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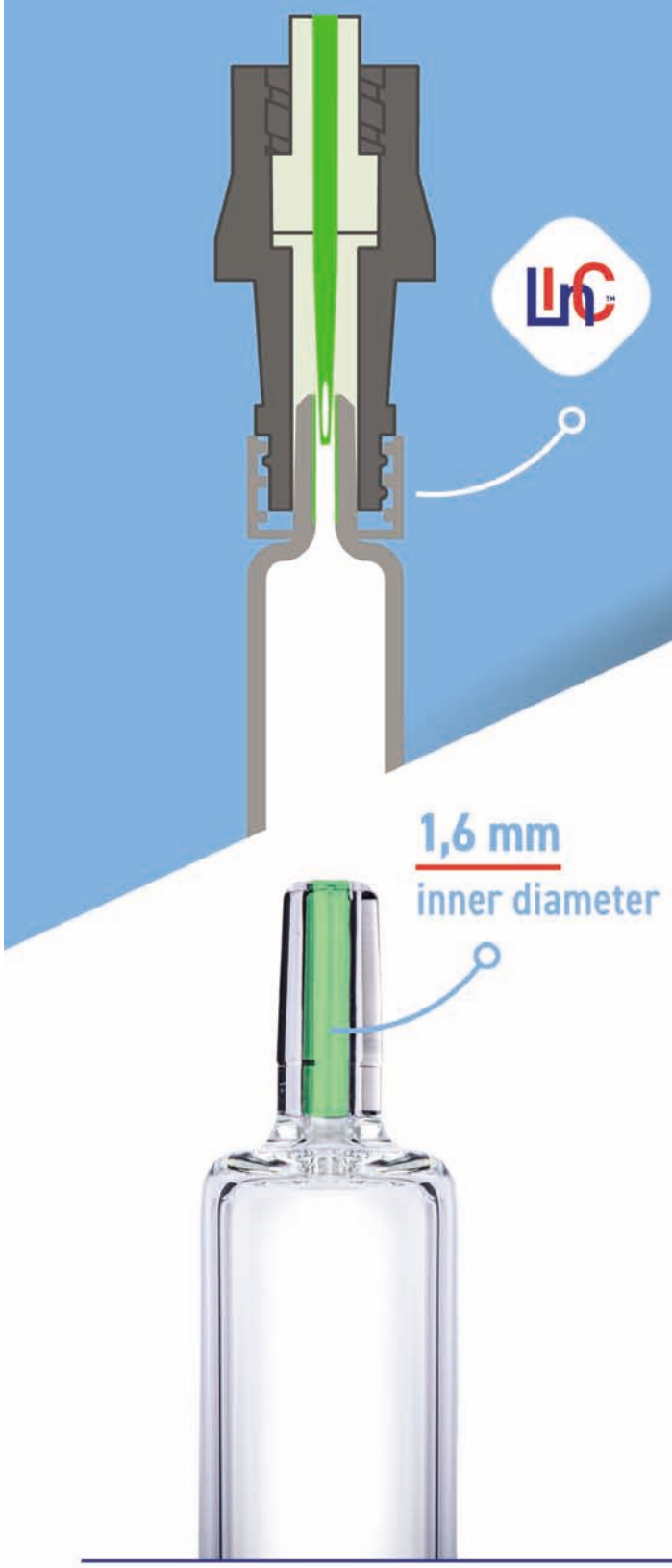

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Post event

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NAVIGATING A VUCA WORLD

From supply disruptions to rising operational uncertainty, geopolitics is reshaping the pharma landscape. Experts discuss what it will take for organisations to stay resilient and future-ready

+

Interviews

Sarvesh Chaubey
Founder,
National Accreditation Body for Cold Chain Management

Amit Patni
Founder,
Raay Neo Pharma

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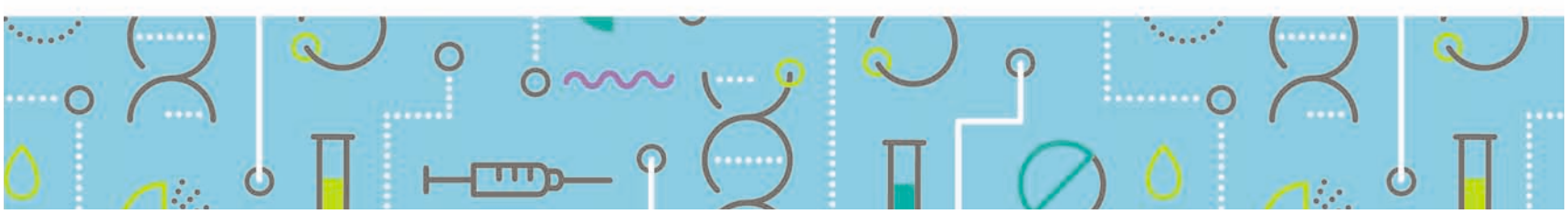

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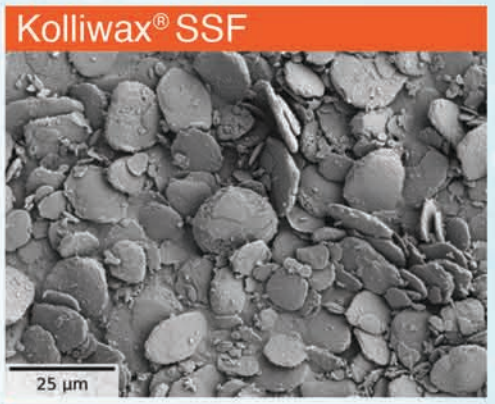

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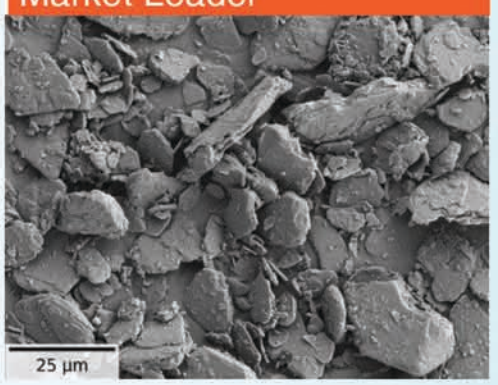

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Editor: Viveka Roychowdhury.* (Editorial & Administrative Offices: Mafatlal Centre, 7th floor, Ramnath Goenka Marg, Nariman Point, Mumbai 400021)

India Pharma's new resilience mantras

Despite near-term uncertainties related to US tariffs and increased input/logistic cost led by geopolitical factors, a May 19 analysis from India Ratings and Research (Ind-Ra) forecasts that demand visibility for India-based contract development manufacturing organisations (CDMO)/contract research and development organisations (CRDMO) remains strong.

While revenue growth for the sector was impacted during FY26, led by destocking issues and molecule attrition, new order wins in late-stage pipelines improved growth visibility for the near to medium term. Ind-Ra predicts that high capex intensity will continue among CDMO/CRDMOs, with the balance sheet set to improve in FY26.

For FY27, Ind-Ra believes the credit metrics of Indian CDMO/CRDMO companies will remain comfortable, even though there may be some near-term margin pressure in 1HFY27 due to higher logistics and input costs amid geopolitical uncertainties, although operating leverage should provide partial offsets.

"We see FY27 as a year of operational harvesting, despite accelerated capex spend for the CDMO/CRDMO sector. This is in view of firm order visibility, building momentum in newer modalities including biologics, and the capacity added over the past two years that will translate into higher utilisation without compromising balance-sheet strength. CDMO/CRDMO are increasingly calling out investments into Artificial Intelligence (AI) to improve productivity especially on the discovery side," says Nishith Sanghvi, Director, Ind-Ra.

In fact all experts who spoke to us for our cover story in the June 2026 Express Pharma edition, seem to treat geopolitical disruptions as the new normal. Finetuning supply chain resilience, manufacturing fluidity, etc was triggered during the COVD pandemic and continues to this day, displaying agility to adapt.

In fact, the irony is that these geopolitical flashpoints have revealed new opportunities. And while finance heads are closely monitoring spends and calling for sharper prioritisation of investments, risk mitigation and growth acceleration, they are also not shy to take bold bets on new therapy areas, to explore new geographies etc. The trick will be to find the right balance between resilience and expansion. Both larger pharma enterprises and smaller promoter-driven entities are playing for the long term, balancing near-term financial prudence while laying the foundation for measured, even aggressive, future bets.

India's pharma supply chains are being forced to rethink resilience, adapt to disruption, and prepare for a far more unpredictable global environment, moving from cost optimisation to continuity planning. Supply chain resilience has become a competitive advantage, as will quality compliance.

To compound matters, pharma quality heads are dealing with increased regulatory scrutiny even as they are forced to balance rising compliance costs with operational efficiency.

As geopolitical disruptions, increasing ESG pressures and shifting supply chains become the new normal, Indian pharma companies are balancing resilience, compliance and growth

Pharma manufacturing leaders have exchanged cost-based, just-in-time schedules for just-in-case scenario planning. Companies are increasing inventories, rationalising that a shutdown due to lack of materials is more costly than inventory cost.

ESG compliance is an additional pressure on India's pharma sectors, especially exporters. ICRA ESG Ratings' latest report on the sustainability landscape of India's pharmaceutical sector points out that with frameworks like the EU's CSRD and the UK NHS's net-zero procurement requirements raising the bar globally, Indian pharma exporters face growing pressure to decarbonise faster, improve supply chain transparency, and build more robust governance structures.

The good news is that approximately 83 per cent of pharma companies in India have adopted Zero Liquid Discharge (ZLD) systems, while the sector's renewable energy share has increased to 25 per cent in FY2025 from 17 per cent in FY2023. API manufacturers carry the heaviest environmental burden, with high energy consumption, water use, and hazardous waste generation stemming from complex, multi-step chemical synthesis. Formulation players sit at the other end of the spectrum, with lower emission and waste intensity. Integrated companies strike the best balance, benefiting from scale, operational efficiency, and more mature ESG frameworks. Waste management remains a critical ESG concern, given the structurally high hazardous waste share (~67 per cent in APIs) and constraints on recycling, underscoring the need for stronger circularity and advanced treatment systems.

The not-so-good news is that while sustainability governance is gaining increasing traction, only around 35 per cent of companies have dedicated ESG committees, while 59 per cent have established formal emission reduction targets.

As ICRA ESG Ratings' Chief Ratings Officer Sheetal Sharad points out, "API manufacturers continue to face structural challenges related to energy intensity and hazardous waste, and governance frameworks across the sector remain at an evolving stage. At the same time, global customers are increasingly positioning ESG as a core procurement criterion rather than a compliance exercise. In this context, continued focus on decarbonisation, improved Scope 3 visibility, and the strengthening of governance frameworks will be critical for Indian pharma companies to enhance competitiveness and sustain export growth over the long term."

All in all, a perfect storm is brewing. India's pharma leaders seem primed to ride it out, by adapting strategies in real time, investing for the future and making compliance a competitive advantage.

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The regulatory landscape in India is becoming more structured and globally aligned

Raay Neo Pharma has officially unveiled its operations with the aim to contribute to quality healthcare for all Indians. The company will be introducing its range of more than 90 formulations in both acute and specialised therapy segments, along with promising pipeline of novel formulations under development. **Amit Patni,** Founder, Raay Neo Pharma discusses the company's market strategy, therapeutic focus areas, quality and compliance framework, affordability approach, and investments in indigenous R&D, in an interview with **Kalyani Sharma**

Raay Neo Pharma has entered a competitive branded generics market. How does the company plan to differentiate itself in terms of quality, portfolio or market approach?

The branded generics space in India is undoubtedly crowded. However, it is also deeply fragmented, which creates room for disciplined, quality-led players to build differentiated positions. At Raay Neo Pharma, our approach is anchored in a simple principle: consistency in quality, clarity in portfolio strategy, and credibility in execution.

We are not attempting to build a broad, undifferentiated basket of products. Instead, we are focusing on select therapy areas where prescribing behaviour is driven by trust and clinical outcomes rather than just price. This allows us to invest more deeply in formulation quality, stability, and physician engagement. Our portfolio decisions are deliberate, not opportunistic.

The go-to-market model also holds prime significance for us. We are consciously building a system that prioritises long-term relationships with healthcare professionals, supported by reliable supply chains and predictable product performance. In a market where variability often exists, reliability itself becomes a differentiator.

With a portfolio spanning acute and specialty therapies, what role does data, epidemiology and unmet clinical need play in guiding your therapeutic focus areas?

Our portfolio strategy is powered by a combination of epidemiological data, prescribing trends, and a clear understanding of gaps in patient access. India's disease burden is evolving, with a steady rise in chronic and lifestyle-related conditions alongside persistent acute care needs.

We closely study disease prevalence patterns and regional variations to identify where interventions can be most meaningful. This is complemented by insights from clinicians, which often reveal nuances that data alone cannot capture. The objective is to align our product pipeline with areas where there is both clinical relevance and a tangible gap in treatment accessibility or affordability.

In specialty therapies, the approach becomes even more targeted. Here, we are guided by unmet need and the potential to improve treatment adherence or outcomes through better formulations. The idea is not to chase scale immediately, but to build depth and credibility in chosen segments.

Raay Neo Pharma follows a model combining branded formulations with manufacturing partnerships. How do you ensure regulatory consistency, quality assurance, and traceability across this ecosystem?

A partnership-led manufacturing model requires strong governance frameworks, and that is where we have invested considerable effort from the outset. Our focus has been on building a tightly controlled ecosystem rather than a loosely connected vendor network.

We work with a curated set of manufacturing partners who meet stringent regulatory and quality benchmarks. Each facility undergoes a detailed qualification process, and we maintain ongoing oversight through audits, process validations, and batch-level monitoring. Quality is not treated as a checkpoint; it is embedded into every stage of the lifecycle.

Traceability is another critical pillar. We have implemented systems that allow end-to-end visibility, from raw material sourcing to finished product distribution. This ensures that we are not only compliant with current regulations but are also prepared for increasing expectations around transparency and accountability in the pharma supply chain.

In an evolving regulatory environment for pharma in India, how is the company aligning its quality, compliance, and approval processes with current and anticipated policy frameworks?

The regulatory landscape in India is becoming more structured and globally aligned, particularly in areas such as quality standards, documentation, and pharmacovigilance. We see this as a positive shift, as it raises the overall bar for the industry.

At Raay Neo Pharma, we have taken a forward-looking approach to compliance. Our internal processes are designed not just to meet existing requirements but to anticipate the direction in which regulations are

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evolving. This includes strengthening documentation practices, enhancing quality control protocols, and ensuring that our partners adhere to the same standards.

We also maintain continuous engagement with regulatory developments, both at the central and state levels. The idea is to remain agile without compromising on scientific rigor. In a sector where trust is fundamental, compliance is not just a requirement but a core business imperative.

As the government continues to emphasise affordable healthcare and domestic manufacturing, how does your pricing and sourcing strategy align with broader policy priorities such as access and self-reliance?

Affordability and accessibility are central to the long-term sustainability of the pharma sector in India. Our pricing strategy is designed to balance commercial viability with the need to make therapies accessible to a wider patient base.

We are conscious of the role that branded generics can play in bridging the gap between innovation and affordability. By optimising our cost structures through efficient sourcing and manufacturing partnerships, we are able to offer competitively priced products without compromising on quality.

On the sourcing side, there is a clear emphasis on strengthening domestic capabilities. Wherever feasible, we prioritise local sourcing to align with the broader push for self-reliance. This not only supports national priorities but also enhances supply chain resilience, which has proven increasingly important in recent years.

The company has indicated investments in indigenous R&D. Could you elaborate on the focus areas within your pipeline and how you see innovation evolving in the branded generics space?

Innovation in the branded generics space is often misunderstood as being limited, but in reality, it is evolving in meaningful ways. At Raay Neo Pharma, our R&D focus revolves around improving formulations, enhancing bioavailability, and developing differentiated delivery mechanisms that can positively impact patient outcomes.

We are particularly interested in areas where incremental innovation can lead to better adherence or reduced side effects. This includes modified-release formulations and combinations that simplify treatment regimens. The goal is to make existing therapies more effective and patient-friendly.

Over time, we see branded generics moving towards a more value-driven model, where differentiation is built on clinical relevance and patient experience rather than just branding. Our R&D investments are aligned with this shift, with an emphasis on building capabilities that can effectively support sustained innovation within this segment.

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Future will belong to collaborative and implementation-focused ecosystems

As India's pharma cold chain industry evolves to support biologics, vaccines and other temperature-sensitive therapies, the focus is shifting toward compliance, digitalisation and workforce competency. **Sarvesh Chaubey,** Founder, National Accreditation Body for Cold Chain Management (NAB-CCM), shares insights on the sector's key challenges and the importance of building a more integrated and resilient cold chain ecosystem, with **Swati Rana**

How do you see the pharma cold chain industry evolving in India over the next decade?
India's pharma cold chain industry is entering a transformative phase, driven by biologics, vaccines, specialty drugs, cell and gene therapies, and increasing global regulatory expectations. Over the next decade, I believe the industry will move from infrastructure-focused growth to ecosystem-driven growth, where compliance, digitalisation, workforce competency, traceability and sustainability become equally important. India has the potential to emerge as a global leader in GDP-compliant, temperature-sensitive supply chains if industry, academia and regulatory bodies collaborate more closely.

What role does the National Accreditation Body for Cold Chain Management (NAB-CCM) play in strengthening the pharma supply chain ecosystem?
NAB-CCM has been conceptualised as an industry-focused platform aimed at strengthening cold chain awareness, workforce competency, implementation-focused discussions, and collaboration between industry, academia and regulatory stakeholders. Our objective is to encourage practical dialogue around GDP implementation, operational excellence, sustainability and future-ready cold chain ecosystems. Through initiatives such as industry roundtables, training frameworks and knowledge-sharing platforms, we aim to contribute to building a more resilient and compliant cold chain ecosystem in India.

What are the biggest risks facing temperature-sensitive pharma logistics today?
The biggest risks today are not only infrastructural but also operational. Temperature excursions, inadequate workforce training, inconsistent monitoring practices, documentation gaps, lack of accountability systems, and fragmented implementation of GDP principles continue to challenge the sector. In many cases, cold chain failures occur because of execution gaps rather than the absence of SOPs. As products become more sensitive and valuable, even minor deviations can significantly impact patient safety and product efficacy.

