise

- Map current spend, suppliers and tools across clinical categories.
- Standardise RFx templates, basic scorecards and contract clauses for key risk areas (e.g. data integrity,



[CHART 2: Three-Horizon Procurement Transformation Roadmap]

Digital transformation in clinical trial procurement is not about adopting "shiny" tools; it is about creating better, faster and more resilient decisions across the study lifecycle

temperature excursions, business continuity).

- Implement or stabilise core e-sourcing/CLM and basic analytics, with at least a consolidated view of category and supplier spend.
- Identify "quick-win" RPA use cases in procure-to-pay (invoice processing, PO creation, data extraction)^{[9][10]}

Horizon 2 (12-24 months): Integrate and optimise

- Connect procurement tools with CTMS, IRT and finance systems to improve forecast accuracy and visibility.
- Introduce predictive analytics for enrollment and supply planning and begin using scenario analyses in sourcing decisions^{[3][4]}
- Pilot a centre-led operating model for one or two categories (e.g. CRO and logistics), with global frameworks and local draw-down.
- Formalise supplier performance management and QBRs with your most critical partners.

Horizon 3 (24+ months): Orchestrate and innovate

- Develop digital twin pilots for complex, multi-country studies to de-risk depot networks, overage strategies and sourcing options^{[6][7]}
- Expand AI/ML use cases beyond forecasting to contract analytics, risk-sensing and proactive issue detection.
- Explore blockchain-based traceability where it meaningfully complements existing serialisation and GDP controls.
- Embed digital and strategic procurement KPIs into R&D scorecards -- not just cost savings, but impact on cycle time, recruitment, deviations and audit findings.

Procurement as a lever for smarter, faster, more resilient trials

As the clinical trials ecosystem becomes more competitive and more digital, procurement is no longer a support function sitting in the background. It directly influences:

- **Speed** -- through smarter

supplier choices, better forecasting and streamlined contracting.

- **Cost and productivity** -- by controlling key cost drivers and reducing waste from rework, change orders and write-offs.
- **Quality and compliance** -- by ensuring that vendors, data and physical flows meet the expectations of regulators and patients.
- **Resilience** -- by diversifying supply options, modelling scenarios and leveraging real-time visibility.

For sponsors and CROs that embrace a strategic, digitally enabled procurement model, the prize is not only lower unit prices, but better clinical outcomes, more predictable timelines and a stronger competitive position in an increasingly demanding global environment^{[1][2][15]}.

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INTERVIEW

Local focus to strengthen Indian pharmaceutical manufacturers

For the Indian pharmaceutical industry, competitiveness not only means access to international markets, but also establishing expertise and operational capabilities on an equal footing directly in India. This is precisely what pharmaceutical machinery manufacturer Romaco supports as it implements a strategic realignment: namely, localising the production of format parts for blister packaging machines of the successful Noack 900 series in India.

Sanjeev Nimkar, Managing Director of Romaco India, **Amol Nikam**, Director of Customer Service at Romaco India and **Gero von Stackelberg**, Director of Customer Service at Romaco Group, explain in an interview with **Express Pharma** what this means for Indian pharmaceutical manufacturers and how this commitment to the Indian market came about



Sanjeev A. Nimkar, Managing Director of Romaco India



Amol Nikam, Director of Customer Service at Romaco India



Gero von Stackelberg, Director of Customer Service at Romaco Group

Why is localising format part production an important step for Indian pharmaceutical companies and Romaco?

Sanjeev Nimkar: It makes it easier for Indian manufacturers who want to benefit from the advantages of our blister packaging machines, such as excellent OEE, high output and great quality, to access our equipment. The local production of format parts tremendously reduces delivery times, which makes our customers more flexible,

minimises downtime and speeds up the commissioning of newly purchased machines. This is not only due to shorter delivery routes, but also to the elimination of considerable organisational workload and bureaucratic hurdles. Previously, test material and placebo tablets had to be delivered to Germany for all work on new format parts, which has become very costly and time-consuming in recent years given the sometimes very strict import regulations and customs rules. Among other things, this resulted in

considerable air freight costs and significant effort in preparing the export documents. Localisation in India now makes all this complexity obsolete.

What was also crucial for us in terms of localisation was that these fast delivery times do not compromise the quality of the format parts and end products. The blister packaging manufactured with the parts produced in India has the same quality characteristics in terms of tightness and sealing properties as European

output.

Amol Nikam: The localisation is also supported by the availability of the blister machines at our Romaco India Experience Centre in Hyderabad, for running in and approving new format parts, as well as for adjustments to existing formats. Film tests and operator training can additionally be carried out in the modern customer and training centre, which also includes a spare parts warehouse and a process technology laboratory that combines Romaco's expertise

in the areas of granulation, tableting and coating of pharmaceutical solid products.

With the localisation of the format part production and the Experience Centre, we can now provide even better blister production support to Indian pharmaceutical manufacturers and help them achieve the fastest possible ROI. This includes having Indian technicians on site in Hyderabad who have been trained on the blister packaging machines at Romaco headquarters in

Germany by our experts from Romaco Noack and thus have the expertise to locally train or directly assist customers in India.

Gero von Stackelberg: All of this shows why the localisation is a milestone for Romaco India and Romaco as a whole. Decentralisation and customer focus have always been core objectives of the Romaco Group – and format part production in India is the practical realisation of this.

And it will not stop there: Within the next months and years, most of the format

parts required in India will also be designed here.

What was central to the implementation of localisation in India?

Amol Nikam: Teamwork was key here. In order to implement this approach “local for local”, as a local production that directly addresses customer needs, we collaborated internationally. The strategic placement of this step was carried out by management from Germany, while the organisational work and concrete implementation was executed in India. Overall,

it can be said that we at Romaco are exploiting international opportunities to support our Indian customers and help to shape the global growth of the Indian market with attractive solutions.

Gero von Stackelberg: A perfect example of this international collaboration for the benefit of the customer is the combination of expertise from Germany, Romaco White Line machine production in China and format part manufacturing in India. This enables us to combine quality, speed in delivery and cost efficiency.

Romaco is a sustainability enabler. Does localisation reflect this?

Sanjeev Nimkar: Absolutely. Of course, localising the production of format parts in India is primarily intended to guarantee our customers a quick start to production, flawless machine operation and a secure supply of format parts. But localisation is also a matter of sustainability. For example, it is directly related to our sustainability strategy, as the shorter transport distances have a

positive effect on the carbon footprint of the machine components.

Gero von Stackelberg: Additionally, sustainability is also achieved in the sense of further developing not only the market in India, but the Asian market as a whole. This commitment is illustrated, for instance, by the Noack N 950E, the first blister packaging machine to be installed at the Customer Experience Centre in Hyderabad, which was manufactured at Romaco Changsha in China. In other words, the localisation in India is an investment in the future.

INTERVIEW

Speed and flexibility play a critical role in how we compete with larger global players

Kriti Jajoo, VP-BD and Strategy, Shriji Polymers, as the next-gen leader, speaks on how the company is evolving with a leadership approach that balances technology, sustainability, and customer-centricity to create long-term value, in an interview with **Express Pharma**

As a young leader stepping into a global business, how do you envision the next phase of growth for Shriji Polymers?

As a young leader stepping into a global business, I see the next phase of growth for Shriji Polymers as an evolution rather than a transformation. My focus is on strengthening our role as a solutions-oriented packaging partner, moving beyond transactional manufacturing to offering deeper value to our customers.

This phase is about building capabilities, systems, and relationships—investing in quality, innovation, and people so that the organisation is prepared for larger opportunities ahead. I believe sustainable growth comes from being dependable, adaptable, and willing to learn continuously, especially in a highly

regulated industry like pharma. For me, this journey is also personal. It's about learning from experienced teams, understanding customer pain points closely, and ensuring that as we grow, we remain grounded in the values that have shaped Shriji Polymers so far.

What is your long-term vision for business expansion over the next five to ten years? What new markets (geographic or vertical) are you actively planning to enter?

Over the next five to ten years, our vision for expansion is both structured and scalable. From a geographic standpoint, we are actively evaluating opportunities in the Middle East, Latin America, and select European markets, where demand for high-quality pharmaceutical packaging is growing alongside regulatory

maturity.

Alongside geographic expansion, we also see strong potential in new verticals within healthcare and allied industries, including advanced drug delivery systems, medical devices, and specialised packaging for injectables and complex formulations. These segments require high precision and strong quality systems, which align well with our long-term capabilities.

Our approach to expansion will be measured rather than aggressive—prioritising regulatory readiness, customer alignment, and operational excellence. The aim is not just to enter new markets, but to build long-term, credible presence in them, supported by consistent quality and strong partnerships.

Where do you see the most

impactful applications of Artificial Intelligence (AI) within the pharma packaging industry, and how is Shriji Polymers preparing to leverage it?