What are the operational challenges in maintaining cold chain integrity across India's diverse geography?
India's geographical diversity creates multiple operational complexities, including extreme climatic conditions, infrastructure variability, transportation delays, power reliability issues, and uneven cold chain awareness across regions. Maintaining temperature integrity consistently from the manufacturing site to last-mile delivery requires strong coordination, validated packaging systems, real-time monitoring, trained personnel and robust contingency planning. Rural and remote connectivity also remain important areas requiring further attention.

How important are training and certification in cold chain management?
Training and certification are extremely important because cold chain management is highly execution-driven. Even the best infrastructure or monitoring systems cannot compensate for a lack of operational understanding. Regular training helps improve compliance awareness, risk management, handling practices and decision-making capabilities. Going forward, workforce competency development will become one of the key pillars of GDP-compliant supply chain systems.

Is there enough skilled talent available for the rapidly growing pharma logistics sector?
The sector is growing faster than the availability of specialised cold chain talent. While infrastructure investments are increasing rapidly, workforce competency development still requires greater attention. There is a strong need for structured training, implementation-focused learning and industry-aligned competency frameworks to prepare professionals capable of handling complex temperature-sensitive supply chains.

Are Indian pharma companies investing enough in digital supply chain transformation?
Awareness and investment are certainly increasing, especially among larger pharmaceutical and biopharma organizations. However, the industry still has significant scope for broader and deeper digital transformation. Many companies are implementing real-time monitoring systems, IoT devices and digital documentation platforms, but true digital integration across the supply chain ecosystem is still evolving. The focus now should move beyond technology adoption toward data integrity, interoperability and implementation effectiveness.

How are AI and predictive analytics changing pharmaceutical logistics?
AI and predictive analytics are gradually shifting pharmaceutical logistics from reactive management to proactive decision-making. These technologies can help predict temperature excursions, optimise routes, improve inventory planning, monitor equipment health, strengthen risk management and enhance supply chain visibility. In the coming years, AI-driven insights will play an increasingly important role in ensuring operational efficiency, compliance and faster responses to supply chain disruptions.

Sustainability is becoming central to logistics. How can cold chain operations become greener without compromising quality?
Sustainability and quality must go hand in hand. The industry can move toward greener cold chain operations through reusable packaging systems, optimised transportation planning, energy-efficient refrigeration technologies, passive cold chain solutions, route optimisation and reduced packaging waste. ESG-focused logistics strategies will become increasingly important in the coming years. The challenge is to balance environmental responsibility with strict temperature compliance and patient safety requirements.

If you had to describe the future of the pharma cold chain in one word, what would it be and why?
Integrated. Because the future of pharma cold chain will depend on stronger integration between technology, compliance, infrastructure, workforce competency, sustainability, and collaboration among industry, academia and regulatory bodies. No single stakeholder can strengthen the ecosystem alone. The future will belong to collaborative and implementation-focused ecosystems.

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EXPRESS PHARMA WORLD EXPO

The platform for India Pharma Inc's next leap

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

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

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

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

Why this platform, why now

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

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

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

Who will attend

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

Attendees will include:

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

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

The expo floor

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

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

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

Turning presence into progress

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

Attendees can expect to:

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

Conversations that matter

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

Key themes include:

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

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

Beyond an event: Building an ecosystem

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

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

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

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

The arrival of digital twins in drug development

The FDA's pivot away from animal testing and toward AI-generated patient avatars is reshaping what counts as evidence for drug approval. **Dr Rajpushpa Labh,** Consultant Physician, health-tech entrepreneur,and AI researcher examines whether India's pharma industry is building the right capabilities, or just the adjacent ones?

On 27 April 2026, a four-author commentary in Nature Medicine made a quiet but consequential argument: the regulatory landscape for drug evaluation is shifting, and unless public-sector regulators and ethicists shape the rules now, the standards for digital twins and in silico trials will be written by industry alone. The piece, by Ashley Eadie and Ravi Parikh of Emory, Holly Fernandez Lynch of Penn, and Naomi Scheinerman of Ohio State, landed at a moment when the underlying technology is no longer hypothetical. It is already inside Phase II and III trials at the European Medicines Agency — and the United States Food and Drug Administration is moving in the same direction, fast.

For Indian pharma, this matters in two ways at once. Submissions to the FDA and EMA will increasingly require credibility evidence for any artificial intelligence used in development. And, more strategically, the indigenous Indian capability to generate that kind of evidence — to build, validate, and defend digital-twin methodologies — is still being assembled. The window to shape it, rather than inherit it, is open now.

A regulatory pivot, not a policy whim

On 10 April 2025, FDA Commissioner Martin Makary announced that the agency would begin phasing out animal testing requirements for monoclonal antibodies and other drugs, replacing them with what the agency called New Approach Methodologies, or NAMs. The list spans AI-based computational toxicity models, organ-on-chip systems, organoids, microphysiological systems, and human-relevant cell-line testing. The accompanying Roadmap to Reducing Animal Testing in Preclinical Safety Studies set a three-to-five-year horizon and listed in silico modelling and microdosing in human volunteers among the replacement technologies.

In December 2025, the FDA followed up with draft guidance on streamlined nonclinical safety studies for monoclonal antibodies — the first concrete operational step. The pattern is clear: this is not a press release that will quietly disappear. It is a regulatory programme with milestones.

The European Medicines Agency and Japan's Pharmaceuticals and Medical Devices Agency have moved in parallel. The EMA's 2024 reflection paper on AI in the medicinal product lifecycle, and its earlier qualification of the PROCOVA methodology in September 2022, signalled that machine-learning-based approaches to trial design were no longer fringe. PMDA has been engaging with sponsors on similar terms. Together, these moves represent the most significant change to how regulators think about preclinical and clinical evidence in a generation.

Three forces drove the shift. First, the cost arithmetic of drug development is getting worse, not better — preclinical programmes routinely cost between 15 and 100 million US dollars, with high attrition into Phase I. Second, animal models have known predictive limitations, particularly for biologics where species differences in target binding distort safety extrapolation. Third, the technology has matured: between 2019 and 2025, computational and AI-driven approaches went from research curiosities to systems that regulators could meaningfully assess. The FDA Modernization Act 2.0, passed in 2022, removed the strict legal requirement for animal testing in many categories, and a proposed Modernization Act 3.0, reintroduced in the US Senate in January 2025, would extend that further.

What a digital twin actually is

In a drug-development context, a digital twin is a virtual model of an individual patient — built from genomics, transcriptomics, proteomics, biomarkers, lifestyle data, and real-world clinical history — that can simulate disease progression and therapeutic response. An in silico trial uses these twins as synthetic control arms, virtual cohorts, or prognostic covariates inside conventional trials. The aim is straightforward: fewer real patients exposed to placebo, smaller sample sizes, faster enrolment, and earlier signals of efficacy or harm.

The technology is not new in concept. The term originated at NASA in the 1960s for spacecraft simulations and matured through industrial adoption in aerospace, automotive, and energy. What changed in healthcare was the convergence of three things: cheap genomics, large-scale electronic health records, and machine learning architectures capable of integrating them. By the early 2020s, individual organ twins for the heart and liver were producing clinically useful predictions, and patient-level twins for narrow disease contexts were entering trials.

PROCOVA: the statistical mechanics of a digital twin in trials

The most prominent commercial application comes from San Francisco-based Unlearn.AI, founded in 2017 by Charles Fisher. The company builds disease-specific neural networks — specifically conditional restricted Boltzmann machines, or CRBMs, which are unsupervised probabilistic models pre-trained on historical clinical trial data. For each enrolled participant in a new trial, the model takes baseline measurements and forecasts what that individual's outcome would be under placebo. That prediction folds into the trial's statistical analysis as a prognostic covariate, a method the company calls PROCOVA — Prognostic Covariate Adjustment.

The statistical elegance of this approach is worth pausing on. Adding a prognostic covariate to an analysis of covariance, or ANCOVA, cannot inflate the Type I error rate. At worst, with an uninformative covariate, the trial loses one degree of freedom. In practice, the covariates Unlearn produces are strongly prognostic, and statistical power increases reliably. This is why the EMA's Committee for Medicinal Products for Human Use was willing to issue a positive qualification opinion in September 2022 — the first time any regulator backed a machine-learning approach for sample-size reduction in pivotal Phase II and III trials with continuous outcomes.

The FDA has confirmed that Unlearn's covariate adjustment strategy is consistent with current guidance, and the company has held successful Type C meetings. Reported control-arm reductions reach 22 percent in Phase III trials for Huntington's disease and amyotrophic lateral sclerosis. The PROCOVA-MMRM extension, published by Unlearn researchers in 2024, applies the same logic to longitudinal endpoints with mixed-models for repeated measures — directly relevant to Alzheimer's, Parkinson's, and other progressive conditions.

"The technology is no longer hypothetical. It is already inside Phase II and III trials."

How the FDA wants to govern AI evidence

On 6 January 2025, the FDA released draft guidance titled Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products. At its core is a seven-step Risk-Based Credibility Assessment Framework. The guidance is the agency's attempt to make a complex technology fit inside the familiar discipline of risk assessment that pharma already practises. Sponsors are expected to:

- Step 1. Define the question of interest the AI model will address.
- Step 2. Define the context of use, or COU, in detail — what will be modelled, and how outputs will be used.
- Step 3. Assess the AI model risk as a function of model influence and decision consequence.
- Step 4. Develop a credibility assessment plan tailored to the COU and risk.
- Step 5. Execute the plan.
- Step 6. Document the results in a credibility assessment report, including any deviations.
- Step 7. Determine model adequacy for the COU — confirm fitness, or revise the model, the risk mitigation, or the plan itself.

A lifecycle maintenance plan is required throughout, with rigour proportional to model risk. The FDA illustrated the framework with a worked example: a drug with life-threatening side effects, where an AI model classifies patients as outpatient-monitorable or requiring inpatient surveillance. The decision consequence is severe; the credibility bar is correspondingly high.

The framework explicitly excludes early discovery applications such as target identification and lead optimisation — even though that is where AI activity is fastest — and applies only to AI outputs that feed regulatory submissions or quality systems. Critics have pointed out two structural weaknesses. First, ensemble models and AI-as-a-service vendors create ambiguity about who owns the credibility assessment. If a sponsor uses a hosted predictive model from a third party, who validates it for the FDA's purposes? Second, the EMA's complementary framework covers the entire product lifecycle, while the FDA's narrower scope creates mapping problems for companies running integrated AI platforms across discovery, trials, and manufacturing. A February 2026 review in the Journal of Chemistry recommended expanding the FDA's guidance to include discovery and operational applications with risk-appropriate requirements.

Oncology: where the technology is most mature

Cancer is the proving ground for digital twins, and the work splits into several distinct schools. Mechanistic quantitative systems pharmacology models, particularly from Aleksander Popel's group at Johns Hopkins, have produced virtual clinical trials in HER2-negative breast cancer combining epigenetic modulators with checkpoint inhibitors, QSP predictions for atezolizumab plus nab-paclitaxel in triple-negative breast cancer, and combination optimisation for anti-PD-L1 with T-cell engagers. These models are mechanism-based rather than pure machine learning — they encode the biology of antigen presentation, T-cell trafficking, and tumour-microenvironment dynamics into systems of differential equations.

Hybrid spatial agent-based models, coupled with whole-patient QSP layers, address tumour heterogeneity — the fact that immunotherapy response depends on where T cells actually are in relation to neoantigens, not just whether they are present. A 2022 paper in PLoS Computational Biology by Ruiz-Martinez and colleagues showed how this coupling could simulate tumour growth and immunotherapy response in three dimensions. A 2024 Cancer Research paper by Zhang and co-authors integrated trial-derived spatial multi-omics with virtual trials for immunotherapy biomarker discovery — exactly the kind of work that translates twin technology into actionable biomarkers.

Predictive twins for treatment planning operate in a different register. Chaudhuri and colleagues, in 2023, used a predictive digital twin to optimise radiotherapy regimens for high-grade gliomas, fine-tuning individual doses to maximise tumour control while sparing healthy tissue. MD Anderson's Institute for Data Science in Oncology runs a broader patient-and-tumour twin programme, described in a 2025 Nature Reviews Cancer commentary by Asghar and Chung. The article walks through how molecular information, individual drug-response data, and microenvironmental modelling can inform individualised treatment, accelerate drug development through trial simulation, and explore multiscale relationships across the entire human body.

A worked clinical example illustrates the trajectory. Consider an acute myeloid leukaemia patient who has re-

ceived a haematopoietic stem-cell transplantation from an unmatched donor and then relapses. The optimal next treatment may involve sequences of drugs and immunotherapies at multiple time points. A Cancer Patient Digital Twin, or CPDT, can simulate those trajectories before any commitment to a specific real-world intervention. As CPDTs accumulate from real-world deployment, the cohorts can power in silico trials and population studies — the boundary between bedside care and trial evidence dissolves into a continuum.

An honest caveat is warranted. Immunotherapy response depends on tumour mutational burden, neoantigen presentation, immune-cell infiltration, checkpoint-molecule expression, and immunosuppressive signals in the tumour microenvironment. Digital twins must integrate all of these. In practice, predictions are more reliable at the population probability level than for any individual patient. The technology is real; it is also not magic.

Beyond oncology: cardiology, neurology, rare diseases

Cardiology was the first medical domain to demonstrate clinically useful digital twins at scale. Dassault Systèmes' Living Heart Project, launched in 2014, produced a multiscale anatomically accurate model of the human heart that has been used to study arrhythmias, drug-induced QT prolongation, and device performance. The FDA's 2023 guidance on computational modelling and simulation in medical-device trials drew explicitly on this body of work, and Dassault has since released the Enrichment Playbook — a 44-page peer-reviewed document, co-developed with the FDA and now in the agency's Regulatory Science Tools Catalog — focused on establishing credibility in trials using simulated patient populations.

In neurology, the AWARE trial in early Alzheimer's disease used Unlearn's CRBM-based digital twins to assess sample-size reduction potential in PROCOVA models. Positive partial correlation coefficients between twins and observed change-from-baseline scores in cognitive assessments confirmed the approach's viability. A separate Unlearn analysis, applied retrospectively to the TRAILBLAZER-ALZ 2 donanemab trial, showed how prognostic covariates could power secondary endpoints and subgroup analyses that the original underpowered design could not robustly answer. Multiple sclerosis digital twin models have replicated disease progression with sufficient fidelity to support trial-design decisions.

Rare diseases may, paradoxically, be where digital twins make the greatest near-term impact. When the eligible patient population numbers in the hundreds globally, every avoided placebo enrolment is ethically significant. A synthetic or covariate-augmented control arm built from historical natural-history data can shrink trial sizes from infeasible to feasible. This is one reason regulators have qualified PROCOVA for continuous outcomes in Phase II and III studies — the rare-disease use case is where the methodological flexibility matters most.

The validation challenge: VVUQ and context of use

Underneath all of this sits a methodological problem regulators have not fully solved. The technical scaffolding for trustworthy digital twins is called VVUQ — Verification, Validation, and Uncertainty Quantification — borrowed from engineering. Verify that the mathematics and code behave correctly. Validate predictions against real-world outcomes for the intended population. Quantify confidence at each step. The central regulatory concept binding this together is context of use: sponsors must specify exactly how a model will be used, identify potential risks, quantify them, and articulate how they will be mitigated.

The unresolved tension is that digital twins require ongoing updates to reflect changes in their physical counterpart, and their dynamic nature is something the existing regulatory framework — built around fixed devices — does not fully address. A January 2025 npj Digital Medicine paper by survey authors at the University of Texas examined VVUQ across cardiology and oncology twin applications and concluded that traditional regulatory frameworks for medical devices are not fully suitable for ensuring effectiveness and safety in the dynamic, learning context of digital twins. The paper called for personalised trial methodologies, validation metrics tailored to context, and standardised VVUQ processes — work that remains in progress.

Hybrid trial designs offer a practical bridge. Combining real and virtual control arms, with adaptive methodologies, allows evidence generation without sacrificing ethical standards. International harmonisation will eventually require organisations like the FDA, EMA, and World Health Organization to converge on a common classification system for digital twins and modular approval pathways based on risk level, intended use, and autonomy. Future regulatory expectations will likely include transparency requirements, audit trails, and model version control — particularly for autonomous or semi-autonomous systems.

Equity, consent, and the data-ownership debate

This is where the Nature Medicine commentary lands its sharpest argument. Digital twins inherit whatever biases live in their training data. Historical trial datasets overrepresent majority, wealthy, urban populations; twins consequently perform less accurately for underrepresented groups, creating algorithmic bias that exacerbates inequality rather than reducing it. The pattern is not new. Obermeyer and colleagues, in a widely cited 2019 Science paper, demonstrated that a major US healthcare algorithm systematically underestimated Black patients' healthcare needs compared to equally sick White patients. The mechanism was the use of historical healthcare spending as a proxy for need — a proxy that itself encoded structural inequity.

Quote: "If sponsors set the standards for what counts as valid training data, equity becomes a downstream afterthought."

A specific and well-documented gender data gap propagates into models that may miss real differences in drug metabolism, disease progression, and symptom presentation. A 2025 Frontiers in Digital Health paper on equitable digital patient twins argued that beyond dataset biases, structural exclusions in clinical research and AI model development further contribute to disparities, and that gender-sensitive model design must be co-created with affected communities rather than retrofitted later. A systematic review of 90 studies, published in 2025, found that fairness in digital twin models is operationalised primarily through group fairness metrics such as demographic parity and equalised odds, but that key gaps remain: lack of global standards, underrepresentation in model training, and infrastructural disparities.

Consent is murkier still. Patients who originally agreed to share data for their own treatment, or for a specific older trial, did not anticipate that data being used to train commercial models for unrelated indications a decade later. Whether the original consent legally covers this downstream use is jurisdiction-dependent; ethically, most observers think it does not. Because digital twins are dynamic and continuously updated, even a robust initial consent becomes stale. Pediatric trials face an even sharper version of this problem: National Institutes of Health guidance on consent for digital health technologies covers wearables but not virtual-patient AI, leaving a hole exactly where in silico tools could most reduce the burden on vulnerable participants.

The accountability chain is equally unsettled. If a clinician follows a digital twin's recommendation and a patient is harmed, it remains unclear whether liability falls on the clinician, the software developer, or the institution. Without transparent decision-responsibility chains, building trust at the bedside will lag adoption at the trial level. Some research groups have proposed pairing digital twins with interactive consent software — letting patients see what models use their data, adjust permissions over time, and engage with trial participation in a more autonomous way. European consortia are piloting this. It is operationally heavy, and depends on patient engagement that may not scale across whole populations.