I see the most impactful use of AI in pharma packaging emerging at the intersection of design validation, quality assurance, and operational efficiency. At the very initial stage, AI has the potential to help assess whether a packaging concept can be practically manufactured—by simulating designs, predicting outcomes, and identifying possible limitations before physical trials begin. This can significantly reduce development time and material wastage while improving decision-making.

Beyond design, AI can play a meaningful role in quality inspection and process monitoring. Intelligent vision systems can detect micro-defects,

dimensional deviations, or inconsistencies that may not always be visible through manual inspection, thereby strengthening compliance in a highly regulated industry. AI-driven analytics can also support predictive maintenance, helping manufacturers anticipate machine issues and reduce downtime.

At Shriji Polymers, we view AI as a supporting enabler rather than a replacement for human expertise. Our focus is on gradually integrating digital tools that enhance accuracy, consistency, and learning across operations. By strengthening our data systems, standardising processes, and upskilling our teams, we are preparing ourselves to adopt AI in a way that is practical, responsible, and aligned with regulatory expectations—ensuring that technology ultimately translates into

better outcomes for our customers.

How does Shriji Polymers strategically position itself for contending with worldwide market leaders? What are your key competitive advantages (e.g., technology, cost, service, time-to-market) that allow you to challenge global giants?

Shriji Polymers positions itself by combining the strength of a multi-geography presence with the agility of a focused, customer-centric organisation. Operating across multiple markets allows us to better understand regional regulatory expectations, customer preferences, and supply-chain dynamics, while also reducing over-dependence on any single geography. This global exposure enables us to respond faster and more effectively to evolving customer needs.

One of our key competitive advantages lies in our ability to balance quality with cost efficiency. By maintaining strong in-house manufacturing capabilities and lean operational structures, we are able to offer globally competitive solutions without compromising on regulatory compliance or product consistency. This becomes especially relevant for customers looking to scale across markets while managing cost pressures.

Speed and flexibility also play a critical role in how we compete with larger global players. Our relatively agile decision-making structure allows us to move quickly—from development to execution—resulting in shorter time-to-market and greater customisation. Customers value this responsiveness, particularly in fast-changing pharma and healthcare environments.

Additionally, our focus on long-term partnerships rather than transactional relationships sets us apart.



From a geographic standpoint, we are actively evaluating opportunities in the Middle East, Latin America, and select European markets, where demand for high-quality pharmaceutical packaging is growing alongside regulatory maturity. We also see strong potential in new verticals within healthcare and allied industries, including advanced drug delivery systems, medical devices, and specialised packaging for injectables and complex formulations

We work closely with customers to understand their challenges, align with their growth plans, and co-develop solutions that add sustained value. Supported by robust quality systems and continuous process improvement, this approach allows Shriji Polymers to compete not just on scale, but on reliability, adaptability, and trust—which are critical differentiators when

contending with global market leaders.

When developing new packaging solutions, what is the process for ensuring a patient-friendly pack design? How do you gather user feedback on features like ease of opening, dosing accuracy, and accessibility? Ensuring patient-friendly pack design is a collaborative and iterative process at Shriji Polymers. Every new

development begins with regulatory compliance and customer requirements, followed by a deeper evaluation of user experience—particularly in areas such as ease of opening, dosing precision, and accessibility.

We rely on a combination of market research, global case studies, and application-specific testing to develop solutions that align with evolving consumer

expectations. Prototypes and samples are shared with customers to gather practical feedback, which helps us optimise design, functionality, and performance before scaling.

With experience across diverse segments including pharma packaging, rigid packaging, FMCG, home care, cosmetics, nutraceuticals, and agrochemicals, we are able to transfer learnings across industries. This continuous learning mindset ensures that our packaging solutions remain compliant, innovative, and truly user-centric.

What are Shriji Polymers' core commitments and practical steps towards sustainability in your manufacturing processes? How do you balance cost efficiency with environmentally friendly practices?

Sustainability is a continuous journey at Shriji Polymers, supported by practical actions on the ground. We have invested in renewable energy through solar power installations and partial in-house electricity generation to reduce environmental impact and improve energy efficiency.

Our waste management strategy focuses on recycling and reuse, where production scrap is responsibly repurposed for suitable product lines across various industries. Water stewardship is addressed through rainwater harvesting systems and groundwater recharge initiatives, ensuring efficient use of natural resources.

We have also decentralised our manufacturing footprint by developing plants at multiple locations, which helps reduce transportation-related emissions and contributes to smoother logistics. Through these initiatives, we strive to balance sustainable practices with operational efficiency and long-term business growth.

What It Takes to Build Pharmaceutical Facilities That Perform from Day One

As regulatory expectations tighten and speed-to-market pressures intensify, pharmaceutical facilities must be designed for certainty from day one. Drawing from large-scale project experience, **Mr Subhendu Mohanty**, Vice President, Projects - Pharma Access outlines how integrated engineering, simulation-led design, and early validation are redefining successful facility delivery

The pharmaceutical facility landscape has become increasingly complex. Regulatory expectations, operational efficiency, sustainability requirements, and speed-to-market pressures must all be addressed simultaneously. From my experience, the single biggest pitfall companies face when starting a major construction or expansion project is the lack of upfront integration.

Building a modern pharmaceutical facility is not just about civil construction. It requires the seamless integration of process design, utilities, automation, and regulatory compliance, including USFDA guidelines, cGMP, Annex 1, and other global regulatory frameworks. As I often say, "One of the biggest challenges in pharma projects is anticipating compliance and operational needs before the first brick is laid." When integration is considered late in the process rather than from the very start, it leads to fragmented execution and costly rework.

Integration from Conceptualisation to Commissioning

At Pharma Access, we fundamentally change the traditional approach to designing and building pharmaceutical facilities through what we call Integration from the Ground Up.

We embed compliance and efficiency from the outset. By incorporating regulatory considerations into every phase of the project, from conceptualisation to commissioning, we ensure the final facility is not only compliant but also optimised for seamless, high-performance operation. This integrated approach reduces execution risk and enables smoother commissioning and validation.

Simulation-Based Engineering and Digital Twins

Our team relies heavily on Simulation-Based Engineering, because simulation is a powerful predictive tool.

Simulation allows us to foresee potential issues and optimise systems in ways that are simply impossible with conventional drawings. We build complete digital twins of pharmaceutical facilities, including process flows, HVAC systems, piping, and electrical circuits. These virtual replicas allow us to anticipate operational challenges, optimise layouts, and drastically reduce the risk of costly field modifications.

A key application of this approach is cleanroom design. We use Computational Fluid Dynamics (CFD) simulations to guarantee adherence to ISO 14644 standards. By calculating the precise Air Changes Per Hour (ACPH), where airflow rate and room volume are balanced, we ensure proper contamination control while maintaining energy efficiency. This is a critical metric for aseptic manufacturing environments.

$$ACPH = \frac{(Q \times 60)}{V}$$

Here, Q is the airflow rate (ft³/min) and V is the room volume (ft³).

Quality by Design as a Planning Principle

Quality by Design means quality is engineered in, not inspected in. By embedding Quality by Design (QbD) into the initial planning stages, we are able to anticipate process variability and embed controls proactively. This allows us to identify Critical Quality Attributes (CQA), Critical Material Attributes



(CMA), and Critical Process Parameters (CPP) early in the project lifecycle.

This synergistic design, where digital twin insights inform optimisation and QbD principles embed controls, guarantees consistent, high-quality outcomes across the facility lifecycle.

De-Risking Timelines Through FEL and Early CQV

Project delays and compliance issues are costly in pharmaceutical manufacturing. To de-risk timelines and budgets, we rely on two cornerstone philosophies, Front-End Loading (FEL) and early integration of CQV.

Front-End Loading is intensive upfront planning to define scope, technical requirements including URS, costs, and schedules before significant capital commitment. This approach minimises scope creep and reduces downstream uncertainty.

At the same time, embedding CQV early is a game-changer. It ensures all systems are designed for validation from day one. We develop a comprehensive Validation Master Plan detailing

URS, FAT, SAT, IQ, OQ, and PQ. This ensures documentation is audit-ready for USFDA inspections and compliant with regulations such as 21 CFR Part 11, preventing costly surprises and enabling immediate operational readiness after handover.

Sustainability and Safety as Design Pillars

Sustainability and safety are not afterthoughts. They are woven into the design DNA of every project we deliver.

Classified cleanrooms are known for over-ventilation. By using validated CFD modelling, we precisely optimise airflow and typically achieve a 10 to 25 percent reduction in energy use on HVAC systems alone. In parallel, we integrate Zero Liquid Discharge (ZLD) systems into our designs, preventing 70 to 80 percent of wastewater from being lost to drainage. This is crucial for achieving water neutrality and long-term sustainability.

We track this performance through our Sustainability Index, which is based on energy savings, water conservation, and material optimisation.

$$SI = \frac{(E_s + W_s + M_s)}{3}$$

Turnkey Delivery and Single-Point Responsibility

Our approach provides seamless integration from conceptual engineering through procurement, construction, commissioning, and validation.