China's lead — and what it means for India

An honest competitive picture matters here. China is the current frontrunner in AI-driven drug discovery patents and methodology. Multibillion-dollar deals between global pharmaceutical giants — Sanofi, Pfizer, AstraZeneca, Eli Lilly — and Chinese AI biotech firms have signalled a shift from generic manufacturing to innovative drug development, fuelled by considerable state and private investment in life-science R&D, dedicated policies to expand manufacturing capacity, prioritisation of AI in the country's 2025 Five-Year Plan, access to vast patient datasets for AI training, and a multidisciplinary talent pool reinforced by brain-gain policies.

The United States, meanwhile, is undergoing structural changes that may slow its AI-pharma innovation engine: funding cuts to the National Institutes of Health and National Science Foundation, stricter visa regulations, and revenue pressure from expiring drug patents. For India, this creates both a challenge and an opportunity. As China strengthens its capabilities and global pharma seeks investment partners, India's talent pool, patient datasets, and life-science policies — particularly the BioE3 framework — provide a credible foundation. But the foundation is not yet a building.

The Indian opportunity — and the gap

India's pharma industry is deeply engaged in AI — but mostly upstream and adjacent to the digital-twin frontier rather than at it. Sun Pharma uses AI for molecule screening, toxicity prediction, and literature review automation. Dr Reddy's deploys computer vision for packaging validation and chatbots for chronic-therapy adherence. Cipla has integrated AI into smart inhalers and partnered with Indian Institutes of Technology for respiratory diagnostics. Glenmark uses AI for tumour profiling and dermatology. Biocon invests in protein modelling and genomics-driven cancer therapies. Zydus Lifesciences applies machine learning to vaccine efficacy and diabetes care. Novartis's Hyderabad unit reportedly accelerated participant selection for global submissions, with cost and enrolment efficiency gains around 20 percent and database lock times cut by more than half.

The pattern, however, is telling: discovery, manufacturing, pharmacovigilance, recruitment optimisation. Not synthetic control arms feeding regulatory submissions. There is no Indian equivalent of Unlearn.AI. The Central Drugs Standard Control Organisation, or CDSCO, has not yet issued AI guidance comparable to the FDA's seven-step framework or the EMA's reflection paper.

Where India does touch the digital-twin frontier is through Global Capability Centres, or GCCs. India accounts for over 55 percent of the world's GCCs, and the life-sciences slice of that workforce — over 15 percent of the total Indian GCC base — increasingly handles strategic R&D, regulatory analytics, and post-market surveillance for global parents. Hyderabad's Novartis Biome focuses on AI integration into pharma R&D. Bristol Myers Squibb has invested 100 million US dollars in an Indian GCC for AI in drug discovery. Alphabet has announced a 15 billion US dollar AI hub in Visakhapatnam. So when global sponsors run digital-twin pilots, a meaningful share of the engineering happens out of Bengaluru, Hyderabad, or Pune — but the methodology IP and the regulatory filings sit with the parent company.

Indian academic and research efforts deserve more attention than they currently receive. Kalyanasundaram Subramanian's Virtual Liver paper, published in the Journal of the Indian Institute of Science in 2020 and originating at TCS Research and Strand Life Sciences, integrated liver functions, diseases, and drug effects into a mathematical framework based on ordinary differential equations. More recently, researchers at IIT Kharagpur — collaborating with Purdue and the German firm ESQlabs — published DigiLoCS in PLOS ONE in January 2025: a digital-twin model of liver clearance on a liver-on-chip system. This is precisely the kind of work the FDA's NAMs roadmap now blesses, and Indian groups are well positioned to provide regulatory-relevant data rather than just academic publications, if they build credibility-assessment evidence alongside their models.

Three structural drags must be acknowledged. First, Indian pharma has been flagged repeatedly for FDA compliance gaps and for relatively lax data-privacy and clinical-trial-ethics standards — concerns that matter doubly when training-data provenance comes under regulatory scrutiny. Second, fragmented healthcare data sits across providers, laboratories, insurers, and pharma companies in legacy systems with limited interoperability — the raw material that digital twins need is hard to assemble. Third, while China's pharmaceutical-AI ecosystem races ahead with state investment and multibillion-dollar deals between global pharma and Chinese AI biotech, India still lacks comparable scale of indigenous capital deployment in innovation.

Data infrastructure: Ayushman Bharat, ABHA, and DPDP

India has, almost incidentally,

built one of the most ambitious public health-data platforms in the world. The Ayushman Bharat Digital Mission, with its Ayushman Bharat Health Account, or ABHA, identifier system, the Healthcare Professionals Registry, and the Health Facility Registry, creates the administrative spine that longitudinal patient digital twins would need. The Digital Personal Data Protection Act, enacted in 2023 and operationalised through 2024 and 2025 rules, creates the consent and grievance-redressal architecture that GDPR-equivalent training-data governance requires.

The pieces exist. What is missing is the connective tissue: a regulatory pathway that explicitly contemplates AI/ML model training on de-identified longitudinal Indian health data, with clear consent, equity, and validation standards. The Indian Council of Medical Research's 2017 ethical guidelines for biomedical research mention AI only obliquely; an updated framework specific to AI-derived evidence and digital twins would close a meaningful gap. Such a framework, if drafted with input from regulators, ethicists, patient advocates, and industry — rather than industry alone — could position India as a trusted source of digital-twin evidence rather than a contested one.

CDSCO and the regulatory imagination question

CDSCO has historically followed FDA and EMA leads on therapeutic-product regulation, with India-specific overlays for clinical trial conduct, ethics committee oversight, and pricing. The agency has shown adaptive capacity — its handling of COVID-19 vaccine emergency-use authorisations was operationally credible — but the formal AI-and-digital-twin guidance that the FDA produced in January 2025 has no Indian counterpart yet.

What would an Indian framework need to address that the FDA's does not? At least four things. First, the use of Indian-cohort training data versus global trial data — a sponsor running a Phase III in India should not be allowed to cite a digital twin trained exclusively on US-Caucasian historical data without explicit demographic-validity discussion. Second, language and literacy considerations in dynamic consent — India's 22 scheduled languages and varying digital-literacy levels make the European interactive-consent model harder to deploy at scale, but more important to design properly. Third, accountability allocation between sponsors, contract research organisations, and AI vendors — the Indian CRO industry is large and globally competitive, and many digital-twin pilots will run through it. Fourth, post-market surveillance for AI models that continue to learn after approval — a problem the FDA has flagged but not solved, and one where Indian pharmacovigilance infrastructure could lead rather than follow.

The deeper point is the one Eadie, Lynch, Scheinerman, and Parikh raised in Nature Medicine. If the standards for valid training data, acceptable twin performance, and equitable consent are written by sponsors first, the resulting infrastructure will be optimised for sponsor convenience rather than patient autonomy or scientific rigour. India has a window to engage on those standards now — through CDSCO, through the Indian Council of Medical Research, through the Department of Biotechnology, and through the bioethics community — rather than inheriting them later.

Five things Indian pharma should do now

- Build credibility-assessment capacity, not just AI capacity. Every Indian sponsor that touches AI in development — even just for recruitment optimisation or pharmacovigilance signal detection — should map its activities against the FDA's seven-step framework. The exercise costs little and surfaces gaps before regulators do.
- Invest in indigenous validation infrastructure. Organ-on-chip platforms, microphysiological systems, and computational modelling groups in Indian academia (IIT Kharagpur, IISc, IIT Bombay, IIT Madras, the Translational Health Science and Technology Institute) are credible, but they need bridge funding to build the credibility-assessment evidence packages that turn academic models into regulatory tools.
- Engage CDSCO formally on AI guidance. The Organisation of Pharmaceutical Producers of India and the Indian Pharmaceutical Alliance should jointly request a consultation paper from CDSCO modelled on the EMA's 2024 reflection paper, with a six-to-twelve-month comment window.
- Treat the DPDP Act as enabling, not just compliance. The Act's consent architecture, if implemented well, is a competitive advantage for Indian sponsors seeking to use longitudinal patient data for AI training in ways that satisfy FDA and EMA equivalency expectations.
- Partner, but with IP terms that build domestic capability. The next wave of GCC contracts should include IP-sharing provisions for digital-twin methodology, not just service-delivery efficiency. Otherwise India will continue to engineer the future of pharma without owning any of it.

What comes next

The BioE3 policy, Department of Biotechnology and BIRAC Bio-AI workshops, the AI India Impact Summit, and BioAsia 2026 have collectively established that Indian biopharma is undergoing a structural reset — moving from one-off products to platform-led innovation that integrates discovery, AI-native R&D, and advanced manufacturing. The AI-in-precision-medicine market in India is projected to reach 710.9 million US dollars by 2030 at a compound annual growth rate of 37.2 percent. Apollo has launched India's first AI-Precision Oncology Centre. Karnataka and Telangana are positioning themselves as life-sciences GCC hubs.

Two practical implications matter for Indian sponsors filing in US and European jurisdictions. First, the FDA's seven-step credibility framework will increasingly apply to any AI or machine-learning model that supports a regulatory submission — not just synthetic control arms. Indian companies filing Abbreviated New Drug Applications or innovator Investigational New Drug applications will need to bring credibility-assessment plans to the table whether or not they think of themselves as AI-first. Second, the FDA's NAMs roadmap explicitly blesses organ-on-chip and in silico approaches as preclinical evidence, which means Indian academic and CRO infrastructure around organoids, microphysiological systems, and computational modelling has a regulatory route forward — provided the credibility evidence is built alongside the science.

The country has the talent. It has the data. It has emerging policy frameworks in BioE3 and the DPDP Act. Whether it builds the regulatory imagination to match — and the indigenous methodology firms to compete with Unlearn.AI rather than only to engineer for them — is the open question. The window is open now. It will not stay open indefinitely.

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About this article

This feature draws on the April 2026 commentary in Nature Medicine by Eadie, Lynch, Scheinerman and Parikh; FDA and EMA primary documents; peer-reviewed work in oncology, cardiology, and neurology digital twins; and reporting from BioSpectrum India, Applied Clinical Trials, the Observer Research Foundation, and EY-Parthenon. Statistics on Indian pharma AI markets, GCC concentration, and policy developments are as cited in publicly available industry reporting through April 2026. All inline references appear in the numbered list above.

The author welcomes correspondence on factual corrections, additions, and counterarguments — particularly from Indian regulatory practitioners, clinical investigators, and AI methodologists working at the digital-twin frontier.

NAVIGATING A VUCA WORLD

From supply disruptions to rising operational uncertainty, geopolitics is reshaping the pharma landscape. Experts discuss what it will take for organisations to stay resilient and future-ready

It is an irony that medicines, meant to save lives in moments of crisis, are also among the first products to be affected when the world becomes unstable. Wars, blockades and missile strikes on shipping lanes directly affect the supply chains that carry life-saving drugs across the world.

And India sits at the centre of this paradox.

As the "Pharmacy of the World," the country supplies nearly 20 per cent of global generic medicines and over 60 per cent of vaccines. In many ways, India has become a global health asset. But it is also deeply exposed to geopolitical instability. Every conflict in West Asia, every disruption in a key shipping corridor, and every spike in energy or freight costs eventually finds its way into the pharma supply chain.

The impact is real. Delayed deliveries to hospital pharmacies, rising input costs for Indian manufacturers already operating on tight margins, pressure on margins, fears about availability of essential medicines, and growing uncertainty in sourcing, production planning and exports. Ultimately, it is the patient who pays the price.

The question is no longer whether geopolitics will disrupt pharma manufacturing. It already has, repeatedly, and with escalating severity. India Pharma Inc can no longer afford to treat these events as temporary crises. They are now part of the operating environment itself.

The Red Sea to the Strait of Hormuz: Faultlines and risks

The warning signs first emerged in the Red Sea. Houthi attacks on commercial shipping in late 2023 and 2024 forced vessels to reroute around the Cape of Good Hope.

Shipping costs surged and lead times stretched. A shipment that once took 25 days began taking 34 days or more.

At first, many believed the disruption would pass, but it didn't. Critical pharma ingredients and chemicals, including API shipments moving from APAC, especially India and China, to the US and Europe, came under pressure. And with over 65 per cent of India's pharma exports moving by sea, the impact was significant.

Now, the West Asia conflict has brought the Strait of Hormuz, a far more dangerous chokepoint, into focus.

Any disruption in Hormuz threatens far more than shipping. Through this narrow passage flows an estimated 20 per cent of global oil supply. Thus, it is a direct risk to the raw materials and energy ecosystem that pharma manufacturing depends on.

The numbers reveal the scale of the risk.

India exported pharma products worth $1.75 billion to the West Asia and North Africa (WANA) region in FY25. That accounted for nearly 5.7 per cent of India's total pharma exports of $30.38 billion. Major destinations included the UAE, Iraq, Egypt and Saudi Arabia, markets now either inside conflict zones, close to them, or heavily dependent on vulnerable shipping corridors.

And the impact is escalating rapidly.

Far reaching consequences

A recent report by Primus Partners on the West Asia crisis, which also looks at its effect on the pharma sector, states, "The scale of disruption is already visible in the trade data. In March 2026, India's pharma exports fell from $3.68 billion to $2.83 billion, a 23 per cent decline and the first monthly drop in three years.Industry and government sources attribute 80 to 90 per cent of this fall directly to logistics disruptions resulting from the West Asia conflict. Freight surcharges and capacity constraints at key trans-shipment hubs, particularly Dubai and Abu Dhabi, have created vessel shortages, delays, and detention charges that have cascaded beyond the Gulf, disrupting onward shipments to the US, Europe, and Africa. Pharmexcil estimates the monthly losses to the Indian pharmaceutical industry at $26-32 million.This is not a demand-side problem, it is a supply chain shock to one of the most consequential trade routes in global healthcare."

Indian pharma companies could face losses of up to $750 million if the West Asia conflict continues, according to industry executives and analysts. What was initially seen as a short-term disruption has evolved into a far more serious crisis.

This, in turn, has ensured that business sustainability is no longer just an operational concern. It is becoming a strategic priority for pharma leaders across functions. Companies now need to plan and preparing for a future where uncertainty itself becomes constant.

Preparing for the future

Against this backdrop, *Express Pharma's* team will examine how different functions across Indian pharma are evolving to tackle these pressures. From procurement and manufacturing to R&D, supply chain, quality, finance and commercial strategy, the feature will look at how each function is being forced to rethink old ways and build new capabilities for a volatile world.

The feature will assess the current landscape and the strategies companies are adopting to navigate uncertainty, both now and in the years ahead. At its core, it will explore one central question: how can Indian pharma future-proof itself in an increasingly unpredictable world?

Because the next phase of India's pharma story will be defined by resilience. And, the companies that succeed will be the ones that will not just respond to change, but prepare for it before it arrives.

THE WAR IN WEST ASIA

How geopolitics is disrupting India Pharma Inc

$500–750 mn

Estimated losses for Indian pharma

if the West Asia conflict persists

Source
Pharmexcil spokesperson

Why pharma is highly exposed

65%+
Indian pharma exports move via sea routes
Source: PharmaSource Global

$31.11B
India pharma exports in FY26
Source: Media reports

$1.75B
Exports to West Asia/WANA region in FY25
Source: Pharmexcil

5.58%
GCC share in Indian pharma exports
Source: Pharmexcil

200+
Countries dependent on Indian generics
Source: Pharmexcil, Industry estimates

10–20%
Global pharma trade linked to Middle East routes
Source: Council on Foreign Relations, Axios

The global chokepoint Strait of Hormuz

- 20% of global oil trade passes through it
- 20% of global LNG trade passes through it
- No practical bypass route exists
- Energy-intensive pharma operations become vulnerable

Source
IEA · Visual Capitalist

The cost cascade

- Conflict escalation
- ↓
- Oil and LNG prices rise
- ↓
- Petrochemical feedstock costs surge
- ↓
- Packaging, polymers, solvents become costlier
- ↓
- Energy costs rise for API manufacturing
- ↓
- Shipping and insurance premiums increase
- ↓
- Working capital remains stuck longer in transit
- ↓
- Medicine prices rise globally

Source
Media reports

Industry-wide impact

PHARMA	IMPACT
Exports	Longer delivery timelines
Procurement	Raw material volatility
Manufacturing	Energy and solvent inflation
Supply	Route disruptions and congestion
Finance	Higher inventory and freight costs
Patients	Risk of medicine inflation
Government	Pressure on essential drug access

Sources: Pharmexcil, Media reports

What gets impacted

667
drug categories
Face pricing pressure due to cost escalation

- Antibiotics
- Painkillers
- Heart medicines
- Diabetes drugs
- Antipyretics

Source
Media reports

Industry demands growing for

- Freight insurance support
- Crisis-triggered green-lane customs
- Domestic specialty chemical manufacturing
- National digital logistics control towers

Source
Pharmexcil · Industry proposals

The bigger shift

The West Asia crisis is no longer only a geopolitical issue. It is reshaping:

- Global medicine supply chains
- Pharma manufacturing economics
- Drug pricing
- Export strategies
- National healthcare security

Source
Pharmexcil, Industry reports, Media reports

The bottom line

The next decade will belong not to the most efficient pharma companies, but to **the most resilient.**

Source
Industry analysis · Pharmexcil

Financial strategies for uncertain times

Inspite of current geopolitical disruptions, both larger pharma enterprises and smaller promoter-driven entities are playing for the long term, balancing near-term financial prudence while laying the foundation for measured, even aggressive, future bets, analyses **Viveka Roychowdhury**

The current geopolitical disruptions have pharma finance heads and founders advocating fiscal discipline but almost paradoxically, aggressively pursuing opportunities coming out of the same crisis. Boardroom strategies are choosing to keep their gaze on long term gains, while dealing with the short term pain.

As Ashok Nair, MD, RPG Life Sciences puts it, "Our capital allocation philosophy remains being prudent, balanced and long-term oriented. In periods of uncertainty, our focus is on sharper prioritisation of investments rather than short-term reactions.

We continue to invest in core growth areas including manufacturing modernisation, R&D, digital capabilities and supply chain resilience, while focusing on margin protection and improvement. Maintaining a strong balance sheet, diversified business model and execution agility remains critical for us as we navigate evolving geopolitical conditions and prepare for long-term growth."

Casting a CFO lens, Ramesh Swaminathan, Executive Director, Global CFO, Head of IT and API Plus SBU, Lupin is unequivocal, when he says, "In a volatile environment, the strength of the balance sheet becomes a key enabler. We will continue to focus on cost optimisation, improving operational efficiencies, and ensuring disciplined capital allocation. At the same time, we are committed to investing in areas with strong long-term potential, so it's about striking the right balance between prudence and growth."