As our director, Mr. Shams Parvaz often says, "Our turnkey approach is not about speed alone. It is about delivering facilities that are ready to

operate efficiently, safely, and compliantly from day one." Clients benefit from a single point of responsibility, integrated project management, scalable cleanroom solutions, and a regulatory-aligned CQV strategy, eliminating friction between multiple stakeholders.

Modular Facilities and Future Agility

Modular and mobile facilities are gaining prominence as the industry demands speed-to-market and flexibility. Modular construction allows activities to happen in parallel, with prefabricated modules built in controlled factory environments while site work progresses simultaneously.

This approach reduces timelines by 30 to 40 percent, improves quality and safety, provides scalability, and is inherently sustainable by design.

Engineering and Execution as One Philosophy

We often use the analogy of $E=mc^2$ to describe our operational philosophy. It represents the fusion of engineering mastery with execution capability.

This philosophy captures how we combine advanced engineering, disciplined execution, Quality by Design, simulation-led planning, and sustainability strategies to solve complex pharmaceutical facility challenges. The outcome is facilities that are operationally robust, compliant, and strategically transformative.

In today's pharmaceutical environment, this integrated approach is no longer optional. It is essential.



Vizag rising: Shaping India's pharma future

At the **Vizag Pharma Summit 2025**, hosted by Express Pharma, industry leaders discussed how quality, R&D, compliance, and emerging technologies are driving India's next phase of pharma growth, reports **Neha Aathavale**

As the Indian pharmaceutical industry grapples with a defining question: What comes after scale?; the conversations in Visakhapatnam (Vizag) on December 17, 2025 offered some clear answers. At the Vizag Pharma Summit 2025, hosted by Express Pharma, industry leaders, policymakers and decision-makers came together to confront the hard realities of a sector under global scrutiny, even as it stands on the cusp of unprecedented opportunity. The message was unmistakable: cost leadership may have built India's pharma reputation, but global excellence will demand far more rigour, innovation and long-term vision.

Held in a city fast emerging as a serious pharma contender, the fourth edition of Express Pharma's national summit series reflected the shifting centre of gravity within Indian manufacturing and R&D. From debates on policy direction and supply chain resilience to the push for quality-first growth and innovation beyond generics, the discussions mirrored Vizag's own trajectory: ambitious, infrastructure-backed and export-oriented. What unfolded over the day was not just a regional narrative, but a broader blueprint for how Indian pharma must evolve if it hopes to remain relevant in a rapidly transforming global market.

Why not Vizag? A call for excellence

Setting the context for the day's deliberations, K Raja Bhanu, Director General, Pharmexcil, delivered the Special Address with a clear-eyed assessment of where Indian pharma stands, and where it must go next. Pointing to the unmistakable slowdown in the plain generics growth story, he noted that the industry can no longer rely on volume-led expansion alone. The next phase, he stressed, will



L-R: Naimish Mishra, Site Quality Assurance Head-FTO11, Dr Reddy's Laboratories; Dr T Pavan Pradeep, CEO, Actimus Biosciences; K Raja Bhanu, Director General, Pharmexcil; K V Sreenivasa Babu, VP-Operations, Natco Pharma; Subba Reddy Arumalla, Associate VP – Cluster Head API Plant Management, Amneal Pharmaceuticals

have to be driven by movement into more complex and differentiated territories, such as complex generics, biosimilars and innovative formulations that demand deeper scientific capability and higher execution standards.

However, market expansion without credibility, he cautioned, would be a hollow victory. Drawing a sharp distinction between economic and reputational risks, Mr Bhanu observed that while trade deficits can be managed, a trust deficit cannot. For Indian pharma, this translates into raising the bar on quality, consistency and compliance; not merely to satisfy global regulators, but to earn long-term confidence and set benchmarks of its own.

He also underlined the urgency of building a self-reliant yet globally integrated ecosystem, one that strengthens domestic capabilities while reducing strategic dependencies across the supply chain. Such resilience, he argued, would be central to sustaining competitiveness in an increasingly volatile global environment.

Lastly, bringing the spotlight back to the host city, Bhanu concluded on a decisive note: as the industry debates whether Vizag can become India's next pharma capital, the more pertinent question, he said, is simply - why not Vizag?

Vizag's next leap

With the larger vision firmly in place, the conversation shifted from why Vizag matters to what it will take for the city to translate potential into leadership. Moving decisively from aspiration to execution, the panel discussion 'Vizag Rising: Can it be India's next pharma capital?' brought together voices from manufacturing, operations, quality and leadership to examine the realities on the ground.

Moderated by Subba Reddy Arumalla, Associate VP – Cluster Head API Plant Management, Amneal Pharmaceuticals, the panel featured Dr T Pavan Pradeep, CEO, Actimus Biosciences; K V Sreenivasa Babu, VP-Operations, Natco Pharma; and Naimish Mishra, Site Quality Assurance Head-FTO11, Dr Reddy's Laboratories. Together, they examined whether Vizag's advantages, spanning infrastructure, land availability and ecosystem support can be translated into a sustainable, globally competitive pharma hub, or whether deeper systemic shifts are still required.

While acknowledging Vizag's growing industrial footprint, the panellists were candid about the gaps that still need attention. Regulatory delays, infrastructure bottlenecks and process inefficiencies were flagged as challenges that could slow momentum if not addressed de-

cisively. For Vizag to attract higher-value investments particularly in complex and innovation-driven segments the ecosystem, they agreed, must offer speed, predictability and execution excellence alongside scale.

A recurring theme was talent. Building a robust, future-ready workforce through targeted skill development and deeper industry - academia collaboration was seen as non-negotiable for the region's next phase of growth. At the same time, Vizag's availability of land was highlighted as a strategic advantage, one that could enable the creation of integrated pharma clusters capable of competing with global manufacturing and R&D hubs.

Ultimately, the panel concluded that Vizag's success will not be determined by infrastructure alone. Sustainability, technology adoption, quality and regulatory compliance will define whether the city can sustain its ambitions over the long term. The opportunity is real, the consensus suggested—but realising it will require coordinated action, not incremental change.

From compliance to operational excellence

As the discussion moved from regional ambition to operational reality, a clear throughline emerged across subsequent sessions: global excellence in pharma will be defined by how well quality, compliance and manufacturing intelligence are embedded into everyday decision-making. The focus shifted from what India and Vizag aspire to become, to how organisations must re-engineer systems, partnerships and processes to get there.

Addressing the theme of raising the bar on quality and compliance, Manas Kumar, Global Director – Pharma, Strategic Marketing and Business Devel-

opment, Lindström Oy, highlighted a dimension of compliance that is often underestimated: risk mitigation through strategic outsourcing. He explained how outsourcing garment processing to specialised partners like Lindström not only reduces contamination and compliance risks, but also frees up valuable in-house capacity, allowing pharma manufacturers to focus on core operations without compromising regulatory expectations.

The emphasis on building resilient, end-to-end manufacturing ecosystems continued with Rajesh Sopan Sudit, AGM – Sales, Romaco India, who presented Romaco as a one-stop solution provider for both OSD and injectable manufacturing. With a comprehensive portfolio spanning processing to packaging, he underlined how integrated equipment partnerships can simplify complexity, enhance efficiency and support pharma companies as they scale up while maintaining consistency and compliance.

Delving deeper into the often-overlooked micro-details that can have macro implications for product quality, Nitin R Khaladkar, Head – R&D, Bharat Rubber Works, spoke on Moisture Vapour Transmission Rate (MVTR) in pharmaceutical rubber stoppers. He highlighted how innovative coating technologies that significantly reduce moisture vapour transmission can dramatically improve the stability and protection of moisture-sensitive medicines, reinforcing the idea that quality is built not just at the formulation level, but across every component of the drug product.

Process optimisation and manufacturing intelligence were further explored by Parag S Radia, Director, L.B. Bohle India, who showcased innovative OSD manufacturing solutions from L.B. Bohle, Germany. He empha-



K Raja Bhanu, Director General, Pharmexcil



Manas Kumar, Global Director - Pharma, Strategic Marketing and Business Development, Lindstrom Oy



Rajesh Sopan Sudit, AGM - Sales, Romaco India



Nitin R Khaladkar, Head R&D, Bharat Rubber Works



Parag S Radia, Director, L.B. Bohle India

sised how advanced equipment design enables faster, gentler and more consistent processing, while simultaneously lowering maintenance and operating costs, an increasingly important balance as manufacturers face pressure to improve both productivity and compliance.

The conversation then moved from compliance as an obligation to quality as a strategic differentiator. In his session on creating future-ready quality systems, Jyothi Venkata Prasad V, Head - QA API (Site-6), Biocon, stressed that robust GMP frameworks, when combined with automation, are critical to ensuring consistent product quality, strengthening regulatory trust and safeguarding patient safety. Compliance, he noted, must evolve from a reactive checklist to an integrated, technology-enabled culture.

Reinforcing this theme, Dr Shankar Varaganti, Commercial Marketing Manager, Merck Life Science, addressed the role of pharma secondary standards in securing quality control outcomes. He highlighted how Merck's fully traceable secondary standards, supported by dual traceability and dual values, help manufacturers strengthen data integrity and regulatory confidence. Particularly in increasingly complex analytical environments.