We maintain a prudent financial approach and make measured choices — balancing growth investments with flexibility to adapt as conditions evolve

Ramesh Swaminathan
Executive Director,
Global CFO, Head of IT and API Plus SBU,
Lupin

Our capital allocation philosophy remains being prudent, balanced and long-term oriented. In periods of uncertainty, our focus is on sharper prioritisation of investments rather than short-term reactions

Ashok Nair
MD,
RPG Life Sciences

Spelling out the strategy when it comes to allocating investments for such times and preparing for what comes next, Swaminathan says, "In such an environment, we maintain a prudent financial approach and make measured choices — balancing growth investments with flexibility to adapt as conditions evolve."

Lupin's approach is to stay focused on long-term value creation, continuing to invest in areas where they have a clear strategic advantage, while being mindful not to overextend the balance sheet. At the same time, the company will ensure they have enough financial flexibility to navigate volatility—whether it's cost pressures or emerging opportunities.

In addition, Swaminathan says, "We also prioritise investments that strengthen the fundamentals—like quality, supply chain resilience, and operational efficiency—because these are critical to staying competitive in the long run. Our R&D investments remain focused on differentiated, high-barrier opportunities where we see durable global demand and greater value-creation potential. This ensures our future pipeline remains highly insulated from standard market volatility."

Not just surviving but thriving beyond disruptions

For Lupin it sounds like business as usual. Larger pharma companies have the wherewithal to withstand headwinds but would such disruptions see smaller promoter driven companies fold up and pull out of the sector?

Manish Jain, Director, Naprod Life Sciences, which specialises in oncology and anesthesia, spells out that the most immediate threat in the current environment is raw material supply instability, driven by geopolitical conflicts and concentrated sourcing. He points out that India still imports a majority of its API and KSM needs, and disruptions in petrochemical feedstocks or transport routes have rapidly caused price increases of key inputs like paracetamol and solvents by up to 30–40 per cent or more.

Reflecting the realities for India's large pharma MSME base, he points out that smaller firms without buffer capacity are especially exposed, and such pressures can quickly compress margins and disrupt production schedules if not proactively managed.

Inspite of current disruptions, smaller pharma companies seem more prepared this time. In fact, like their larger peers, they are also planning for the long term. Perhaps the bounce back after a global pandemic like COVID has honed survival instincts and pharma companies across the spectrum are now more confident of not just surviving but thriving beyond such disruptions.

Balancing operational stability with capability creation

Representing the Federation

of Pharma Entrepreneurs (FOPE), National President, Harish K Jain avers that in periods of uncertainty, capital allocation becomes less about maximising short-term returns and more about building strategic resilience without losing growth momentum. According to him, "The capital allocation should be a careful balance of operational stability of today and capability creation for the long term, say 10 years. The mistakes many firms make during uncertainty is either becoming excessively defensive or overextending aggressively. The right approach is disciplined selective aggression."

He recalls McKinsey's Three Horizon Framework, which was designed to help companies of all sizes balance their focus between short term and long term goals, by segregating the horizon into three timeframes:

1. Now: Defending and extending your existing money-making operations. Invest in quality systems, regulatory compliances, optimise processes, maximise profits, and increase efficiency to fuel future investments. In uncertain times, continuity itself becomes a strategic asset.

2. Near future: Nurturing rising, entrepreneurial ventures and scaling new business models. Allocate resources to digital transformation, new markets, and rapidly scaling pilot programs.

3. Distant future: Creating viable, disruptive options for long-term growth. Invest in exploratory research, speculative technology, and pilot programs that may take years to mature.

Summing up, he advocates that in uncertain times companies need to preserve strategic liquidity, staying financially disciplined, but technologically ambitious.

For example, as Director, Embiotic Laboratories Harish Jain's priorities for FY2026-27 will be firstly, to move from cheap manufacturing to differentiated science and execution with special emphasis on specialty formulations, complex generics and CDMO partnerships. His second priority will be to build quality reputation and thirdly to create a talent pool.

In this period of heightened uncertainty, our investment strategy is balanced between risk mitigation and growth acceleration

Manish Jain
Director,
Naprod Life Sciences

In the current environment, investments are being prioritised towards resilience rather than only expansion

Saurabh Agarwal
Director at HAB Pharma

The mistakes many firms make during uncertainty is either becoming excessively defensive or overextending aggressively. The right approach is disciplined selective aggression

Harish K Jain
National President,
FOPE & Director,
Embiotic Laboratories

Global instability as the new normal?

Saurabh Agarwal, Director, HAB Pharma emphasises that the one thing the industry has clearly learnt (thanks to the geopolitical disruptions) is that "inventory is cheaper than shutdown."

As Agarwal spells out, "In the current environment, investments are being prioritised towards resilience rather than only expansion. Compliance investments remain non-negotiable, especially with increasing global scrutiny and revised Schedule M expectations. Alongside this, capital allocation is focused on five aspects: supply chain stability, automation and data integrity, energy optimisation, vendor diversification and critical inventory management."Reflecting the export-oriented nature of pharma operations, Agarwal mentions that HAB Pharma is "also balancing forex exposure carefully. While USD-INR volatility increases input costs, export receivables in US dollars provide a partial natural hedge for Indian exporters."Zooming out to the big picture, Agarwal says that the broader strategy is to build an organisation that can continue operating efficiently even during periods of global instability, rather than depending on ideal market conditions.

For the current financial year, Manish Jain reveals that Naprod Life Sciences' strategic priorities focus on supply chain resilience, quality-led manufacturing, and portfolio expansion in high-value therapeutic areas. It follows that their investment strategy is balanced between risk mitigation and growth acceleration. On the mitigation side, Naprod Life Sciences is allocating funds to strengthen supply chain visibility and flexibility, including advanced demand-forecasting systems, buffer inventory strategies, and diversified logistics options. This helps ensure they are less susceptible to sudden spikes in input costs or transport delays that have recently been triggered by geopolitical tensions.

"At the same time, we are directing resources toward quality and capability enhancement, such as upgrading manufacturing technologies, investing in regulatory compliance infrastructure, and expanding into high-growth product segments like oncology and specialty injectables. These areas not only command better margins but also deepen strategic value for global partners who increasingly prioritise reliable, high-quality sources," explains Manish Jain.

Preparing for the next

There is no doubt that the old pharma playbook no longer

works. The solution is to rewrite the rules of play and change the collective mindset.

As FOPE's Harish Jain cautions, "We can future-proof ourselves only if we can evolve from being the "lowest-cost generic supplier" into a trusted, technology-enabled, innovation-driven healthcare ecosystem. The next decade will not be defined only by FDA approvals or ANDA filings. It will be shaped by geopolitical fragmentation, AI-led disruption, climate and ESG pressures, supply-chain nationalism, biologics and precision medicine, and trust in quality systems. India already supplies ~20 per cent of global generics, but the old model of scale + low cost is becoming insufficient."

Nair of RPG Life Sciences reveals that as disruptions can create short-term pressure on raw material availability, freight costs and lead times, RPG Life Sciences has proactively strengthened strategic procurement across key products, built adequate inventory levels and activated alternate sourcing programmes to minimise disruption risk.

Thus while they are closely monitoring the evolving geopolitical situation, Nair believes that as of now, there is no material impact on the business, and they do not foresee any significant disruption at this stage, given their current inventory levels. "We are also working closely with global customers on calibrated price pass-throughs, along with upside expected due to exchange rate fluctuations," discloses Nair.

Turning threats into opportunities

All companies, large and small, are bullish on turning threats posed by geopolitical flashpoints into long term opportunities.

Spelling out the significant opportunities emerging from this flux, Lupin's Swaminathan points out, "Global customers and healthcare systems are actively looking to diversify their supply base and reduce dependence on single geographies, which plays to India's strengths as a reliable, high-quality, and cost-competitive manufacturing hub. There is also a clear opportunity for Indian companies to move up the value chain—whether in complex generics, specialty products, or biosimilars—where capabilities, scale, and regulatory track record become key differentiators."

For Lupin, this creates an opportunity to strengthen their position through differentiated capabilities, global scale, and scientific depth. The focus, explains Swaminathan, has been on building resilience through geographically diversified operations, a balanced market mix across developed and emerging markets, investments in complex manufacturing platforms, stronger backward integration in selected areas, and disciplined quality and compliance systems.

Emphasising Lupin's belief in the importance of advancing the value chain, Swaminathan predicts, "The future will increasingly favour companies with differentiated portfolios, complex technologies, strong regulatory track records, and the ability to serve global healthcare systems reliably during periods of disruption. In parallel, we continue to assess vulnerable links across the value chain and build mitigation strategies through alternate sourcing, strategic partnerships, manufacturing flexibility, and prudent inventory planning."

It's not just marque pharma names who are preparing to ride the tide. Naprod Lifesciences' Manish Jain too believes that "volatility also brings distinct opportunities. There is a renewed global emphasis on de-risking supply chains, and India's established pharma ecosystem is well positioned to attract long-term business from partners seeking reliable, quality-focused manufacturing. By leveraging strong compliance records, regulatory expertise, and emerging capabilities in complex formulation processes, we can expand into new markets and reduce dependency on commoditised product lines. To address vulnerabilities, we are accelerating backward integration of critical inputs, expanding inventory safety cushions, and collaborating more closely with logistics partners to manage trade route risk. This combined approach balances short-term risk mitigation with long-term competitive positioning."

Thus there are many emerging opportunities for companies that lay the groundwork today. Echoing his peers on how global customers are increasingly looking at supply chain diversification and long-term reliability, HAB Pharma's Agarwal points out that this creates opportunities for Indian manufacturers with "strong compliance systems and stable operations."

Thus the hard learnings of the current geopolitical crisis can turn into soft landings if companies work on vulnerabilities, leverage strengths and take calculated risks.

If evolution was a series of geological changes that ensured survival of the fittest and most adaptable species, geopolitical flashpoints will test the business instincts of many sectors. Pharma companies will be no different. CFOs and promoters of pharma companies will have to steer this evolution beyond geopolitical uncertainties.

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The winds reshaping Indian pharma supply chains

As the era of hyper-globalisation appears to have run its course,with geopolitics increasingly shaping geoeconomics,Indian pharma supply chains are being forced to rethink resilience, adapt to disruption, and prepare for a far more unpredictable global environment, reports **Neha Aathavale**

For years, Indian pharma has been preparing to build walls against uncertainty. But as global winds continue to shift, the industry is now realising that it may need to learn to build windmills instead. Pharma supply chains, once backstage operational functions, are now at centre stage, forcing companies to rethink continuity, sourcing, inventory, and resilience in a world where disruption is no longer occasional, but constant.

Against this backdrop, the conversation is no longer only about whether supply chains are prepared to tackle these pressures, but how quickly and effectively they can be re-engineered for it. What is emerging is less a question of readiness in isolation, and more a reading of how the sector is already adapting in real time. Perhaps the answer lies in the current temperature of the sector itself.

Gauging the industry's pulse

The current pressure on pharma supply chains is no longer theoretical. The industry is already beginning to feel the impact operationally. According to trade data highlighted by FinTrekk Capital, India's drug exports in March 2026 declined 23 per cent year-on-year to $2.83 billion, marking the steepest drop in over five years, largely driven by transit disruptions rather than weakening demand. Rerouting around the Red Sea and Strait of Hormuz has extended delivery timelines by up to two weeks, while rising dependence on air freight has significantly inflated logistics costs.

Yet, despite these disruptions, the broader sentiment across the industry is not one of panic, but recalibration. "While global demand for Indian medicines remains strong, geopolitical tensions have introduced greater complexity and cost into supply chain operations through rising input costs, freight costs, insurance premiums, and transit uncertainties. However, the Indian pharmaceutical export ecosystem remains stable and resilient," says Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA).

Since the COVID-19 pandemic and ongoing geopolitical tensions, the importance of resilient and diversified pharmaceutical supply chains has become increasingly vital

Sudarshan Jain
Secretary General,
Indian Pharmaceutical Alliance (IPA)

Organisations are increasingly moving away from a traditional "cost vs resilience" trade-off toward a more holistic understanding of the total cost of risk

Nihar Medh
Global Head of Supply Chain,
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The question is no longer how lean we can operate, but how prepared we are for the next disruption

Akhlas Ahmed
Associate Vice President - New Product Development & Supply Chain Management, Mankind Pharma

What appears to be changing more fundamentally is the industry's approach towards supply chain risk itself. "The industry has moved beyond 'lowest cost' optimisation to a more balanced approach where supply continuity, resilience, and predictability carry equal weight alongside efficiency," explains Nihar Medh Global Head of Supply Chain, Piramal Pharma. Companies are increasingly reassessing dependencies across APIs, key starting materials, and logistics routes while simultaneously reducing concentration risks and diversifying sourcing models.

A similar shift is also becoming visible at the operational level. "The question is no longer how lean we can operate, but how prepared we are for the next disruption," notes Akhlas Ahmed, Associate Vice President - New Product Development & Supply Chain Management, Mankind Pharma adding that successive geopolitical shocks and trade restrictions have exposed deep structural dependencies across the pharma supply ecosystem. The response, increasingly, is centred around agility, supply buffers, and building resilience into the network itself rather than treating disruptions as temporary events.

Where the cracks are beginning to show

If the current disruptions have exposed anything, it is that the

vulnerability of pharma supply chains extends far beyond manufacturing floors.

One of the key concerns that continues to remain under discussion is import dependence, particularly in critical APIs, intermediates, and fermentation-based key starting materials. According to MedPharma Global data, India imported nearly $4.35 billion worth of APIs, bulk drugs, and drug intermediates in FY 2024–25, with China accounting for close to 74 per cent of these imports.

At the same time, India's growing trade footprint has also increased its dependence on global maritime routes that facilitate the procurement of raw materials and movement of finished formulations. According to a research paper published by the Indian Institute of Strategy, Policy and Public Research (IISPPR), nearly 95 per cent of India's trade by volume moves through maritime routes. This places greater strategic importance on chokepoints such as the Strait of Hormuz, the Red Sea corridor, the Bab-el-Mandeb Strait, the Suez Canal, the Strait of Malacca, and the Panama Canal for exports to the US market.

With geopolitical tensions continuing to rise across regions, these chokepoints can no longer be seen as distant geopolitical flashpoints. The Strait of Hormuz remains central to global energy flows, directly influencing fuel and freight costs. The Bab-el-Mandeb Strait and the Suez Canal continue to act as key trade corridors linking Indian exports to Europe and North America, where even small disruptions can stretch transit timelines by days or weeks. The Strait of Malacca, meanwhile, remains critical for the movement of APIs and intermediates from East Asia into India. Any prolonged disruption across these routes now risks cascading effects across sourcing, production schedules, inventory cycles, and export commitments all at once.

"Recent global events have demonstrated how disruptions in shipping routes or energy flows can quickly translate into extended lead times, capacity constraints, and elevated cost structures, even when manufacturing operations remain stable," states Medh. The focus, he notes, is increasingly shifting from pure production efficiency towards building systems capable of absorbing volatility.

For many companies, the Red Sea crisis became one such inflection point. "Rerouting added 10–14 extra days to Europe-Asia shipping routes and sharply increased freight costs. Temperature control, shelf-life compliance, and documentation timelines also came under pressure simultaneously. These are patient safety issues, not just logistics issues," says Ahmed. He adds that concentration risk remains another major challenge, particularly when critical APIs or intermediates depend heavily on limited suppliers or geographies.

Industry leaders, however, remain cautiously optimistic that the sector is gradually moving towards stronger resilience-building through domestic capacity expansion, supplier diversification, and long-term localisation efforts. "Since the COVID-19 pandemic and ongoing geopolitical tensions, the importance of resilient and diversified pharmaceutical supply chains has become increasingly vital," says Jain. While acknowledging that import dependence still exists across certain critical segments, he points towards growing domestic API capabilities, supported by the Government's PLI scheme and new manufacturing capacities coming online. "The broader direction is toward building a more diversified, resilient, and self-reliant pharma supply ecosystem in India," he adds. As a result, supplier diversification, alternate logistics routes, regional buffer stocks, and stronger end-to-end visibility are increasingly being viewed less as contingency measures and more as long-term operating necessities.

The recalibration has already begun

Companies appear to be recalibrating the very framework through which supply chains are designed and evaluated. The earlier dominance of cost efficiency and lean inventory models is gradually giving way to a more layered approach where risk, continuity, and predictability are becoming equally central to decision-making.

"The post-pandemic period marked a fundamental shift in mindset, from prioritising efficiency through just-in-time models to building resilience through just-in-case preparedness," says Jain. He notes that companies are now carrying higher inventory buffers, often three to four months for critical APIs and raw materials, alongside multi-source procurement strategies and greater use of digital tools to strengthen visibility and forecasting. "Supply chain resilience is no longer viewed as a contingency measure; it has become a strategic business imperative," he adds.

This shift is also reflected in how organisations are approaching trade-offs that were earlier treated as straightforward cost decisions. "Organisations are increasingly moving away from a traditional 'cost vs resilience' trade-off toward a more holistic understanding of the total cost of risk," explains Medh. According to him, companies are now selectively building redundancy in high-criticality areas such as APIs and key intermediates, while also investing in multi-regional supply networks that reduce exposure to concentrated geographies.

At the same time, this transition is not uniform across the value chain. While resilience is becoming a strategic priority, companies continue to operate within regulatory, cost, and capacity constraints, which prevent a complete structural overhaul. As a result, the shift appears less like a replacement of the existing model and more like an additional resilience layer built over efficiency-driven systems.

This balancing act is also being reinforced by regulatory tightening. As Ahmed points out, upcoming IP amendments expected to come into effect in July 2026 will require stricter quality systems and deeper supplier oversight.

He notes that for companies with large, multi-layered networks across formulations, APIs, and packaging, this is not just a compliance update but a structural push to strengthen systems that can audit, track, and manage suppliers more rigorously across the value chain.

"For a company with Mankind's large network across formulations, APIs, and packaging, this is not just a routine compliance update. It requires stronger systems to audit, track, and manage the wider supplier network." adds Ahmed.

From cost optimisation to continuity planning

As this strategic shift begins to take shape, its impact is also becoming visible in day-to-day supply chain design. What was earlier treated primarily as a cost optimisation function is now increasingly being reframed as a continuity and risk management exercise, where sourcing, logistics, and planning decisions are evaluated through disruption readiness.

"Definitely, and this shift is long-term and structural, not temporary," says Ahmed. He explains that supply chain decisions are now carrying geopolitical weight, with procurement moving beyond price-based evaluation to include supplier concentration risk, route stability, and regulatory exposure. According to him, companies are actively investing in supplier diversification, regional hubs, and flexible manufacturing setups, even when these come at higher short-term costs. "Earlier, supply chain performance was mainly measured through cost per unit and delivery speed. Today, continuity has become equally important," he adds.

A parallel shift is also underway in how visibility and control are being strengthened across networks. "Real-time visibility has moved from a capability to a necessity," he notes, highlighting how disruptions in freight routes, policy changes, or energy shocks can quickly cascade into shortages if not detected early. Companies are increasingly building digital systems that track shipments, supplier health, compliance status, and cost volatility across multiple tiers of the supply chain, enabling faster course correction when disruptions emerge.

Beyond internal restructuring, organisations are also focusing on deeper ecosystem coordination. "Enhanced end-to-end visibility, faster tech transfers, and deeper ecosystem collaboration will be critical going forward," says Medh. He points to a growing emphasis on shared risk frameworks across suppliers, logistics partners, and manufacturers, where resilience is being built not just within companies but across interconnected networks.

Companies are also increasingly exploring more distributed and geographically balanced sourcing models. "At the same time, friend-shoring and cross-regional collaboration models are gaining traction—enabling companies to leverage the strengths of different geographies while maintaining regulatory alignment and market proximity," notes Medh. He adds that this is enabling organisations with integrated, multi-region capabilities to better combine resilience with efficiency, positioning them to respond more effectively to volatility without compromising competitiveness.

This structural recalibration is also reflected in how supply chain decision-making itself is evolving within organisations. Ahmed explains that supply chain performance is no longer defined purely by cost efficiency metrics such as per-unit cost or delivery speed, but increasingly by geopolitical exposure, network resilience, and continuity planning.

According to him, procurement has now become a strategic function where decisions around suppliers, logistics, and inventory carry long-term business implications. "The industry is now moving away from purely cost-focused models towards resilience-led planning," he notes, adding that this includes supplier diversification, flexible

manufacturing models, and stronger network visibility, even where short-term costs may be higher. He also points to regulatory tightening, including upcoming IP amendments, as further reinforcing the need for stronger supplier governance systems and long-term planning frameworks.

Resilience as the new measure of leadership

The focus is no longer only on managing the next shock, but on building systems that can continuously absorb, adapt, and recover without breaking the flow of medicines across markets.

"Looking ahead, three priorities will be critical in building stronger and more resilient pharma supply networks," says Medh. He highlights faster and more predictable tech transfers and regulatory pathways to enable redundancy across sites, enhanced end-to-end visibility through digitised supply ecosystems for earlier disruption detection, and deeper ecosystem collaboration across suppliers, logistics partners, and customers built on shared risk frameworks. He adds that capability alone is no longer sufficient, with execution speed, regulatory predictability, and trust emerging as decisive factors in how supply chains perform under stress.

He further notes that resilience is no longer a defensive construct but a competitive advantage, with organisations that embed it structurally into their operating models increasingly emerging as partners of choice in an uncertain global environment.

This redefinition of competitiveness is echoed across industry leadership. "I believe resilience and supply continuity are becoming just as important as scale and cost competitiveness in defining global pharma leadership," says Ahmed. He points to repeated global disruptions—from the pandemic to geopolitical conflicts and trade restrictions—as evidence that scale alone is no longer sufficient to ensure continuity or credibility in global supply chains.

He adds that expectations from regulators, governments, and healthcare systems have also evolved significantly, with frameworks such as the US FDA's drug shortage mechanisms, the EU's Critical Medicines Act, and India's PLI-driven API push reflecting a stronger emphasis on supply security and local manufacturing capability. According to him, future pharma leadership will be defined across three dimensions: reliability of supply, cost competitiveness, and strategic agility. While efficiency and scale will remain important, he notes that the real differentiator will be the ability to withstand disruption, reroute supply quickly, and maintain continuity under pressure.

For companies like Mankind Pharma, he adds, this shift represents both responsibility and opportunity—particularly for organisations with large and diversified supplier networks, where resilience is no longer a parallel goal but an embedded part of long-term ecosystem design.

What does the future hold?

Overall, what is becoming increasingly visible is that the era of hyper-globalised supply chains built purely around cost efficiency may slowly be giving way to a more regionalised and strategically balanced model. India's long-standing positioning as a trusted global partner, backed by strategic relationships across regions, may place it in a stronger position to build more resilient, diversified, and trusted pharma supply networks in the years ahead. Perhaps the larger opportunity now lies in how effectively the industry can absorb and adapt these situations.

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The new playbook for pharma manufacturing

Freight disruption, energy volatility, raw material dependencies and geopolitical tensions are reshaping pharma manufacturing. As a result, leaders must move beyond cost optimisation and build systems designed for resilience, flexibility and continuity, writes **Lakshmipriya Nair**

The global operating environment has changed fundamentally. Wars are disrupting trade routes and political tensions are reshaping supply chains. Energy markets are volatile, export restrictions are increasing, and governments are prioritising healthcare security and domestic manufacturing capability.

These are no longer isolated disruptions but significant shifts. As a result, the old manufacturing playbook is becoming outdated. For years, pharma manufacturing was built for efficiency. Today, it must also be built for resilience.

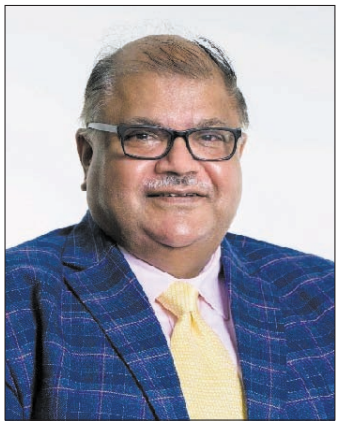
This matters because pharma depends on uninterrupted product movement through interconnected supply chains. In such an environment, instability quickly becomes a manufacturing problem.

And the challenge goes beyond just freight disruption.

Pharma is a downstream industry of petrochemicals. APIs rely on solvents and intermediates linked to crude oil and natural gas. Packaging materials such as blister packs, plastic bottles, and vials also depend heavily on petrochemical derivatives.

When conflict disrupts energy and petrochemical markets, the creates a ripple effect across pharma manufacturing, from raw materials and packaging to utilities and transportation. That means the challenge is no longer only operational. It is strategic.

Manufacturing leaders are now being forced to rethink long-held assumptions around sourcing, inventory, operations and investment priorities.



Crises can no longer be treated as exceptional events; they are now part of the operating environment

Himanshu Saxena
Pharma/Biopharma Manufacturing expert

The companies best prepared for the next disruption will be the ones building optionality now — across sourcing, logistics, regulatory filings, and manufacturing partnerships — rather than waiting for the next crisis to force those decisions

Dr Sanjit Singh Lamba
Managing Partner,
Trillyum Consultin

From cost optimisation to operational resilience

The pharma industry has always rewarded efficiency. Companies reduced inventory aggressively and supplier bases became narrower. So, manufacturing had also moved toward scale concentration.

But recent disruptions have exposed the weakness of over-optimised systems.

"Efficiency without resilience is a fragile advantage," says Dr Sanjit Singh Lamba, Managing Partner, Tryllium Consulting. He points out that "the old formula of single-source procurement, maximum cost efficiency, and lean inventories worked in a more stable world. In the current environment, it exposes manufacturers to avoidable risk."

That reality is now reshaping manufacturing strategy.

The COVID-19 pandemic was the first major warning. Since then, Red Sea disruptions, West Asia tensions, freight instability, and energy volatility have reinforced the same lesson repeatedly. Continuity matters as much as cost.

Dr Himanshu Saxena, a pharma veteran in manufacturing and supply chain operations, explains that companies are now reworking their operations around disruption readiness.

He informs, "Plants are also carrying higher levels of critical raw materials to buffer against increasingly frequent disruptions. Operating models have become more agile, with shorter planning cycles, more frequent scenario reviews, and tighter coordination across sourcing, manufacturing, logistics, and commercial teams."

This marks a major shift in manufacturing thinking. The objective is no longer only to manufacture at the lowest cost, but to continue manufacturing during instability.

That distinction is becoming strategically important.

Over-concentrated supply chains: A clear risk

One of the biggest vulnerabilities exposed over the past few years has been geographic concentration.

Many pharma supply chains became heavily dependent on limited regions for APIs, intermediates, chemicals, and packaging materials. That concentration improved efficiency during stable periods. But it also increased systemic risk.

Today, manufacturing leaders are rethinking dependence on single geographies and single-source suppliers.

According to Dr Lamba, "Procurement is no longer just about negotiating cost. It now sits at the center of risk management, with sourcing decisions shaped as much by geopolitical exposure and route reliability as by price."

Thus, diversification is increasingly being viewed as business protection.

Dr Bikash Kumar Nayak, Plant Head, Aurobindo Pharma states, "Geopolitical friction, protectionist tariffs, and severe maritime bottlenecks have transformed regionalisation, flexibility, automation, and digital visibility from forward-looking goals into immediate, non-negotiable operational requirements."

Naresh Kumar Gaur, Ex-Executive VP-Operations, Stallion Laboratories highlights how supply chain teams are already responding to this reality. "In pharma it has led to increase of alternate sources (approved) of materials, focusing more on indigenous ones," he says.

This shift is also influencing manufacturing strategies at the policy level. The government is now encouraging domestic manufacturing capabilitities for healthcare and

pharma. India's push toward API self-reliance and production-linked incentive schemes reflects this broader trend.

Thus regional manufacturing is no longer only an economic discussion. It is becoming an important security discussion.

Inventory: Not just a finance metric

For decades, lean inventory was considered as a best practice in operations. But when shipping routes become unreliable or lead times expand suddenly, low inventory becomes a vulnerability. Manufacturing leaders are therefore reassessing how inventory is positioned across the supply chain.

The shift is not toward excessive stockpiling but towards intelligent buffering of critical materials.

Not every material requires the same level of protection. But critical APIs, key starting materials, and high-risk imports increasingly require stronger inventory safeguards.

Inventory is no longer simply a finance metric. It is now part of manufacturing resilience strategy.

The shift to predictive intelligence

Traditional manufacturing systems were designed to respond to disruption after it occurred but that approach has become redundant.

In a volatile world, manufacturing leaders need earlier visibility into operational risk. They must now continuously assess geopolitical exposure, logistics vulnerability, energy shortages and supplier dependency.

This needs investment in digital systems, integrated planning, and predictive intelligence. Luckily, many companies have taken note.

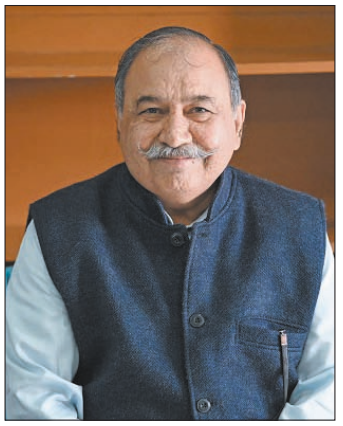
Saxena explains that many organisations are "investing in real-time monitoring, digital dashboards, and stronger planning visibility so they can spot disruptions earlier and respond faster across the network."

This shouldn't be viewed only as a technology upgrade, but also as a leadership shift.

So, scenario planning is becoming essential. Companies can no longer assume stability and must prepare for volatility as a constant operating condition.

Dr Nayak captures this shift clearly. "The industry has shifted away from cost-focused, 'just-in-time' models toward resilient, agile, and 'just-in-case' planning," he says.

This defines the manufacturing transition now underway across the industry.



There are organisations that are creating the facilities of the future with robotics and automation so as to be classified as 'Dark Factories' with minimal human touch

Naresh Kumar Gaur
Ex-EVP-Operations,
Stallion Laboratories

Geopolitical friction, protectionist tariffs, and severe maritime bottlenecks have transformed regionalisation, flexibility, automation, and digital visibility from forward-looking goals into immediate, non-negotiable operational requirements

Dr Bikash Kumar Nayak
Plant Head,
Aurobindo Pharma

Disruption readiness: A key imperative

1. Build redundancy before disruption happens
2. Treat digitalisation as core infrastructure
3. Shift from "just-in-time" to "just-in-case"
4. Make resilience measurable

From fixed to flexible manufacturing

Traditional manufacturing systems struggle during disruption and hence the industry is moving toward greater operational flexibility.

This includes regional manufacturing capability, multi-site production strategies, faster technology transfer systems and distributed supply networks.

According to Saxena, "regional networks are proving more resilient because they distribute risk more effectively and reduce the impact of localised disruptions."

This flexibility is becoming very important for both operational continuity and regulatory compliance. Companies are also redesigning production structures to improve agility.

Saxena explains, "Teams are also building greater operational flexibility by splitting production stages across sites, and producing bulk intermediates in selected plants while carrying out final processing and regional packaging closer to demand centres."

This, in turn, reduces concentration risk while improving agility and responsiveness to market disruption.

Smart manufacturing: A non-negotiable

Another major shift underway is automation and digital manufacturing.

Labour shortages, rising compliance complexity, energy costs and operational volatility are pushing the industry toward smarter systems.

Gaur believes this transition has become urgent. "Lean operations is no more a fancy word but has to be practiced day in day out by each team member. Rework has become non affordable; cost of poor execution is a killer," he says.

That pressure is increasing investment in automation, digitalisation and AI-led manufacturing and operations.

Saxena argues that "AI, machine learning, automation and digitalisation should move from side conversations to the centre of operating strategy." This is becoming especially important as manufacturing complexity increases.

Modern pharma operations now require faster decisions, tighter compliance control, stronger traceability, and better resource utilisation.

Digital systems help manufacturers improve visibility, reduce process losses, lower human error and strengthen operational consistency.

That is particularly relevant in a highly regulated industry where quality failures carry major consequences.

Manufacturing leadership must be strategic

One of the biggest transformation is probably the role of the manufacturing leader itself.

Historically, manufacturing leadership focused on operational execution. Productivity, quality, compliance and cost management defined success.

But, that role is now expanding rapidly. Manufacturing strategy can no longer operate separately from business strategy. This is because manufacturing resilience now directly affects corporate resilience.

The strongest manufacturing organisations will be the ones that combine efficiency with adaptability, visibility and foresight.

As Saxena puts it, "crises can no longer be treated as exceptional events; they are now part of the operating environment."

That may be the defining lesson for pharma manufacturing leaders today.

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Resilience: The new mantra for R&D

Geopolitical fragmentation is accelerating the shift toward regional trials, localised manufacturing, and flexible drug development models across the pharma industry, finds **Swati Rana**

The impact of geopolitical instability on the pharma industry is no longer limited to supply chains and exports. Increasingly, it is beginning to reshape the very foundation of pharma R&D. From clinical trial planning and regulatory approvals to manufacturing strategies, sourcing models, and innovation investments, global conflicts and trade disruptions are forcing pharma companies to rethink how and where they develop medicines.

For years, pharma R&D operated within a highly globalised ecosystem. Clinical trials were spread across continents, APIs and intermediates moved seamlessly between countries, and manufacturing networks were optimised largely around cost efficiency. But the repeated shocks of recent years — the pandemic, Red Sea disruptions, growing US-China tensions, and the ongoing West Asia conflict — have exposed the vulnerabilities of this model.

Today, resilience has become as important as scientific capability.

Yogesh Joshi

Dr Madhusudhan Bommagani

Dr Ravikumar N

Clinical trials move closer to regional ecosystems

One of the most visible shifts is the growing move towards regionalised clinical trials and localised manufacturing. According to Yogesh Joshi, Associate Director and Head – Formulation Development (CDMO vertical)/Head Clinical Manufacturing, Piramal Pharma Solutions, geopolitical fragmentation is accelerating the transition away from centralised global operating models toward more regionally resilient frameworks.

"Companies are moving away from centralised global supply models in favour of regionally resilient frameworks that better support business continuity," he says. "This change is becoming particularly evident in clinical research. Pharma companies are increasingly expanding trials into regions such as Asia-Pacific and Latin America, driven by the need to diversify operational risk while accessing large and diverse patient populations. In the future, resilience and geographic diversification will become just as important as speed and cost efficiency in clinical development planning."

"The regionalisation of clinical trials is driven by inconsistencies in trade policies among sponsors and limitations associated with centralised global hubs," Joshi explains. "As a result, pharma companies are increasingly turning to regions such as Asia-Pacific, particularly India and South Korea, and Latin America."

He adds that these regions offer several strategic advantages beyond cost arbitrage.

"These regions provide lower operational costs, dense patient populations, faster recruitment potential, and increasingly stronger scientific capabilities. However, the shift also introduces new complexities. Companies must now navigate varying regional regulatory requirements, differences in data standards, fragmented approval systems, and evolving compliance expectations. Designing trials that remain globally acceptable while meeting local regulatory realities is becoming a far more complex exercise than before."

"Designing trials to meet varying regional regulatory requirements remains challenging, particularly when local regulatory environments lack flexibility," Joshi adds.

The shift toward decentralised and regionalised trial ecosystems is also changing how pharma companies think about patient diversity, real-world evidence generation, and regulatory submissions. Multi-regional clinical strategies are becoming critical not just from a compliance standpoint, but also from a commercial and operational risk-management perspective.

Resilience becomes new strategy

Dr Madhusudhan Bommagani, President, FR&D, Cadila Pharmaceuticals believes this transformation reflects a much deeper structural reset underway across the pharma industry.

"Geopolitical fragmentation is undeniably acting as a primary catalyst for a structural shift toward regional clinical trials and localised manufacturing strategies," he says. "Historically, pharma manufacturing decisions were driven almost entirely by cost optimisation, leading to heavy concentration of API and key starting material production in a few geographies. But geopolitical uncertainty has fundamentally altered industry priorities. Geopolitical friction has transformed 'resilience' into the new metric of efficiency."

According to Dr Bommagani, the global pharma industry is gradually moving away from hyper-centralised supply chain models that dominated the last two decades. "The industry historically depended on a highly interconnected and centralised global manufacturing ecosystem. But repeated disruptions — from the pandemic to geopolitical conflicts — have demonstrated that overdependence on limited geographies creates long-term operational vulnerabilities. Today, governments and pharma companies alike are focusing on building redundancy, supply continuity, and regional self-sufficiency into the system."

Governments across the world are now pushing domestic manufacturing and near-shoring strategies to reduce dependency on single geographies for critical medicines. India's Production Linked Incentive (PLI) schemes, alongside similar policy interventions in the US and Europe, are part of a broader global effort to secure pharma supply chains.

Bommagani believes this transition is also changing the role of R&D itself. Traditionally, R&D focused heavily on speed, formulation efficiency, and regulatory timelines. Today, however, development teams are increasingly expected to integrate supply chain resilience, manufacturing flexibility, and geopolitical risk assessment into development strategies from the earliest stages of product planning.