Closing this segment with a forward-looking lens, Vijay Kumar, Regional Manager - South, Sun Teknovation, explored AI as the new foundation of zero-defect pharma manufacturing. Emphasising the shift toward edge AI, he explained how AI-driven solutions can deliver real-time insights, speed and compliance without dependence on cloud infrastructure. Marking a significant step toward smarter, more autonomous manufacturing systems.

Together, these sessions underscored a central truth echoed throughout the summit: the future of Indian pharma will not be built on scale alone, but on systems that are intelligent, compliant, resilient and relentlessly focused on quality.

Roadmap to 2035

As the day's discussions progressed, it became evident that

operational excellence and advanced technologies, while essential, are only part of the equation. To sustain momentum over the next decade, Indian pharma will need clear policy direction, cross-sector partnerships and a fundamentally different growth mindset. This set the stage for the panel discussion 'Pharma 2035: Policies, partnerships and pathways to growth', which examined how the industry must prepare for its next chapter.

Moderated by Deepthi Cherukuri, Head - Global Clinical Development & Biopharmaceuticals, Cronus Pharma Specialities, the panel brought together diverse perspectives from R&D, quality and engineering. The panellists included Dr Mahendar Velisoju, AVP - Head of R&D, PharmaZell (India), Axplora Group; Ravi Sankar Vankayala, GM - Quality Assurance, Gland Pharma; P Veerabhadra Rao, Head - Quality, Natco Pharma; and Sriramulu Bhaskar, Head of Engineering, Aurobindo Pharma.

Together, they stressed that the next phase of India's pharma journey will be defined not by volumes alone, but by R&D depth, technology adoption, infrastructure readiness and a fundamental shift in growth mindset.

A strong emphasis was also placed on patient-first thinking, which the panellists agreed must remain non-negotiable. Beyond regulatory compliance, every medicine must meet the core test of being safe, effective and accessible, with patient safety acting as the unifying thread across product development, manufacturing and quality systems. In this context, safety was discussed not just as a regulatory requirement, but as a pillar supporting the credibility of the industry itself.

Quality and compliance emerged once again as decisive factors for future growth. The panel noted that being audit-ready at all times is no longer optional, it is a strategic necessity in a globally competitive and highly regulated environment. As regulatory scrutiny intensifies, organisations that embed quality into design, systems and culture will be best positioned to scale responsibly.

Looking ahead, the discussion also highlighted the importance of public-private partnerships in building a skilled, future-ready workforce. From talent development and upskilling to creating innovation-friendly ecosystems, collaboration between industry, academia and government was seen as essential. Particularly in emerging hubs like Vizag, where the foundations for long-term growth are already taking shape.

Building tomorrow's medicines today

As conversations around Pharma 2035 laid out the strategic and policy framework for the decade ahead, the focus naturally shifted to the scientific and technological capabilities that will determine whether those ambitions can be realised. If Indian pharma is to move from value creation to value leadership, advances in drug delivery and manufacturing paradigms will play a defining role.

Speaking on generic complex injections, Gurupyar Reddy, Head - Production, Complex Injections, Dr Reddy's Laboratories, highlighted how the industry's growth trajectory is increasingly tied to its ability to master complexity. He emphasised that advanced drug delivery systems, including NDDS, are no longer optional add-ons but critical enablers of improved therapeutic efficacy, better patient outcomes and long-term differentiation. As regulatory and clinical expectations rise, he noted, capability in complex injectables will be central to the future value of pharmaceutical innovation.

Extending this perspective to the broader evolution of manufacturing, Dr Bikash Kumar Nayak, Plant Head, Aurobindo Pharma, traced the industry's shift from Pharma 4.0 to Pharma 5.0. While automation and digitalisation have transformed efficiency, he argued that the next leap will be defined by precision rather than scale. Leveraging rapid genomics, AI-driven insights and an increasingly connected healthcare ecosystem, Pharma 5.0 represents a move toward truly patient-centric care, where manufacturing, data and



Jyothi Venkata Prasad V, Head – QA API (Site-6), Biocon



Dr Shankar Varaganti, Commercial Marketing Manager, Merck Lifesciences



Vijay Kumar, Regional Manager-South, Sun Teknovation



Gurupyar Reddy, Head-Production Complex Injections, Dr Reddy's Laboratories



Dr Bikash Kumar Nayak, Plant Head, Aurobindo Pharma

clinical outcomes are seamlessly aligned.

Together, these sessions reinforced a central idea echoed throughout the summit: the future of Indian pharma will be shaped by its willingness to embrace complexity, intelligence and precision; not just capacity.

Innovation beyond scale

As the Vizag Pharma Summit 2025 drew to a close, the conversation returned to the question

that had quietly underpinned the day's discussions: what lies beyond generics for Indian pharma? The concluding panel discussion, 'Beyond generics: From Make in India to Innovate in India', brought together leaders across R&D, manufacturing and quality to examine how the industry must reorient itself for long-term relevance.

Moderated by Dr Anil Khile, Deputy Head and Senior Director, R&D, Eisai Pharmaceuticals



L-R: Subba Reddy Arumalla, Associate VP – Cluster Head API Plant Management, Amneal Pharmaceuticals (Moderator); Dr T Pavan Pradeep, CEO, Actimus Biosciences; K V Sreenivasa Babu, VP-Operations, Natco Pharma; Naimish Mishra, Site Quality Assurance Head-FTO11, Dr Reddy's Laboratories



L-R: Deepthi Cherukuri, Head- Global Clinical Development & Biopharmaceutics, Cronus Pharma Specialities (Moderator); Dr Mahendar Velisoju, AVP – Head of R&D, PharmaZell (India) (an Explora company); Ravi Sankar Vankayala, GM-Quality Assurance, Gland Pharma; P Veerabhadra Rao, Head - Quality, Natco Pharma; Sriramulu Bhaskar, Head of Engineering, Aurobindo Pharma



L-R: Dr Anil Khile, Deputy Head & Sr Director, R&D, Eisai Pharmaceuticals India (Moderator); Sita Ram Pottumuttu, Lead-MSAT (FTO-7), Dr Reddy's Laboratories; Ramalingam K, Plant Head-API Manufacturing, Mankind Pharma; Kamutham Siddaiah, Head Quality Assurance, Biocon

India, the panel featured Sita Ram Pottumuttu, Lead, MSAT (FTO-7), Dr Reddy's Laboratories; Ramalingam K, Plant Head, API Manufacturing, Mankind Pharma; and Kamutham Siddaiah, Head, Quality Assurance, Biocon. The discussion centred on how new modalities and emerging therapies are reshaping healthcare and redefining expectations around innovation, speed and patient outcomes.

The panellists were aligned in their view that future growth will not come from scale alone but from the ability to develop innovation-led therapies that address unmet medical needs. As global markets become more competitive and complex, India's next growth curve will depend on how effectively it can translate scientific capability into differentiated, high-value products.

Technology also emerged as a critical enabler in this transition. Digitalisation, AI and automation are already opening new pathways for faster development, smarter manufacturing and data-driven decision-making, accelerating India's innovation potential across the value chain. However, technology without strong systems risks fragmentation rather than progress. Building robust, integrated frameworks for faster drug discovery and development will be essential to maintaining global competitiveness.

Threaded through the discussion was a familiar but uncompromising message: quality must be built in by design. Sustainable innovation requires not only advanced tools and platforms but also a deep-rooted culture of excellence that places quality, compliance and patient safety at the core of every process.

Conclusion

As the summit concluded, the narrative that emerged was clear: Indian pharma's journey from Make in India to Innovate in India is no longer aspirational. It is imperative. The conversations in Vizag demonstrated that the pathways to global excellence are already taking shape.