At the same time, AI and digitalisation are beginning to play a much larger role in helping pharma companies build more agile R&D systems. Predictive analytics, digital twins, AI-driven process optimisation, and automated documentation systems are helping organisations reduce development delays while improving operational visibility.

Why localisation may not work for generics

While localisation is increasingly becoming the dominant narrative globally, some R&D leaders caution against treating it as a universal solution.

Ravikumar N, President – Formulations R&D, MSN Laboratories argues that for the generics industry, complete onshoring may not be commercially sustainable. "Let's be brutally honest: as generic R&D leaders, are we designing pipelines for political applause, or are we designing them to

survive the market?" he asks.

"The economics of generics are extremely unforgiving. In a hyper-commoditised market governed by aggressive tenders and reference pricing, even a moderate increase in manufacturing costs can destroy the commercial viability of a product. If resilience strategies are implemented without commercial realism, we risk creating development models that look strategically attractive on paper but fail economically in the market."

According to Ravikumar, the economics of generics leave very little room for expensive restructuring. In highly commoditised markets driven by aggressive tender systems and reference pricing, even a modest increase in manufacturing costs can destroy commercial viability.

"If an on-shored supply chain increases our Cost of Goods Sold by even 15 per cent, the product is dead on arrival," he says. "The generics industry cannot absorb large-scale cost inflation in the same way high-margin innovative businesses can. Commercial sustainability must remain central to every localisation discussion," he adds.

He also points out that shifting final API synthesis to Western markets does not necessarily eliminate supply vulnerabilities if the foundational key starting materials (KSMs) remain heavily concentrated in Asian manufacturing clusters.

"If the foundational KSMs remain 80 per cent concentrated in Asian industrial clusters, have we actually removed the single point of failure? No," Ravikumar notes. "We may simply be relocating the visible part of the supply chain while the real dependency remains unchanged upstream."

Instead of pursuing localisation, he advocates what he describes as a 'bifurcated' R&D strategy — one that separates low-margin commodity generics from high-value complex products.

Flexible formulation science and agile manufacturing

For commodity small molecules, Ravikumar believes the answer lies not in expensive manufacturing duplication but in smarter formulation science. He argues that R&D teams must develop highly robust "platform formulations" capable of tolerating variations in API particle size, polymorphic forms, or impurity profiles across multiple suppliers.

"If we design formulations that can seamlessly accommodate varying API profiles, we break our dependency on any single synthesis route," he explains. "The future of generics resilience lies not just in where we manufacture, but in how intelligently we design formulations and regulatory strategies from the very beginning."

He also stresses the importance of leveraging regulatory flexibility through frameworks such as ICH Q12 to accelerate supplier substitution during disruptions. By establishing broader pre-approved conditions and multi-source Drug Master Files (DMFs), companies can respond faster when supply routes are interrupted.

"When a chokepoint closes, the regulatory switch can be executed through an internal protocol rather than waiting through multi-month variation approvals," he says. "That level of regulatory agility will become increasingly critical in a fragmented global environment."

For higher-value therapies such as peptides and complex biologics, however, Ravikumar believes greater localisation and manufacturing redundancy may make commercial sense. In these segments, he sees significant potential for modular Continuous Flow Manufacturing (CFM) technologies that can support smaller, flexible, and geographically distributed production models.

"CFM units have a shipping-container footprint and can be deployed domestically within modern green-chemistry compliance frameworks," he explains. "For high-value products, the economics of redundancy are fundamentally different. Here, investing in domestic capabilities and upstream integration can become a strategic competitive advantage."

At the same time, Ravikumar cautions against unrealistic expectations around complete supply chain decoupling from China, especially in small molecule chemistry. "Let's be realistic: there is no viable workaround for Chinese small molecule KSMs," he says.

"The scale and capital efficiency of East Asian chemical clusters cannot be replicated domestically without a low return on investment that no corporate board will fund. Rather than pursuing unrealistic chemical decoupling, companies should focus on designing structural agility into products and development systems."

Instead, he argues that pharma companies should focus on designing structural agility into drug development itself, ensuring products can rapidly adapt to changing supplier ecosystems and geopolitical disruptions.

India's opportunity beyond "pharmacy of the world"

Despite differing approaches, all three R&D leaders agree on one larger reality: geopolitical uncertainty is no longer a temporary disruption for the pharma industry. It is becoming a permanent feature of the operating environment, forcing pharma R&D to evolve from a cost-driven function into a resilience-driven one.

For India, this transition also presents a major strategic opportunity.

Joshi and Bommagani believe the current geopolitical climate could help India move beyond its long-standing role as the "pharmacy of the world" and emerge as a global innovation hub.

"India is positioned to leverage the current geopolitical environment to emerge as a global innovation hub in pharma and biotechnology," says Joshi. "The ongoing diversification of global supply chains is encouraging multinational pharma companies to explore alternative destinations for manufacturing, research, and development. India's scientific talent, manufacturing scale, regulatory experience, and cost competitiveness position it very strongly in this transition."

The ongoing diversification of global supply chains has encouraged multinational pharma companies to explore alternative destinations for manufacturing, research, and development. India's combination of cost competitiveness, scientific talent, manufacturing scale, and regulatory experience makes it a strong contender.

Importantly, India's strengths are no longer confined to manufacturing alone. Its large and diverse patient population provides a major advantage in clinical research and data generation.

"With a large and diverse patient population, India offers significant advantages for conducting clinical trials across therapeutic areas," Joshi says. "This diversity enables the generation of robust and globally relevant clinical data, which becomes increasingly important for precision medicine, biologics, and real-world evidence generation."

Bommagani believes the global "China+1" strategy has created a historic opening for India to move up the pharma value chain. He says, "The global desire to diversify supply chains presents a historic window for the Indian pharma industry to pivot from high-volume generics to high-value innovation," he says. "India now has an opportunity not just to manufacture for the world, but to become a trusted global partner across innovation, CDMO services, clinical development, and advanced therapeutics."

India's growing biotech ecosystem, digital infrastructure, and expanding CDMO sector are increasingly positioning the country as a preferred partner for global clinical research, biologics, biosimilars, and advanced drug delivery systems.

However, the R&D leaders also acknowledge that India's ambitions will require deeper structural reforms. Regulatory timelines need greater predictability and alignment with global standards. Investments in advanced research infrastructure, translational science, and talent development will be essential. Stronger intellectual property protections will also remain critical for attracting innovation-led investments.

Preparing for uncertain future

Still, the broader direction is becoming increasingly clear. The pharma industry is entering an era where resilience, diversification, and strategic flexibility will define long-term competitiveness.

The traditional pharma operating model, built heavily around centralisation, efficiency, and lean globalisation is now being replaced by a more distributed and risk-aware framework.

Future-ready pharma companies will increasingly need - diversified supplier ecosystems, flexible manufacturing platforms, digitally connected supply chains, regionally balanced clinical strategies, and resilient regulatory planning models.

In many ways, geopolitical uncertainty is now becoming a design parameter for pharma R&D itself. And for India, the next phase of growth may ultimately depend on how effectively it transforms geopolitical disruption into an opportunity in innovation, R&D, and future-ready pharma strategy.

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Quality under pressure: Strengthening continuity amid geopolitical uncertainty

One of the most persistent risks facing Indian pharma manufacturers is the industry's heavy dependence on China for KSMs and APIs.For decades, this arrangement offered cost advantages that were difficult to resist. Today, however, that dependence is being exposed as a serious quality liability, cautions **Kalyani Sharma**

As geopolitical tensions continue to disrupt global trade routes, increase supply chain uncertainty, and intensify regulatory scrutiny, quality operations within the Indian pharma industry are rapidly changing from compliance-focused functions into strategic pillars of continuity. Once considered a back-office discipline, quality management is now firmly in the boardroom, as companies reckon with vulnerabilities that stretch across geographies, logistics networks, and supplier bases.

The sector accounts for over $58 billion in revenues in 2025-26, with projections cited by Dr Ranjit Barshikar, CEO, QbD International and United Nations/MPP Geneva Adviser suggesting it could cross $130 billion by 2030. But getting there demands a fundamental rethink of how quality is structured, staffed, and sustained under pressure.

The China dependency: A quality time bomb

One of the most persistent risks facing Indian pharma manufacturers is the industry's heavy
dependence on China for key starting materials (KSMs) and active pharmaceutical ingredients (APIs). For decades, this arrangement offered cost advantages that were difficult to resist. Today, however, that dependence is being exposed as a serious quality liability.

According to Dr Barshikar, sourcing 65-70 per cent of KSMsfrom China introduces sudden trade-halt risks, where supply shortages force rapid switching to unverified secondary chemical vendors, directly affecting quality standards. He further warns that hurriedly purchased raw material from alternative sources increases the risk of unexpected nitrosamine or mutagenic contamination.

Dr Ranjit Barshikar

When supply from primary Chinese vendors is cut off, whether due to trade tensions, port shutdowns, or regulatory action, manufacturers are forced to find alternatives quickly. But speed and quality assurance are often in conflict. Rushed procurement from unverified vendors introduces risks that can take months or years to fully surface. Nitrosamine contamination, in particular, has been a flashpoint for global regulators over the past several years, triggering large-scale recalls and heightened inspection activity.

Compounding the raw material challenge, Dr Barshikar notes that quality units may also face severe concurrent variations for alternative manufacturing site registrations when primary sources are disrupted, adding a significant regulatory burden on top of an already stretched quality function.

Mohan Jain

Rerouted ships, degraded products: The quality crisis

Beyond raw material sourcing, geopolitical instability is creating serious logistics-related quality risks, particularly for companies handling temperature-sensitive biologics, injectables, and complex formulations. The ongoing conflict in West Asia and US tariffs are putting severe strain on revenue and logistics.

Dr Barshikar points out that extended shipping routes via the Cape of Good Hope are likely to degrade temperature-sensitive biologics and active ingredients, and that longer transit times may cause stability issues before ingredients even arrive at manufacturing sites.

Mohan Jain, Director, Naprod Life Sciences, describes these disruptions as a problem with direct quality consequences. "The ongoing conflict in West Asia has created shipping bottlenecks, sharply increased freight costs (in some cases doubling transport charges and surcharges), and forced rerouting of critical cargo, including APIs and excipients bound for India and exported finished formulations out of India," he says.

"These dynamics extend lead times, create customs unpredictability, and intensify cold-chain failure risks for temperature-sensitive products, thereby escalating the scrutiny and resource requirements for quality control processes and logistics monitoring," Jain adds.

For a specialty manufacturer producing products that require strict cold-chain integrity and cGMP compliance, these pressures mean quality teams must plan for extended transit times, enhanced oversight of logistics performance, and more rigorous inbound inspection protocols, combining risk forecasting and compliance agility to safeguard product integrity during shipment and storage as geopolitical tensions evolve.

Price volatility and the supplier qualification challenge

Geopolitical pressures are not just disrupting logistics. They are also changing the economics of raw material procurement in ways that have significant downstream quality consequences.

As Jain notes, geopolitical tensions have resulted in widespread price volatility for APIs, solvents, and other key raw inputs, particularly those sourced from China. Recent reports cited by Jain highlight surges of up to 60 per cent in raw material prices and significant logistic cost inflation, which strain procurement strategies and force companies to re-evaluate supplier qualification frameworks. Higher freight costs and expensive local KSM alternatives, Dr Barshikar adds, may add further woes to the industry.

This puts quality teams in a difficult spot. Cost pressures push procurement towards cheaper or less-established suppliers, while regulatory expectations around supplier qualification are simultaneously tightening. Jain explains that this environment requires companies to revalidate vendor capabilities continuously, expand supplier directories, and maintain deeper documentation to ensure regulatory compliance and batch traceability.

These sourcing challenges have a cascading effect on compliance processes. As Jain observes, auditors now increasingly expect cross-verified audit trails, digital records, and multi-tier supplier assessments even for alternate sources introduced in response to supply shortages. Maintaining operational continuity means balancing the urgency of diversifying input sources with the rigour of qualification and change control processes. This often results in parallel supplier development tracks, written evidence of qualification activities, and harmonised documentation that satisfies both domestic regulators and global markets.

Dr Barshikar suggest that quality units run parallel qualification protocols to ensure at least three vendors exist per API. He also recommends that companies draft a Supplier Quality Agreement template specifically for high-risk regions.

Regulatory scrutiny intensifies at the worst possible moment

Just as companies are dealing with supply chain volatility, cost inflation, and logistics disruptions, they are also facing sharper scrutiny from global regulators. Dr Barshikar points out that the USFDA, EMA, WHO, and CDSCO are increasing unannounced inspections to detect quality issues caused by supply pressures, and that global regulators now demand rigorous lifecycle risk management reports for every critical starting material.

Delays in regulatory inspections are creating their own bottlenecks. Delay in global regulatory inspections may cause plants to wait months for clearance to launch new products, adding to the pressure on quality teams, who must maintain any-time audit readiness rather than preparing only for scheduled visits.

Geopolitical barriers are also making supplier audits harder to conduct. Dr Barshikar flags that geopolitical border restrictions and costs may prevent quality teams from performing on-site vendor audits. Reliance on remote, desk-based photo or paper audits hides operational deficiencies at the raw material source resulting into higher risks of failures and delay in manufacturing operations and supply chain. Over the period it may result in data integrity issues.

Regulatory expectations are also tightening around traceability, supply-chain transparency, and data integrity, particularly following high-profile quality incidents globally. As Jain notes, pharmaceutical quality teams must invest in enhanced laboratory capabilities, digital record-keeping, and proactive inspection readiness, moving beyond reactive compliance. Balancing rising compliance costs with operational efficiency requires sophisticated risk-based quality management systems that clearly define each control and demonstrate how it mitigates risks to product safety and efficacy.

Digital transformation: From compliance tool to strategic enabler

Against this backdrop, digitalisation is emerging as one of the most important enablers of quality continuity. Dr Barshikar identifies digitised quality ecosystems, predictive AI modelling, in-house analytical facilities and expertise, and advanced quality systems as the key priorities for the next phase of pharma quality management. Transitioning to paperless plants, minimising human errors, and driving quality culture to achieve quality maturity, he says, will be added advantages from a patient safety perspective.

Companies are deploying digital QMS platforms to centralise documentation, automate compliance workflows, and strengthen traceability across multi-tier supplier networks. Dr Barshikar points to the implementation of continuous process verification (CPV) via predictive software that flags material variations instantly, alongside AI-driven document management systems being used to fast-track regulatory variation filings across multiple regions.

The industry is also looking at AI-driven drug discovery as a longer-term strategic lever. Adoption of AI in drug development, Dr Barshikar notes, is expected to reduce development timelines and may save 50 per cent of time and costs, positioning India as an innovator for the world rather than just a generic supplier.

To address the challenge of remote auditing, organisations may deploy high-definition smart glasses for real-time, interactive remote visual facility tours, a technology Dr Barshikar highlights as a practical solution to the on-site audit gap created by geopolitical border restrictions.

For Jain, the technological changes in quality functions are inseparable from broader business continuity planning. He notes that, technologically, adopting advanced quality frameworks with real-time data analytics, integrated supplier portals, predictive risk modeling, and tools like blockchain for traceability enhances transparency, streamlines compliance, and enables faster responses to regulatory or geopolitical shifts, supporting robust product quality and supply chain integrity.

Risk management as organisational culture

Beyond technology and process changes, industry leaders are increasingly recognising that building genuine quality continuity requires a deeper cultural shift. Jain is clear on this point: embedding risk management into organisational culture, rather than treating it as a compliance formality, enables more agile responses to unforeseen global events while maintaining product quality and operational continuity.

To reduce the impact of disruptions, Indian pharma companies are adopting multi-layered strategies, Jain notes. They are diversifying suppliers to avoid dependence on single geographies, increasing buffer stocks for critical inputs, and tracking supplier performance through metrics like on-time delivery, CoA consistency, and audit history. These efforts are supported by digital quality management systems that centralise documentation, automate compliance checks, and enhance traceability across the supply chain.

This cultural shift is also changing the role of the quality professional. Where quality was once seen primarily as a function responsible for catching and correcting defects, it is increasingly being treated as a core part of business strategy, one that informs procurement decisions, supplier strategies, logistics planning, and regulatory engagement. For Jain, maintaining stringent quality management alongside R&D integration is central to how Naprod approaches this challenge, ensuring that quality considerations are built into product development from the start, not bolted on at the end.

Building domestic capacity and going beyond generics

While digital transformation and supplier diversification address immediate vulnerabilities, industry leaders are clear that long-term continuity will require structural investments in domestic manufacturing. Dr Barshikar points to India's investment in 'plug-and-play' mega bulk drug parks as a foundational step, aiming for self-reliance in KSMs and reducing the country's dependence on China.

Jain frames this argument in terms of both quality and continuity. Future-proofing quality functions, he says, requires both structural and technological investments beyond short-term fixes. Structurally, building domestic capacity for key APIs, solvents, and excipients, supported by government incentives and production subsidies, can reduce dependence on international supply chains and strengthen the ability to maintain consistent quality and uninterrupted supply when disruptions occur.

At the same time, companies are shifting their strategic ambitions. Dr Barshikar notes that Indian pharma companies are moving toward high-value biologics and biosimilars, strengthening regulatory standards through USFDA-compliant plants, and diversifying into emerging markets like Africa and Southeast Asia to reduce dependency on the US/China axis. This strategic expansion is inseparable from quality, as entering regulated markets and high-value product segments demands quality systems of a higher order.

According to Dr Barshikar, drugs worth over $236 billion are expected to lose patent exclusivity between 2025 and 2032, a patent cliff that opens significant market share for Indian generic manufacturers in the US and Europe. Capturing that opportunity will require strong quality systems, reliable supply chains, and the ability to sustain compliance across multiple markets at the same time.

Quality as competitive advantage

As geopolitical uncertainty becomes a long-term reality rather than a passing disruption, Indian pharmaceutical companies are arriving at an important realisation: quality continuity is not just a regulatory obligation. It is what sets companies apart in global markets.

Companies that can demonstrate supply chain transparency, consistent product quality, and forward-looking risk management are better placed to retain regulatory approvals, hold on to key customers, and compete for market share as global buyers look to spread their sourcing away from single-country dependencies.

The industry's response is already taking shape through supplier diversification, digital quality transformation, predictive analytics, stronger audit frameworks, and investments in domestic manufacturing. Any-time audit readiness, advanced quality systems, and supply chain de-risking are emerging as the defining priorities for Indian pharma's quality leadership. Going forward, quality systems are expected to become more proactive, technology-driven, and closely tied to broader business continuity strategies as Indian pharma prepares for a more uncertain global environment.

For Indian pharma's ambition to be the world's pharmacy, quality under pressure is not just a challenge to manage. It is what will determine which companies lead, and which fall behind, in the years ahead.

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INDORE PHARMA SUMMIT 2026
INDIA PHARMA RISING
COMPETING IN A NEW GLOBAL ORDER

Indore Pharma Summit: Mapping the future of India pharma

From AI and smart manufacturing to sustainability, quality culture, faster drug development, and CDMO opportunities, the summit highlighted how India's pharma industry is preparing for a more innovation-led and globally competitive future. Reports **Swati Rana**

As India's pharma industry prepares for a future shaped by innovation, AI, sustainability, regulatory transformation, and global competition, one message emerged strongly at the Indore Pharma Summit 2026 — the next phase of India Pharma Inc will not be defined by scale alone, but by how collaboratively the industry evolves.

Held in Indore on 8th May, 2026, the summit brought together pharma leaders, regulators, manufacturing experts, quality professionals, academia, technology providers, and supply chain specialists to discuss the future of Indian pharma across manufacturing, R&D, quality, sustainability, skilling, and global competitiveness.

The summit commenced with a ceremonial lamp lighting led by Ranjit Menon,Site Head - Indore Manufacturing, Cipla; Mahanand Thakur, VP-Operations, McW Healthcare;Amit Malviya, VP-Quality Assurance, Zest Pharma; Suveer Shrivastava, Global Pharma Compliance Expert; ShilpySingh, GM & Head-ProjectManagement, Piramal Pharma; Ajay Singh Dassundi, Secretary, MP Small andMedium Drugs Manufacturers Association; Vikalp Nagori, Associate Director - Formulation TechnologyTransfer, Cipla; and Rajesh Bhatkal, Vertical Head, Express Pharma.

L - R : Ranjit Menon,Site Head - Indore Manufacturing, Cipla; Mahanand Thakur, VP-Operations, McW Healthcare;Amit Malviya, VP-Quality Assurance, Zest Pharma; Suveer Shrivastava, Global Pharma Compliance Expert; ShilpySingh, GM & Head-ProjectManagement, Piramal Pharma; Ajay Singh Dassundi, Secretary, MP Small andMedium Drugs Manufacturers Association; Vikalp Nagori, Associate Director - Formulation TechnologyTransfer, Cipla; and Rajesh Bhatkal, Vertical Head, Express Pharma

India Pharma 2035: The next global leadership story

The opening panel discussion titled 'India Pharma 2035: The Next Global Leadership Story', set the tone for the summit by examining how India can transition from a volume-driven pharma economy into a globally respected innovation-led healthcare ecosystem.

Moderated by Suveer Shrivastava, Global Pharma Compliance Expert, the panel featured Amit Malviya, VP-Quality Assurance, Zest Pharma; Mahanand Thakur, VP-Operations, McW Healthcare; Shilpy Singh, GM & Head-Project Management, Piramal Pharma; and Vikalp Nagori, Associate Director - Formulation Technology Transfer, Cipla.

One of the strongest themes emerging from the discussion was that India's pharmaceutical future cannot remain dependent solely on conventional generic manufacturing. While India's position as the "pharmacy of the world" remains globally significant, panelists argued that the next growth wave would come from innovation-driven areas such as biosimilars, peptides, complex injectables, specialty therapies, and globally competitive drug development.

The panel emphasised that Indian pharma companies must now move from cost leadership to capability leadership.

According to the panelists, innovation itself must become more purposeful and patient-centric. The future of R&D will not be defined simply by the number of products developed, but by whether those innovations address real and underserved healthcare needs.

The panel stressed that proof of concept and patient impact must become central to innovation strategies. Incremental innovation without clear therapeutic value would struggle to remain commercially relevant in increasingly competitive global markets.

The discussion also highlighted the critical role of regulatory support in building a stronger innovation ecosystem. Panelists noted that agencies such as CDSCO will play an in-

L-R: Suveer Shrivastava, Global Pharma Compliance Expert; Amit Malviya, VP-Quality Assurance, Zest Pharma; Mahanand Thakur, VP-Operations, McW Healthcare; ShilpySingh, GM & Head-ProjectManagement, Piramal Pharma; and Vikalp Nagori, Associate Director - Formulation TechnologyTransfer, Cipla

creasingly important role in encouraging entrepreneurship, accelerating approvals, enabling innovation, and retaining scientific talent within India.

Another key focus area was digital transformation. AI and automation emerged repeatedly during the discussion as non-negotiable pillars of the future pharma industry. Panelists agreed that Indian pharma companies can no longer treat digitalisation as an optional operational upgrade.

Instead, AI-enabled systems, automated manufacturing, digital quality systems, and data-driven compliance frameworks are becoming essential for improving transparency, reducing manual dependency, enhancing operational consistency, and preparing Indian pharma for future regulatory expectations.

The panel also emphasised that India's long-term global credibility will depend heavily on ethical practices, accountability, data integrity, quality culture, and patient-centricity.

As regulatory scrutiny increases globally, the speakers stressed that trust and compliance will increasingly become strategic business differentiators rather than just regulatory obligations.

The panel concluded with a broader message that India Pharma Inc must adopt a proactive approach toward innovation, future-ready manufacturing, capability building, and global collaboration if it aims to emerge as a long-term global pharma leader.

Smart manufacturing gains momentum

Technology-driven transformation in pharma manufacturing formed another major pillar of the summit.

In the session on 'Smart Industrial Weighing Solutions', Murali Krishna Veeramallu, Head – Industrial Division, Smart Labtech, highlighted how precision systems and digital manufacturing technologies are becoming increasingly critical for modern pharma operations.

According to Veeramallu, Smart Labtech has evolved into a strong 'Make in India' laboratory and industrial weighing solutions manufacturer with more than 1000 installations across pharma and industrial facilities.

He explained that modern pharma manufacturing now requires far more than standalone instruments. Companies increasingly require integrated, connected, and compliance-focused systems capable of supporting Industry 4.0-ready operations.

The session showcased how smart weighing systems, analytical balances, moisture analyzers, dispensing systems, and digitally connected platforms are helping pharma manufacturers improve traceability, compliance, and operational efficiency. Veeramallu also highlighted the importance of 21 CFR Part 11-compliant systems in ensuring data integrity and audit readiness.

The broader takeaway from the session was clear: digital manufacturing infrastructure is no longer a future investment for pharma companies. It is becoming a present-day operational necessity.

Faster coating technologies

Manufacturing productivity and process optimisation remained another major area of discussion during the summit.

In the session titled 'Faster Coating Technology Advantage', Akil Kadiyavala, GM - Technical Services, Dhara Lifescience, discussed advances in pharma coating technologies aimed at improving manufacturing speed, process consistency, and overall operational efficiency.

According to Kadiyavala, coating remains one of the most time-intensive stages in oral solid dosage manufacturing. Reducing coating cycle time while maintaining uniformity and quality can significantly improve manufacturing productivity and reduce operational costs. He highlighted Dhara Lifescience's coating solutions such as Readycoat HS and Readycoat EZE, which can reduce coating process time by up to 50 per cent.

Murali Krishna Veeramallu, Head – Industrial Division, Smart Labtech

Akil Kadiyavala, GM - Technical Services, Dhara Lifescience

Ranjit Menon, Site Head - Indore Manufacturing, Cipla

Vivek Asthana, Head EHS & Sustainability, Symbiotec Pharmalab

Prof (Dr) Neelesh Malviya, Principal, Smriti College of Pharmaceutical Education

L-R: Sanjay Tiwari, Pharma Consultant, Dayanand More, Head Site - Operation, Alembic Pharma; Nishikant Ghadge, VP (R&D and Manufacturing), Symbiotec Pharma; Nitin Tiwari, VP-CQA and Cluster Head (Indore, Dewas, Ratlam and Wardha), Ipca Laboratories; Dr Bipin Chaubey, Head of Site Process & Technology (Dewas), Sun Pharmaceutical Industries; Dr Sharad Jain, AVP, PSA Chemicals and Pharmaceuticals; and Gopinath Santhosh, GM - Supply Chain Management, Felix Generics

L-R: Dr Vipin Saxena, Director, Vishwa Life Sciences; Paresh Chawla, MD, Alpa Laboratories; Amit Chawla, Director, McW Healthcare; Tapan Das, Sr GM - Quality, Sun Pharmaceutical Industries; Mahendra Kumar Sahu, GM, Sun Pharmaceutical Industries; Nikhil Sahu, Sr Group Leader and Head – Packaging Development, Knovea Pharmaceuticals; and Praveen Jindal, Deputy Chief Manager, Piramal Pharma (Pithampur)

The session demonstrated how advanced polymer science and formulation engineering are helping manufacturers achieve faster processing, improved coating uniformity, and better batch consistency. Kadiyavala also emphasised that globally competitive manufacturing increasingly depends on combining speed with scientific precision. He explained that modern pharma excipient and coating technologies must deliver not only faster throughput, but also improved process robustness, regulatory compliance, and scalability.

The company's focus on strong R&D capabilities, advanced polymer technologies, and global certifications reflects the broader trend of Indian pharma suppliers moving toward higher-value and technology-driven offerings.

Quality becomes a strategic leadership function

One of the summit's most impactful discussions focused on the evolving role of quality within pharma organisations. Speaking on 'Quality as Strategy: Winning Trust in Global Markets', Ranjit Menon, Site Head - Indore Manufacturing, Cipla, pointed out that quality can no longer remain confined to compliance departments.

He stated that, quality is no longer just compliance. It is a strategic leadership function driving business success, Menon highlighted how the pharma industry is increasingly moving toward patient-centric and risk-based quality systems.

Rather than treating compliance as a checklist activity, companies are now expected to embed quality thinking into every stage of manufacturing, operations, decision-making, and leadership. The session focused extensively on the growing importance of data integrity and transparent decision-making.

According to Menon, regulatory confidence and market trust increasingly depend on the reliability, traceability, and transparency of manufacturing data. As global inspections become more sophisticated and digitally driven, pharma companies must create strong quality cultures where accountability and integrity are deeply embedded across functions.

The session also reinforced that quality excellence is no longer merely a regulatory expectation. It has become directly linked to business sustainability, global market access, and long-term reputation.

Gajanan Patil, COO, H&H Healthcare and Cosmetics

Sustainability emerges as a business imperative

In the session titled 'Sustainability as Strategy: The Next Frontier for Pharma Leaders', Vivek Asthana, Head EHS & Sustainability, Symbiotec Pharmalab, argued that ESG is rapidly becoming fundamental to pharma business continuity, investor confidence, and long-term competitiveness.

Asthana pointed out that sustainability can no longer be viewed as a peripheral corporate social responsibility initiative. Emphasising that it is fundamental to survival, credibility and growth,

The session highlighted how regulators, investors, customers, and global buyers are increasingly evaluating pharma companies not just on financial performance, but also on how responsibly those returns are generated.

Asthana discussed how frameworks such as SEBI's Business Responsibility and Sustainability Reporting (BRSR) requirements are increasing pressure on companies to improve transparency around environmental, social, and governance practices.

Global procurement trends are also evolving rapidly. According to Asthana, multinational customers and global pharma buyers are increasingly prioritising ethical, transparent, and sustainable manufacturing partners. The session highlighted that sustainability is gradually moving from a compliance-driven activity toward becoming a core business strategy influencing investment decisions, partnerships, procurement, and long-term market positioning.

Strengthening industry-academia collaboration

Talent development and industry-academia collaboration formed another important dimension of the summit discussions. Addressing the session on 'Academia-Industry Collaboration for the Development of Future Pharma Professionals', Prof (Dr) Neelesh Malviya, Principal, Smriti College of Pharmaceutical Education, Indore, highlighted the urgent need to bridge the gap between academic learning and industry requirements.

According to Prof Malviya, stronger academia-industry collaboration is essential for transforming research into commercially viable innovation. He explained that industry-aligned research can accelerate commercialisation, solve practical manufacturing and R&D challenges faster, and reduce development costs. The session emphasised that

pharma education can no longer remain isolated from industry realities.

Prof Malviya stressed that continuous interaction between academia and industry is critical to developing future-ready pharma professionals capable of adapting to rapidly evolving technologies, regulatory systems, manufacturing techniques, and research environments.

The discussion also highlighted how stronger collaboration can encourage entrepreneurship, modernisation, and sustainable societal growth. The broader message from the session was that India's pharma growth ambitions will depend heavily on building stronger skilling ecosystems and creating a workforce capable of supporting future innovation-led growth.

From molecule to market faster

One of the summit's most engaging and technically rich discussions was the panel discussion titled From Molecule to Market Faster: Rethinking Drug Development.

Moderated by Sanjay Tiwari, Pharma Consultant, the panel featured Dayanand More, Head Site - Operation, Alembic Pharma; Nishikant Ghadge, VP (R&D and Manufacturing), Symbiotec Pharma; Nitin Tiwari, VP-CQA and Cluster Head (Indore, Dewas, Ratlam and Wardha), Ipca Laboratories; Dr Bipin Chaubey, Head of Site Process & Technology (Dewas), Sun Pharmaceutical Industries; Gopinath Santhosh, GM - Supply Chain Management, Felix Generics; and Dr Sharad Jain, AVP, PSA Chemicals and Pharmaceuticals.

The discussion focused on one of the pharma industry's biggest challenges: how to accelerate drug development and commercialisation timelines without compromising quality, scientific rigor, or patient safety.

Panelists repeatedly emphasised that speed alone cannot define successful pharma development. Instead, the future of drug development will depend on balancing scientific understanding, process robustness, analytical excellence, supply chain resilience, and regulatory readiness.

The panel highlighted the growing importance of strong API and Key Starting Material (KSM) ecosystems in enabling resilient and faster pharma development. Given increasing geopolitical disruptions and supply chain volatility, speakers stressed that India must continue strengthening domestic API and intermediate capabilities to reduce dependency risks.

Another major takeaway was the importance of cross-functional collaboration. The panelists agreed that faster commercialisation increasingly depends on stronger coordination between R&D teams, API manufacturers, regulators, analytical experts, supply chain partners, and logistics providers.

The discussion also explored the transformative role of AI and digital technologies across pharma development. According to the speakers, AI-enabled systems are increasingly reshaping drug discovery, clinical trial management, regulatory workflows, documentation systems, process optimisation, and manufacturing analytics. Digital tools are helping pharma companies reduce timelines while simultaneously improving process efficiency, data visibility, and decision-making accuracy.

Integrated supply chains emerged as another critical requirement. The panel highlighted that robust end-to-end visibility across procurement, development, manufacturing, and logistics operations is essential for reducing delays from molecule development to market launch.

The session also highlighted the often-underestimated role of logistics. Speakers pointed out that maintaining product integrity during transportation is just as important as manufacturing quality itself, particularly for temperature-sensitive and complex pharma products.

Overall, the panel reinforced that future pharma competitiveness will depend not only on innovation speed, but on the ability to build scientifically robust, digitally connected, and operationally resilient development ecosystems.

India's CDMO opportunity

Speaking on 'CDMO Opportunity: India's Next Manufacturing Advantage', Gajanan Patil, COO, H&H Healthcare and Cosmetics, highlighted how the global pharma industry is increasingly shifting from traditional manufacturing models toward strategic CDMO partnerships.

According to Patil, pharma companies worldwide are seeking manufacturing partners capable of delivering cost efficiency, speed, innovation, flexibility, and supply chain resilience. He noted that the ongoing China+1 strategy is creating significant opportunities for Indian pharma manufacturers. India's scientific talent base, regulatory credibility, manufacturing capabilities, and cost competitiveness position the country strongly to capture the next wave of global CDMO growth.

Patil also highlighted the strategic advantages of the Indore-Pithampur pharma ecosystem. According to him, the region possesses strong infrastructure, export capabilities, logistics connectivity, industrial ecosystems, and talent availability that could help it emerge as a major global pharma CDMO hub.

The session highlighted that India's future manufacturing opportunity lies not just in scale-based manufacturing, but in building integrated development and manufacturing partnerships capable of supporting complex global pharma programmes.

Indore: Next manufacturing powerhouse

The summit concluded with a high-energy panel discussion titled 'Indore Rising: Central India's Next Manufacturing Powerhouse'.

Moderated by Dr Vipin Saxena, Director, Vishwa Life Sciences, the panel featured Paresh Chawla, MD, Alpa Laboratories; Amit Chawla, Director, McW Healthcare; Tapan Das, Sr GM - Quality, Sun Pharmaceutical Industries; Mahendra Kumar Sahu, GM, Sun Pharmaceutical Industries; Nikhil Sahu, Sr Group Leader and Head – Packaging Development, Knovea Pharmaceuticals; and Praveen Jindal, Deputy Chief Manager, Piramal Pharma (Pithampur).

The discussion focused on how Madhya Pradesh — particularly the Indore-Pithampur belt — is steadily emerging as one of India's important pharma manufacturing ecosystems. Panelists highlighted that proactive governance, infrastructure support, industrial policies, and subsidies are helping create a more industry-friendly environment for pharma investments in the state.

However, the panel also acknowledged several operational challenges that continue to affect pharma MSMEs. One of the biggest concerns raised during the discussion was skilled manpower retention. Despite the region's growing industrial ecosystem, retaining technically skilled professionals remains a challenge for several companies.

The panel also discussed delayed payment cycles and their impact on MSME cash flows, operational stability, and expansion plans. Another major theme was the need to strengthen local support ecosystems. According to the panelists, Indore's next phase of growth cannot rely solely on manufacturing expansion.

Instead, the region must build integrated local ecosystems across R&D, testing laboratories, packaging development, analytical services, regulatory support, and specialised pharma services.

The discussion also explored the role of pharma parks and allied industrial clusters. Panelists emphasised that integrated pharma parks with connected ancillary industries can significantly improve collaboration, productivity, operational efficiency, and supply chain coordination.

The issue of skilling remained central throughout the panel discussion. Speakers repeatedly stressed that the future competitiveness of India Pharma Inc will ultimately depend on continuous skill upgradation. As pharma manufacturing technologies, materials, automation systems, and regulatory expectations evolve rapidly, the industry must continuously invest in workforce development.

The panel also emphasised the need for stronger industry-academia collaboration to build professionals who are truly industry-ready from the beginning of their careers. According to the panelists, pharma education itself must evolve with deeper industry participation and more practical, application-driven learning.