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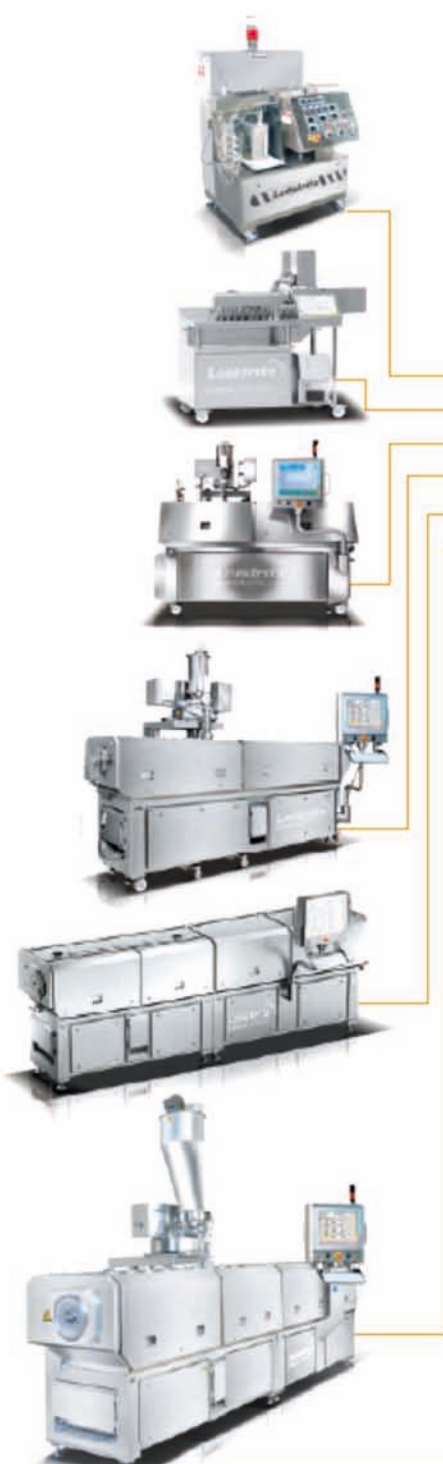
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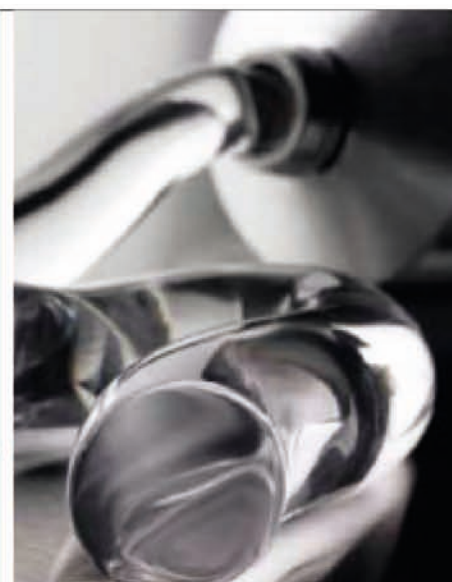
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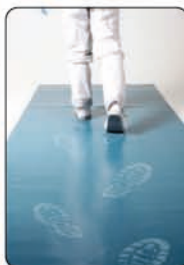
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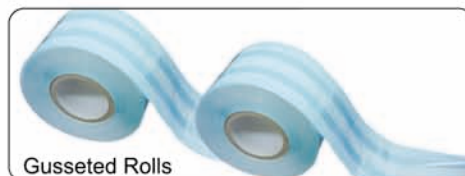
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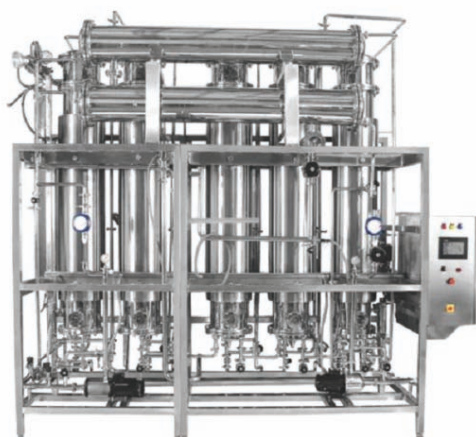
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Future of pharma: Trends, challenges & AI

Industry experts discussed how AI is transforming pharmaceutical R&D, highlighting both the promise and the practical limitations of current technologies

On December 2, 2025, CAS hosted a groundbreaking conference at The Marigold Hotel, Begumpet, Hyderabad, establishing a vibrant hub for knowledge exchange in the pharmaceutical and life sciences sectors. The event drew 82 leading minds from R&D, cheminformatics, and technology, united under the theme “Advance Your Drug Discovery Research with Confidence.”

The highlight was an engaging panel discussion: “Future of Pharma – Navigating Trends, Overcoming Challenges, and Leveraging AI.” Experts shared bold predictions on how AI and data-driven strategies will transform drug discovery, tackling scientific hurdles and accelerating innovation.

The experienced panel, comprised of R&D leaders, IT experts, and industry experts, discussed how AI is transforming pharmaceutical R&D, highlighting both the promise and the practical limitations of current technologies. Participants agreed that AI has delivered clear wins—such as structure prediction, molecular modeling, retrosynthesis planning, and automation of routine tasks—while noting that predictive gaps remain in areas including ADME, toxicology, and translational science. These gaps mean that AI cannot yet replace wet-lab validation or clinical studies; instead, it should augment expert decision-making with a human-in-the-loop approach.

This discussion highlighted the need for high-quality data and curation standards to ensure accuracy in predictions. Curated, AI-ready datasets compatible with AI models, as well as standardized ontologies, and even the requirement of negative results, were described as the essential fuel for reliable AI models. Several concrete examples were discussed to illustrate how AI-assisted predictions provided a solid



From Left to Right, Anand Singh (Moderator, ACSII); Paul Peters (CAS); Dr Arijit Roy (TCS Research); Dr Santosh Patil (Syngene International Ltd.); Dr Santosh Dixit (Persistent System); Dr Sreekanth Ramachandran (PI Health Science Ltd); Dr Sandeep Bharate (CSIR – IICT); Dr Samiron Phukan (Aragen Life Sciences); Yogendra Yadav (Sai Lifesciences Ltd.)



foundation for projects.

Practical applications are emerging fast. Case studies showcased AI-driven yield predictions in manufacturing and multi-parameter optimization in drug design, proving tangible ROI. However, trust and explainability are critical. Scientists must see not just predictions but the “why” behind them. Training teams for AI literacy and integrating AI into workflows—not as a silo—are key to adoption.

Practical deployments were discussed across discovery and manufacturing. In manufacturing, legacy batch production records were digitized (OCR and handwriting recognition) to predict yields and move toward real-time, prescriptive recommendations—always with expert validation. In discovery, AI co-scientists and multi-agent frameworks have been proposed to coordinate specialized agents (such as those in chemistry, biology, and pharmacology) and improve complex workflows, like drug repurposing.

The takeaway? AI is the competitive edge pharma cannot afford to ignore. It promises speed, precision, and cost-efficiency, but demands strategic implementation and human oversight. As one panelist put it, “AI won’t replace scientists—but scientists who don’t embrace AI risk being left behind.”

INTERVIEW

Good pharma-focused developers are now co-designing with GMP/WHO/USFDA consultants from day zero

In a post-pandemic world, pharma real estate has evolved from a cost decision to a strategic one. **Sanjay Rohida**, MD, Aryan Properties, shares how India's pharma companies are rethinking where and how they build their future-ready facilities

How have pharma companies changed the way they plan and choose real estate after the pandemic? What matters most to them now, speed, scalability or sustainability?

After COVID, pharma companies in India have become far more:

- Risk-averse about supply chain disruption as they want redundancy: multiple sites, alternative vendors, and disaster-resilient locations.
- Volume-flexible – facilities that can ramp up quickly for new molecules, vaccines, or contract manufacturing.
- People-centric – better EHS, air quality, and amenities to attract and retain scientific talent.

Speed, scalability and sustainability all being crucial aspects, the focus is equal on these aspects.

What makes India's key pharma hubs like Mumbai, Pune, NCR, Hyderabad and Bengaluru, so attractive for pharma companies today? Are you seeing new smaller hubs coming up beyond these big cities?

Across these clusters, a few common factors have been: Dense pharma + life-science ecosystem, talent + academic linkages, regulatory compliances, road/rail/airport connectivity and export infra.

As the rentals/property prices, base salaries and other administrative expenses are hitting upper circuit month after month, it is quite normal to pick and choose new areas with basic infrastructure ticking all boxes and the same gets developed in a HUB. These



Pharma companies are definitely compelled to look beyond just location and rent as there are many factors such as power quality and reliability including grid stability, backup facilities, power sector norms etc. play a very important role

strategies need to have governmental support and based on that pockets such as Baddi/Solan/Nalagarh (HP), Una, Bharuch/Jambusar/Dahej (Gujarat), Vizag/AMTZ (Andhra Pradesh), Sikkim, Daman, Goa, Indore, Ahmedabad-Vadodara belt.

Pharma is a highly regulated sector. How are developers making sure their facilities meet compliance and audit standards? And how important is regulatory clarity when picking a site?

Good pharma-focused developers are now co-designing with GMP/WHO/USFDA consultants from day zero, focussing on proper zoning of clean/grey/black areas, material and personnel flows to avoid cross-contamination and HVAC that can be validated, pressure cascades, and filtration. This apart, building higher-spec 'base buildings' with Higher floor-to-floor heights, heavier floor loads, robust utilities corridor, pre-planned shafts for process piping and HVAC and keeping/providing shell ready for cleanrooms, labs, or pilot plants.

Pharma sector being highly regularised, the focus is on standardising documentation viz built drawings, MEP schematics, EHS certifications etc which are all very useful during audits.

Regulatory clarity when picking a site is very important.

- Zoning must clearly allow pharma/chemical/life-sciences use with acceptable

norms on effluent, hazardous storage, and emissions. (Red/Orange Category)

- State-FDA, Pollution Control Board (PCB), Drug Controller offices and labs nearby reduce friction and inspection delays.

- Where bulk drug parks or pharma parks exist, common ETPs, CETPs, incineration, and waste handling infrastructure are already approved and monitored is a big plus for clients.

With sustainability and ESG becoming board-level goals, how is this changing pharma's real estate choices? Are companies ready to invest more in green-certified facilities?

Post pandemic, keeping in line with sustainability and ESG becoming board-level goals, the leading Indian pharma companies now publish specific ESG targets for emissions, water, and waste keeping board fully aware of pre requisites and ultimate goals. Global Big Pharma operating in India must align with global net-zero or carbon-reduction commitments, which directly affects real-estate specs. Hence the preference has largely shifted and concentrated upon green-certified buildings (IGBC, LEED) or at least "green-ready" shells with stronger emphasis given on renewable energy access (rooftop solar, open access RE), water efficiency and recycling (STPs, ETPs, rainwater harvesting) and Low-VOC materials and better indoor environmental quality.

Are they ready to pay more?

Large MNCs and top-tier Indian pharma: Yes, within reason. Typically willing to pay a premium if there is a clear OPEX saving (lower energy/water bill), and the building helps with global ESG scores and investor perception. However;

Mid-tier and smaller players being more price-sensitive are reluctant to pay more though they seek all utilities and basic certifications, but not if it pushes rents above market.

When evaluating a site, what should pharma companies look at beyond just location and rent? How can they understand the real cost of running a facility, including power, infrastructure, and maintenance?

The major factors while evaluating site, pharma companies are definitely compelled to look beyond just location and rent as there are many factors such as power quality and reliability including grid stability, backup facilities, power sector norms etc. play a very important role. Utilities and infrastructure such as water

(quantity and quality), ETP and CETP connectivity, waste disposal tie ups etc are given equal or more importance from the long term perspective. Arresting overhead expenses for running/operating facility is the mantra, no company can ever ignore. Overheads, if uncontrolled or not monitored can really cause significant losses especially while looking after housing for workers, commute options, social infrastructure for employee families such as schools, hospitals, markets etc.

Certain hidden opex such as maintaining HVAC, cleanroom systems, annual testing/calibration, filter replacements, statutory compliances, tech compliances, real time pollution tracking etc being critical, are looked into with extreme care and vigilance ensuring no down time affects the production or processes.

How is technology like IoT monitoring, automation, and smart compliance tools changing the way modern pharma facilities are designed and operated?

In this era of modernisation,

the pharma facilities increasingly look into and prioritise :

IoT-based environmental monitoring

- Real-time tracking of temperature, humidity, differential pressure, particulate count in cleanrooms.

- Auto-alerts when parameters drift, creating a continuous audit trail.

BMS/IBMS integration

- HVAC, access control, fire, lighting, DG, and utilities managed through a central Building Management System; easier to demonstrate control to regulators.

Smart compliance tools

- Digital logbooks, e-BMR/e-BPR (electronic batch and production records), validation data directly linked to equipment sensors.

Impact on real estate design

- Need for robust IT backbone – fibre, data rooms, redundancy.

- Space for control rooms, racks, and sensor networks.

- Greater coordination between MEP designers, IT, and process engineers from concept stage.

How are government policies and incentives

influencing the growth of pharma infrastructure across India?

Various state governments have been proactive in getting production facilities in their respective states for the obvious reason of regional growth and certain schemes floated by the state governments has provided big boom to pharma sector, especially after 2021

● Production Linked

Incentive (PLI) schemes for APIs, KSMs, and key drugs – incentivise domestic manufacturing and encourage new greenfield capacity.

- **Bulk Drug Parks scheme** – central grants for common infra (CETP, utilities, testing, etc.) in three big parks (AP, Gujarat, HP). These parks are now in advanced development stages and attracting significant private investment.

- **State-level industrial policies** – concessional land, stamp duty rebates, power subsidies, fast-track approvals for pharma/biotech in Telangana, Gujarat, HP, AP, Maharashtra, etc.

- **Environmental regulations and ESG push** – stricter norms from MoEFCC, CPCB, and state PCBs are

indirectly pushing companies into well-managed pharma parks rather than isolated standalone plants.

Finally, what do you think the 'ideal pharma facility' of the future will look like?

And how can real estate partners help make that vision a reality?

Pharma companies have huge space requirements and real estate partners with bulk land availability goes hand in hand. To be future ready, now the need is campus-style, multi-tenant, tech-enabled life-sciences park with modular, flexible blocks, high-spec utilities zero-liquid discharge or near-ZLD, digital integration, employee-centric, clustered with ecosystem partners government and ecosystem connector. The big real estate players can tie up with the state governments to acquire big land parcels close to growing hubs of major cities (umbrella areas) and start designing big size campuses while the government speeds up infra work including but not limiting to roads, water, electricity, drainage systems etc., prioritising strategic locations for future ready growth patterns.

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Leveraging Microfluidic Technology for mRNA-LNP Manufacturing

Over the past five years, messenger RNA (mRNA) therapeutics have undergone a rapid transition from experimental tools to powerful, life-saving medicines. From vaccines to cancer immunotherapies, mRNA offers the ability to instruct our own cells to produce therapeutic proteins on demand.

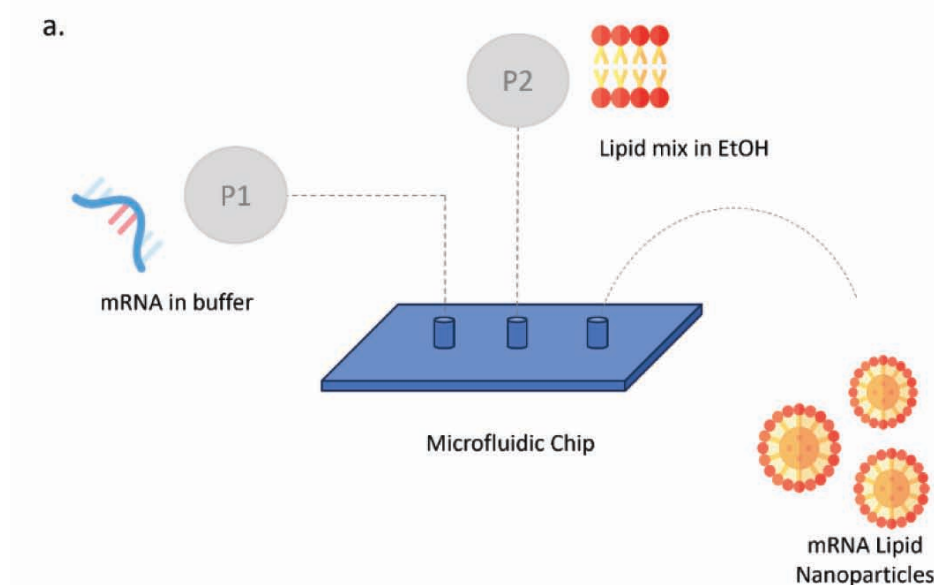
Yet, behind this biological revolution lies a critical engineering challenge – how to deliver the fragile mRNA safely, efficiently, and reproducibly into cells. The answer lies in lipid nanoparticles (LNPs), tiny lipid-based carriers that protect mRNA molecules ensuring efficient cellular uptake. However, as the field races from lab-scale discovery to global commercialization, traditional manufacturing methods for LNPs are proving to be a bottleneck. The next leap forward in scalable, precise, and reproducible LNP production is being driven by microfluidic technology.

Why LNPs Matter?

LNPs are the unsung heroes of the mRNA revolution. They form protective lipid shells around mRNA strands, shielding them from degradation and facilitating delivery into target cells. Their composition; typically, ionizable lipids, cholesterol, phospholipids, and PEG-lipids, must be carefully balanced to ensure stability, efficiency, and biocompatibility (1). Even small variations in formulation can significantly impact potency and safety.

Microfluidics: Precision at the Microscale

Microfluidics, at its core, enables fluids to be precisely manipulated in microscale channels. In the context of LNP manufacturing, traditional bulk methods like ethanol injection or vortexing often lead to inconsistent batches and poor control of particle size (2). To over-



come this, microfluidic systems operate in a laminar regime where diffusion and hydrodynamic focusing govern assembly (3,4) and enable rapid, controlled mixing of lipid and aqueous phases at defined flow rates and ratios. This precise control makes microfluidics ideal for both process optimization and industrial-scale reproducibility, ensuring superior process control, optimization, and scalable reproducibility.

From Lab to Manufacturing Floor

Scaling microfluidic processes from lab to production introduces key challenges, mainly scalability and process robustness. Because microfluidic channels are very small, therapeutic-scale output requires either multiple parallel channels or high-throughput systems. Uniform flow across all channels is crucial to achieve consistent particle size, encapsulation, and reproducibility, as even small deviations can affect nanoparticle formation.

Despite this, microfluidics provides superior precision over bulk mixing, enabling highly uniform LNPs and scalable operation by simply increas-

ing channel numbers. Continuous processing further reduces waste, downtime, and cost.

Across the microfluidic ecosystem, automated platforms now accelerate R&D by enabling rapid, low-volume optimization with clear routes to pilot-scale translation.

One such system is nanomake-L™, a fully automated platform for reproducible nanoparticle production under tightly controlled flow conditions. With independent precursor pumping, programmable flow control, and a reusable chip, it maintains critical parameters like TFR and FRR, supports mRNA-LNPs and other Nano formulations, and delivers narrow size distributions with high encapsulation efficiency. This makes nanomake-L™ an effective bridge between early-stage formulation development and scalable manufacturing.

Local Manufacturing and Adoption

The relevance of an automated microfluidic platform designed for LNP-mRNA production becomes even more pronounced in the context of local manufacturing and technology adop-

tion. Many existing microfluidic platforms are imported, expensive, or difficult to integrate into domestic bioproduction setups. Developing indigenous systems can address these barriers by offering affordable, reliable solutions for mRNA-LNP manufacturing. These platforms must support both research-scale work and pilot production, helping transition toward GMP workflows.

The Road Ahead

As mRNA therapeutics expand, the need for precise and scalable LNP manufacturing becomes essential. Microfluidics enables precise control, highly uniform, and reproducible production. With ongoing improvements in device design and automation, it is set to become a standard approach for reliable mRNA-LNP manufacturing. Platforms like nanomake-L™ showcase how advanced microfluidic engineering can convert scientific innovation into practical, scalable manufacturing solutions, driving pharmaceutical progress and improving access to next-generation therapeutics.

Suggested Artwork

Schematic representation of mRNA-LNP synthesis via a microfluidic chip. mRNA (Pump 1) and lipid mix (Pump 2) are co-injected, forming mRNA-loaded LNPs. (b) Simplified microchannel geometry with two inlets and one outlet for nanoparticle collection.

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Gandhi Automations presents multi-composites, high-performance door PRIME NEO for clean environments

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When it comes to pharmaceutical facilities and laboratories, clean rooms' hygiene and protection from environmental contamination are the most important factors to consider. Gandhi Automation's PRIME NEO High Speed Doors are designed to provide superior sealing and resistance to pressure differences for clean rooms. And the added advantage is that it is absolutely washable.

PRIME NEO High Speed Doors assures:

● Minimized contamination:

The reinforced polymer material is smooth-surfaced and joint-free. The door structure has been designed with full accessibility for water cleaning. Contamination risks are very minimal, making it fully compliant with the requirements of clean environments.

● Just-in-time opening cycle:

Its smart design and German technology cause no delay in operation. Opening and closing in time reduces exposure time to a minimum, resulting in a reduction in energy costs and the risk of airborne contamination.

● Sealing and resistance to pressure differences:

The door has a flexible curtain with horizontal FRP stiffeners guided by vertical guides. Pressure is evenly distributed over the whole curtain, pushing it against the guides, giving a perfect seal. This design allows the door to operate even under pressure differences up to 50 Pa in a controlled room environment.

● **Safety:** PRIME NEO reduces the risk of accidents and damage. The free, flexible, and soft bottom edge minimizes hitting impact. The radar detector and inbuilt photocells reopen the door at the slightest impact.



The toughness of the side guides and their ability to absorb an impact avoid high repair costs. PRIME NEO is anti-corrosion and paint-free, which ensures durability in corrosive and aggressive environments

● **Windows:** The transparent material allows people to see coming traffic. Long-term transparency is assured, as the material is anti-fatigue PVC fabric.

● **Multi-composite structure:** The toughness of the side guides and their ability to absorb an impact avoid high repair costs. PRIME NEO is anti-corrosion and paint-free, which ensures durability in corrosive

and aggressive environments.

● **Auto-reset:** The door is equipped with auto-reset technology. In the event of an accidental crash, the curtain sets itself again. This unique system avoids time loss and reduces the risk of high repair costs.

To know more about PRIME NEO, write us at sales@geapl.com or call 022 6672 0200/0300

PRUV® -The original Sodium Stearyl Fumarate

JRS Pharma's PRUV® is the original sodium stearyl fumarate (SSF) introduced in the market over 20 years ago

Pharma lubricants are the inactive agents i.e. excipients added into tablet and capsule formulations in a very small quantity (usually 0.25-5.0 % w/w) to improve the processing properties of formulations. They decrease the friction at the interface between tablet's surface and the die wall during the compression and ejection phase of the tableting so that the wear on punches and dies are reduced. They prevent sticking of tablets to punch faces as well as sticking of capsules to dosators and tamping pins. In terms of powder flow, lubricants can improve the flowability of blends and aid unit operations^[1].

A good balance between hydrophobic and hydrophilic moieties in PRUV® (Sodium Stearyl Fumarate) makes it an ideal lubricant^[2].

Common lubricants used in drug development

Most of the lubricants used in the pharma processes are boundary lubricants. Certainly, metallic salts of fatty acids such as magnesium stearate; stearic acid and sodium salt of fatty acid such as sodium stearyl fumarate are the most common ones.

A. Fatty acid esters: Fatty acid esters, including glyceride esters (glyceryl monostearate, glyceryl tribehenate, and glyceryl dibehenate), sugar esters (sorbitan monostearate and sucrose monopalmitate) and alcohol ester of stearic alcohol with fumaric acid, including sodium stearyl fumarate are often used as lubricants. In particular, sodium stearyl fumarate and glyceryl dibehenate are effective lubricants to replace magnesium stearate when the latter hampers dissolution and has chemical incompatibility issues. Relative to magnesium stearate, sodium stearyl fumarate has similar lubrication efficiency with a higher optimal concentration (around 2%,

w/w). In addition, the use of sodium stearyl fumarate does not affect compressibility^[1].

B. Metallic salts of fatty acids: Use of the metallic salts of fatty acids as lubricants has a long history in the pharma industry and they are still the most dominant class of lubricants. Magnesium stearate, calcium stearate and zinc stearate are the three common metallic salts of fatty acids used^[1].

C. Fatty acids: Fatty acids are also common lubricants used in the pharma industry with stearic acid as the most popular one. Chemically, stearic acid is a straight-chain saturated monobasic acid found in animal fats and in varying degrees in cotton seed, corn and coco. The commercial material of stearic acid has other minor fatty acid constituents such as myristic acid and palmitic acid^[1].

D. Inorganic materials and polymers: Inorganic materials and polymers are also used as lubricants when magnesium stearate cannot be used. In terms of inorganic materials, talc (a hydrated magnesium silicate ($\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$), is often used as a lubricant or as a glidant in formulations. Talc provides some essential lubricity for pharma operations because of its hydrophobicity and weakly bonded sheet structure^{[1][6]}.

Mechanism of lubrication:

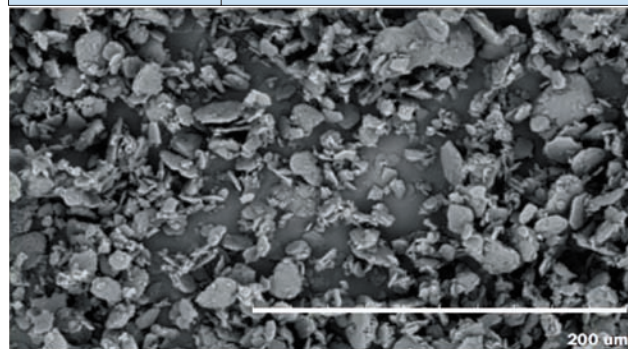
There are four lubrication mechanisms:^[1]

1. Hydrodynamic lubrication,

2. Elasto-hydrodynamic lubrication,
3. Mixed lubrication, and
4. Boundary lubrication.

As their names imply, the first three mechanisms are related to the usage of liquid lubricants to some extent. In the pharma industry, boundary lubrication is the most common mechanism functioning in unit operations.

Typical properties of PRUV®: ^[5]	
pH	About 8.5 (10% aqueous solution at 90°C)
Saponification value	142.2-146.0
Moisture	<5.0%
Solubility	0.5mg/100 ml at 25°C/
	10 g/100 ml at 80°C
	20 g/100 ml at 90°C
Melting point	224-245°C



SEM Picture of PRUV®

For boundary lubrication, a lubricant typically forms layers/film between surfaces or at interfaces to reduce friction, where the penetration of the lubricant into surface asperities

occurs. Structurally, the lubricants commonly used for boundary lubrication are long chain molecules with active end-groups. The typical end-groups include:

1. -OH (long chain alcohol);
2. -NH₂ (long chain amine);
3. -COOH (long chain fatty acids); and
4. Metal ions such as Mg²⁺.

Considerations for selecting a lubricant

There are many factors to be considered for selecting an appropriate lubricant for preparing solid dosage forms, including low shear strength, being able to form a durable layer covering the surface/particles, non-toxic, chemically compatible with APIs and other components in the formulation, low batch-to-batch variability, and

consideration when selecting a lubricant because both of these two parameters greatly affect the performance of pharma products and processes.^{[1][6]}

After understanding what are lubricants, commonly used lubricants in pharma formulation, mechanism of lubricants and considerations for selecting the best lubricant, let's focus on more detail regarding PRUV® (Sodium Stearyl Fumarate) lubricant from JRS Pharma.

PRUV® (Sodium Stearyl Fumarate) characteristics:

- ◆ Highly efficient lubricant and anti-adherent
- ◆ More water-soluble than Magnesium stearate
- ◆ Well-defined particle size and specific surface area
- ◆ High melting point (230°C)
- ◆ Lamellar structure
- ◆ High purity and batch-to-batch consistency

How PRUV® works?

- ◆ PRUV® reduces inter-particle friction during tablet manufacturing while acting as a boundary lubricant in the formulation.
- ◆ PRUV® facilitates lubrication during blending through shearing.
- ◆ PRUV® is more hydrophilic, dissolution is not compromised wherever facing dissolution issue with magnesium stearate.
- ◆ PRUV® goes beyond lubrication and it also accelerates dissolution.

Applications of PRUV®

PRUV® can be used in dry granulation as well as wet granulation technology to avoid sticking of intra-granular blend to roller or RMG wall. PRUV® can also be used in capsule dosage by reducing friction between the particles. PRUV® is a perfect lubricant for high-speed tableting/continuous manufacturing because it is less sensitive to heat. PRUV® can also be used in hot melt

extrusion due to its higher melting point (224-245°C).

Following are the case studies of PRUV® to evaluate the effect on physio-chemical properties on tablet dosage form^[4].

In this study, the effect of different lubricants on Acetaminophen formulation was studied. Acetaminophen API blended with PROSOLV SMCC HD 90 for 15 min and afterwards blended with sieved lubricants for three minutes. Different lubricants like PRUV,

Magnesium stearate, stearic acid and sodium stearate are used. Tablets were compressed to 800 mg weight. tablet.

Magnesium stearate is the most widely used lubricant in the pharma industry. Hence, PRUV® is compared with Magnesium stearate in the following section:

PRUV® helps to avoid API incompatibilities and enhances API stability. With a few exceptions, PRUV® can be applied to any formulation for lubrication,

particularly those in which API stability or tablet taste is compromised due to magnesium stearate. Magnesium cation (Mg²⁺) is electrophilic, it interacts with the free electrons of an API and forms insoluble salts. This is one of the many causes of API incompatibility with magnesium stearate.^[4]

Electrostatic Properties: Magnesium stearate shows higher voltage and retention time than PRUV®. Low electric charge and retention improve lubricant dispersion during blending. As a result, PRUV® due to its low voltage and retention can be considered a superior lubricant with improved lubricant uniformity.

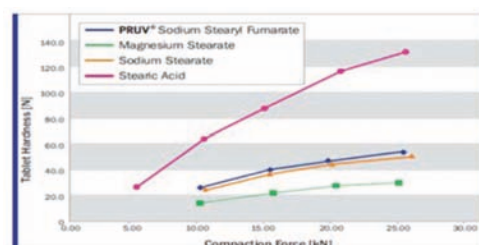
PRUV® was carefully designed to consistently deliver the following functional characteristics:

Ingredients	Quantity (%)	Quantity (mg/unit)
Acetaminophen	62.5%	500 mg
PROSOLV® SMCC HD 90	35.5%	248 mg
Lubricant	2.0%	16 mg
Total	100.0%	800 mg

LUBRICANTS: PRUV® (SODIUM STEARYL FUMARATE), MAGNESIUM STEARATE, STEARIC ACID, SODIUM STEARATE)

Tablet Hardness/Compactability

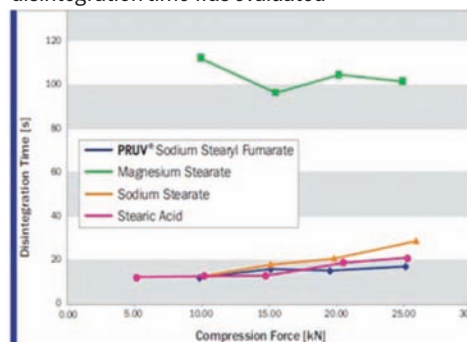
In this study, the effect of different lubricant on tablet hardness was evaluated



Observation: The kind of lubricant used had a significant influence on the hardness of the tablets. While tablet lubricated with stearic acid resulted in the highest tablet hardness, those made from magnesium stearate exhibited the lowest hardness. Tablets made from PRUV show intermediate hardness.

Disintegration time

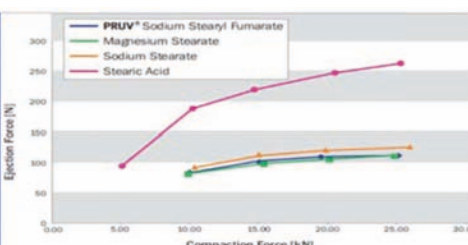
In this study, the effect of different lubricant on disintegration time was evaluated



Observation: Tablets lubricated with magnesium stearate needed by far the longest time for disintegration. All other tablets were found to have disintegration times in the same range

Lubrication efficiency

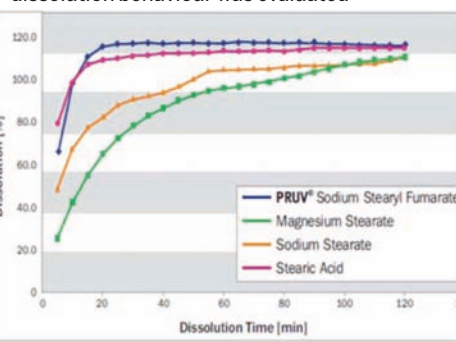
In this study, the effect of lubrication efficiency of different lubricants was evaluated



Observation: As for compactability, a similar trend observed in the ejection forces. The tablets lubricated with stearic acid showed the highest ejection forces, while magnesium stearate was found on the lower end of the ejection force spectrum. Tablets made with PRUV exhibited the same low ejection forces as compared to magnesium stearate.

Dissolution behaviour

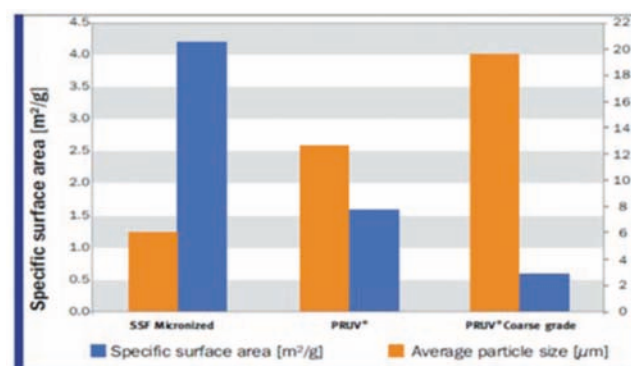
In this study, the effect of different lubricants on dissolution behaviour was evaluated



Observation: Tablets containing magnesium stearate showed by far the slowest dissolution rates. Sodium stearate and stearic acid-lubricated tablets released the API much faster. The faster drug release was observed for tablets lubricated with PRUV®

Grade	D(50)	BET
SSF Micronized	7.6	4.2 m ² /g
PRUV®	13.6	1.6 m ² /g
PRUV® CG (Coarse Grade)	20.4	0.6 m ² /g

PARTICLE SIZE AND SPECIFIC SURFACE AREA FOR DIFFERENT GRADES OF SSF^[4]



- ◆ Tight particle size distribution
- ◆ Well-defined specific surface area
- ◆ Reproducible particle morphology

The outstanding performance of PRUV® is based on its well-controlled particle size and shape. Following studies show the effect of deviating from the ideal values.

Conclusion:

Beyond tablet lubrication properties of PRUV®:

It shows:

- ◆ Improved API stability
- ◆ Superior blending properties
- ◆ Faster disintegration
- ◆ Faster dissolution times

The choice of lubricant can influence the quality of the tablets as well as the dissolution rates. Since APIs tend to be less water-soluble and difficult to compress, choosing the right lubricants continues to become an even more important task.

Most commonly available lubricants are very hydrophobic and thus increase dissolution times significantly. In such cases, a less hydrophobic lubricant can help to decrease the dissolution times as well as increase the API release.

PRUV® Sodium Stearyl Fumarate complies with Ph.Eur., NF and JPE. It has the ideal particle size and specific surface area to offer a perfect balance between all functionality

aspects. It is the preferred choice over magnesium stearate in terms of improving disintegration time and dissolution.

Furthermore, different particle sizes are available, which help to fine tune tablet formulation resulting in the desired dissolution profiles.

Regulatory status of PRUV®:

- ◆ Ph.Eur., NF, JPE, GRAS status
- ◆ C-DMF is available for PRUV®
- ◆ Non-animal origin
- ◆ BSE/TSE-free
- ◆ GMO-free
- ◆ OVI-free (USP<467>) and conforms to the residual solvents requirement of Ph.Eur.(5.4) and USP <467>
- ◆ QBD dossier available
- ◆ Elemental impurity statement available

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