Way forward

As the Indore Pharma Summit 2026 concluded, one message resonated across every session and panel discussion: India's pharma industry stands at a defining inflection point. The future of India Pharma Inc will depend on how effectively the industry builds innovation capabilities, integrates AI and automation, strengthens quality systems, develops sustainable operations, accelerates drug development, creates resilient supply chains, and nurtures future-ready talent.

As India seeks to strengthen its global pharma leadership position, emerging ecosystems beyond traditional pharma clusters are expected to play a critical role in supporting the industry's next phase of growth.

The Indore Pharma Summit 2026 showcased more than just industry perspectives. It reflected a larger transition underway within Indian pharma itself — from scale-driven growth toward innovation-led, technology-enabled, quality-centric, and globally competitive development.

And as industry leaders repeatedly emphasised throughout the summit, the companies and ecosystems that succeed in the coming decade will be those willing to evolve continuously, collaborate deeply, and prepare proactively for the future.

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Kerala makes its MedTech intentions clear at DIA-KMTC Conference 2026

The two-day DIA-KMTC MedTech Conference in Thiruvananthapuram brought together regulators, industry leaders, clinicians, and innovators to have an honest conversation about where India's medical technology sector needs to go and what it will take to get there

Kalyani Sharma

On May 21 and 22, 2026, Thiruvananthapuram became the meeting point for India's medical technology community. The DIA-KMTC MedTech Conference 2026 organised by DIA (Drug Information Association) in partnership with the Kerala Medical Technology Consortium (KMTC) brought together regulators, entrepreneurs, clinicians, and quality professionals under a single theme: Concept to Care-Safe, Smart, and Scalable MedTech.

The timing made sense. India accounts for just about one per cent of the global medical device market-a striking gap given the country's large population, strong research institutions, and fast-growing healthcare system. That number was never far from the conversations across both days.

The event began with welcome remarks from **Dr Ashok Swain, General Manager and Executive Director of DIA** India, who set a warm and collaborative tone for the two days ahead, emphasising that in today's evolving healthcare ecosystem, collaboration is essential, not optional.

C. Padmakumar, Special Officer of KMTC, followed with remarks that were direct and honest. He pointed to a simple but important fact: India had no medical device regulations until 2017, and that gap had held the sector back more than most people acknowledged. Without regulations, most Indian MedTech companies did not meet international standards, leaving the market heavily dependent on imports. His message was clear, "KMTC's work with DIA was built on the belief that meeting global quality standards is not a hurdle to growth, but the very foundation of it."

Ashok Kumar Swain, General Manager and Executive Director of DIA India

C. Padmakumar, Special Officer of KMTC

Balagopal Chandrasekhar, Chairman of the Kerala State Industrial Development Corporation (KSIDC) and Programme Chair for the conference

Balagopal Chandrasekhar, Chairman of the Kerala State Industrial Development Corporation (KSIDC) and Programme Chair for the conference, built on that point in his opening address. He spoke about the need for real trust-not just in products, but in how companies work and how the system is run. He made a distinction that stayed with many in the room: following a process is not the same as having a quality culture. Without that deeper commitment, neither domestic credibility nor export success would be possible.

The opening keynote came from **Gregory Smith, Country Director of the US FDA India Office**. He brought a valuable outside perspective. India, he noted, already supplies approximately 40 per cent of generic and over-the-counter (OTC) drugs used in the United States and its share of the US medical device market is growing too. Since 2019, the FDA has carried out over 1,900 inspections across India, covering food, drugs, and medical devices. One of the most common issues found during inspections, he said, is a weak quality unit and building a strong quality culture is not just a regulatory need, it is what keeps patients safe. He also pointed to India's recent affiliate membership of the International Medical Device Regulators Forum (IMDRF) as an important step toward global alignment, and directed attendees to FDA's free CDRH Learn website that features over 100 mobile-friendly modules available for companies working toward US market access.

The keynote address by **Dr B.V.R. Mohan Reddy, Founder Chairman of Cyient Group, Chairman of the Board of Governors at IIT Hyderabad, and Founding Director of T-Hub**, focused on the insightful topic, "Empowering Doctors, Expanding Access, Enhancing Care: AI and Engineering Transforming Healthcare." He opened with a contrast he called "A Tale of Two Realities"-a child born in a Hyderabad corporate hospital with AI-assisted diagnostics and a full digital health record from birth, versus a child born the same day in a rural Mahbubnagar PHC where the nearest doctor is 40 kilometres away and pregnancy is tracked on paper. Same country. Same day. A world apart. He backed it with numbers: India has 1.3 doctors per 1,000 people, just 0.5 hospital beds per 1,000 in rural areas, and roughly 11 specialist doctors per one lakh rural population compared to 67 in cities. The gap is a scale problem and AI is the tool that can fix it. He highlighted that India's national telemedicine platform has logged over 200 million consultations since 2019, proving that patients in remote areas will use digital health if it is easy, trusted, and free. He closed with five recommendations for government and industry: a National HealthTech Innovation Fund, MedTech incubators at every AIIMS, a 90-day CDSCO fast-track for Made-in-India AI diagnostics, mandatory ABDM compliance in public facilities, and government procurement tied to clinical outcomes-not spec sheets.

The first session, on quality

leadership, moved the conversation away from "audit preparation" toward something more fundamental-quality as a way of running a business. Chaired by Manoj A, a former VP at Terumo Penpol, the session featured Rupam Chaudhury of L&T Technology Services on FDA's alignment with ISO 13485, and Sreejith Viswam of Stryker's Global Technology Center, who made a strong case that quality culture, when done right, actually speeds up the path to market. A panel discussion moderated by Manoj A brought together Sarada Jayakrishnan, General Manager-Quality at Terumo Penpol, Dr P.S. Chandranand, WHO Prequalification Consultant and Director at Iqzyme Medtech, and Srihariraju Manthena, Service Delivery Manager at BSI India Regulatory Services, to dig into the specifics-supplier controls, data integrity, CAPA systems, and design controls.

Adding a strong state-level perspective to the discussions on innovation and ecosystem development, P. Vishnuraj, IAS, Managing Director of KSIDC addressed the conference on the theme "Bio Connect 4.0: Strengthening Kerala's Innovation & Life Sciences Ecosystem"

Session two focused on clinical evidence and performance-a topic that many Indian MedTech companies find difficult to navigate. Chaired by Dr B. Satheesan, Director of the Malabar Cancer Centre, the session asked a basic but important question: what does good evidence actually look like, and how do you generate it without wasting resources? Dr Anju Gopan of IQVIA looked at how clinical trial approaches are changing, while Atonu Dutta of Neujin Solutions spoke to the real challenges of device validation in India. The panel that followed brought in Dr Vivek Ahuja, EVP at Eversana; Dr E. Sreekumar, Director of the Institute of Advanced Virology, Kerala; Dr Vijayakumar Manavalan, Pro Chancellor of Yenepoya University and former Director of KIDWAI Memorial Institute of Oncology; and Dr Deepa Arora, CEO of Clinexel. Together they spoke frankly about where companies get stuck and how to avoid it.

Gregory Smith, Country Director of the US FDA India Office

Dr B.V.R. Mohan Reddy, Founder Chairman of Cyient Group, Chairman of the Board of Governors at IIT Hyderabad, and Founding Director of T-Hub

The afternoon session on AI in MedTech was one of the most closely watched of the conference. Chaired by Dr Sridevi Nagarajan, Founder of AyusArogya Ltd and DIA's Communities Chair for AI in Healthcare, it covered a lot of ground from how Software as a Medical Device (SaMD) is classified under the EU AI Act and FDA guidance, to cybersecurity requirements and post-market monitoring for AI systems. Adarsh Srivastava of Roche presented on AI in diagnostics and drug development, while Dr Vivek Ahuja of Eversana covered validation and lifecycle control for AI systems. A panel that included Mr Aseem Sahu, Deputy Drug Controller at CDSCO, Rohit Philip of KMTC, Dr MiRa Jacobs of the UK's MHRA, and Dr Alberto Gañán Jiménez, Head of Committees and Quality Assurance at the European Medicines Agency, gave the discussion a genuinely international feel.

Day One closed with a session on regulatory pathways-how to actually navigate the approval routes to the Indian, US, and EU markets. Chaired by Sinto Poulose of IQZYME MEDTECH, it featured a virtual presentation from Dr Pooja Jani Medical Officer, Diagnostic Data Program at CDRH, US FDA, and Mr Aseem Sahu's overview of India's framework for medical device software. A panel moderated by Dr P.S. Chandranand that included Sreejith Viswam of Stryker's Global Technology Center, and virtual participants Wil Vargas and Stephanie Shedd, both International Regulatory Policy Analysts at CDRH, US FDA, rounded things off with practical lessons from real market entry journeys.

Day two opened with keynotes that stepped back from regulation and looked at the bigger picture. Reflecting how the "D" in DIA today extends beyond drugs to encompass devices, diagnostics, and digital health, **Dr C. Palani Palaniappan, CEO of Aridica Corporation and DIA Global Board Member**, spoke about the growing convergence of these domains and what that means for how companies need to think about product development. **Mohammed Y. Safirulla K., IAS, Director of the IndiaAI Mission at MeitY**, addressed India's national ambitions in AI-driven healthcare, drawing particular interest from start-ups and digital health companies in the audience.

Session five looked at leadership, talent, and business ecosystems. Chaired by Chetan Makam, MD and Board Chair of Terumo Penpol, it asked how companies build teams and systems capable of scaling MedTech in regulated global markets. Dr Susheela Branham, CEO of the Bio Valley Incubation Council, AMTZ, opened with a presentation on ecosystem building, before a panel with Dr Vibhav Garg, President of Global Government Affairs at Meril, Dr Mrutyunjay Suar, CEO of KIITTBI, Director General Industry-Institute-Innovation- Interface at KIIT University and Chairman of BCKIC (an initiative of the Office of PSA to GoI), and Dr. Vijayakumar Manavalan, Pro Chancellor of Yenepoya University who played a key role in establishing Yenepoya Technology Incubator, took on the harder questions around talent, supply chain resilience, and competitive positioning.

Session Six tried something different. Rather than another panel discussion, the World Café format chaired by Rohit Philip, Senior Program Consultant at KMTC, put delegates into small, facilitated groups to surface the real obstacles: in regulation, clinical evidence, quality systems, digital trust, and export readiness. Each group then presented back to the room. It was one of the more energetic sessions of the conference, and the outputs are expected to feed into KMTC's policy work going forward.

Session seven brought the focus to manufacturing. Himanshu Baid, Managing Director of Poly Medicure Ltd, gave a frank talk on what it genuinely takes to compete at a global level-process validation, supplier qualification, traceability, and the discipline of scaling up without losing quality. A panel moderated by C. Padmakumar, Special Officer of KMTC, and joined by B. Harikrishnan, General Manager at Terumo Penpol Anilraj Radhakrishnan, General Manager at SFO Technologies, Thomas John, Managing Director of Agappe Diagnostics along with a virtual address by CDR Neil Bonzagni of the FDA India Office on device imports and common issues, added useful regulatory and on-the-ground manufacturing context.

Reflecting the shared emphasis on collaboration and collective industry engagement to advance healthcare innovation, day two also featured the formal launch of the Kerala Medical Device Industry Association (KMDIA)-a new body that will represent Kerala's medical device and diagnostics companies. Thomas John, Managing Director of Agappe Diagnostics, took charge as inaugural President, with Jayashankar delivering the welcome address as Secretary, and Binu Augustine, Treasurer of KMDIA, offering closing remarks. The formal launch was marked by remarks from DIA's Palaniappan and KMTC's Padmakumar.

The conference also formally introduced the KMTC Hearing Aid Development Project-an effort to build an affordable, high-quality digital hearing aid from Kerala, bringing together engineering expertise, clinical institutions, and public sector support to address a large and underserved need in hearing healthcare. This session was chaired by Dr Rejeesh GR, General Manager -Marketing at KMTC.

The DIA-KMTC MedTech Conference 2026 showed that the right people are in the room, the conversations are getting more specific, and the structures like KMDIA are beginning to take shape. The work ahead is not simple, but the direction is clear.

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Indian Pharmacopoeia 2026: Raising the bar for quality standards of medicines

Abdul Nazar K, Government Analyst, Kerala, Expert Working Group member of the Indian Pharmacopoeia Commission (IPC), and Research Scholar at the Faculty of Public Health, SRIHER, Chennai, examines the significance of the Indian Pharmacopoeia 2026 and highlights how the latest edition aligns Indian pharmaceutical benchmarks with global standards

The 10th edition of the Indian Pharmacopoeia, which encompasses the upgraded and harmonised quality benchmarks for medicines, has been officially published and is set totake effect on 1stJuly 2026.

- 40 Standards harmonised with PDG
- 121 New Monographs
- 63 Monographs for Blood and Blood Components
- Title Changes of 100 Monographs
- Official book of reference in 23 foreign countries

Pharmacopoeias are the recognised statutory standards of quality for medicines published by different national, regional and international authorities. Pharmacopoeial standards are the backbone of the healthcare system as they are the quality requirements to ensure the safety and efficacy of medicines. Indian Pharmacopoeia (IP) is the standards of quality recognised as per the provisions of the Drugs and Cosmetics Act. 1940 and the Rules made thereunder, for the drugs manufactured and/or distributed in India. The First edition of the Indian Pharmacopoeia was published in the year 1955 by the Indian Pharmacopoeia Committee. Currently the Indian Pharmacopoeia is prepared, upgraded, amended and published periodically by the Indian Pharmacopoeia Commission (IPC). For the digital access to the IP editions, IPC has launched an online portal *(www.iponline.ipc.gov.in)* in August 2024 and all editions from IP 2022 are available for subscription through this platform.

Indian Pharmacopoeia Commission

The Indian Pharmacopoeia Commission (IPC), an autonomous organization under the Ministry of Health & Family Welfare, Government of India, has been fully operational since 2009 with the mission to promote public and animal health in India by establishing authoritative and officially recognised standards of quality for drugs.

In October 2023, the Indian Pharmacopoeia Commission achieved a major milestone by joining the Pharmacopoeial Discussion Group (PDG) as its fourth member, alongside the authorities of the European Pharmacopoeia (Ph. Eur), the United States Pharmacopeia (USP), and the Japanese Pharmacopoeia (JP). The PDG is an informal group of pharmacopoeial authorities that collaborates to harmonise pharmacopoeial standards. The affiliation of the IPC within the PDG plays a pivotal role in upholding the quality of drugs and pharmaceuticals in alignment with international standards and mitigates the demand on manufacturers and laboratories to conduct analytical processes in different ways depending on the regulations.

In addition to publishing the Indian Pharmacopoeia, IPC plays important roles in the development of Reference Standards (IPRS) and Impurity Standards, Pharmacovigilance (PvPI) and Materiovigilance (MvPI) initiatives, Analytical Research and Development, and publication of the National Formulary of India (NFI).

Indian Pharmacopoeia 2026

The Tenth edition of the Indian Pharmacopoeia (IP 2026) has been officially released on 2nd January 2026 and will become effective from 1st July 2026. During this transition period of six months, all stakeholders shall take appropriate steps to ensure that their articles are complying with the new standards of quality. Once these standards became effective, it is a statutory requirement that all the Drugs and Pharmaceuticals available in the domestic market shall comply with all the requirements prescribed in this edition.

This new edition of the IP reflects India's growing pharmaceutical landscape and our commitments in improving the quality of the health of our people and animals through internationally harmonised standards of quality. Notably, it includes harmonised standards of 18 General Chapters and 22 Excipient Monographs developed in alignment with PDG, marking the first full edition prepared after India's inclusion in this international framework.

Structured across four volumes, IP 2026 contain different sections like general notices, general chapters, general monographs for different dosage forms, and individual monographs.The fundamental and essential pertinent information applicable to the whole texts of IP is provided in the General Notices. The General Monographs provide the general quality requirements and specifications for the active pharmaceutical ingredients and different dosage forms. The Individual Monographs prescribe the requirements that constitute the specifications for standards of quality of drug substances, drug products, excipients and other added substances. The General Chapters contain wide range of topics like requirements of apparatus, different types of test-methods, reference data, reagents and solutions, general tests etc. These general chapters are made applicable through the references in general notices and/or monographs. The 4th volume of the IP contains the standards that are exclusively applicable for the veterinary articles.

A total of 121 new monographs, including 62 monographs of drug products and 20

Indian Pharmacopoeia Commission (IPC), Ghaziabad, Uttar Pradesh

monographs of Blood and Blood Components, are introduced in the tenth edition of the IP. Other new additions in this edition include five General Chapters, one General Monograph for the liquids for cutaneous application, and two chapters for the general requirements for Blood and Blood Components. It also features significant amendments, upgradations and revisions in 37 General Chapters, 9 General Monographs and 418 Individual Monographs. Changes in the Titles of 3 General Chapters, and 100 Monographs which encompass Powder preparations for Injections and Suspensions, Blood and Blood Components, and Veterinary Vaccines, will take effect with this edition.

The Pharmacopoeial specifications are designed to ensure the quality of the medicines by prescribing the standard requirements of identity, strength, purity and performance for each article. Compliance of those standards as prescribed in the current edition of the Indian Pharmacopoeia is mandated through the Second Schedule of the Drugs and Cosmetics Act, 1940. As per this Schedule if a drug available in the domestic market is included in the IP, it shall comply with the standards prescribed in the current edition of the IP. Likewise, the requirements prescribed in the General Monographs are legally applicable to all articles, including non-pharmacopoeial articles, as per the provisions of the Schedule V of the Drugs Rules, 1945. The manufacturers are legally bound to comply their products with the requirements of the current edition of the pharmacopoeia to ensure the efficacy and safety of the medicines throughout the shelf life. The testing laboratories are required to follow the current edition of the pharmacopoeia as standards of quality to perform the test / analysis and to declare the quality of the samples received.

Union Minister for Health & Family Welfare and Chemicals & Fertilizers, Shri J. P. Nadda, releasing the Indian Pharmacopoeia 2026

Beyond the National boundaries

Since 2019, the Indian Pharmacopoeia (IP) continues to gain its international credibility through recognition and acceptance by the foreign countries. In alignment with the diligent efforts and guidance provided by the Union Government of India, along with the dedicated initiatives of the IPC, currently the Indian Pharmacopoeia is recognised as a standard book of reference in 23 foreign countries throughout the world spanning various regions including Asia, Africa, South America, Oceania, and Caribbean.

The Tenth Edition of the Indian Pharmacopoeia (IP 2026) is available for purchase in printed form as well as in digital form (as a complimentary package with the printed form) through the official online portal www.iponline.ipc.gov.in

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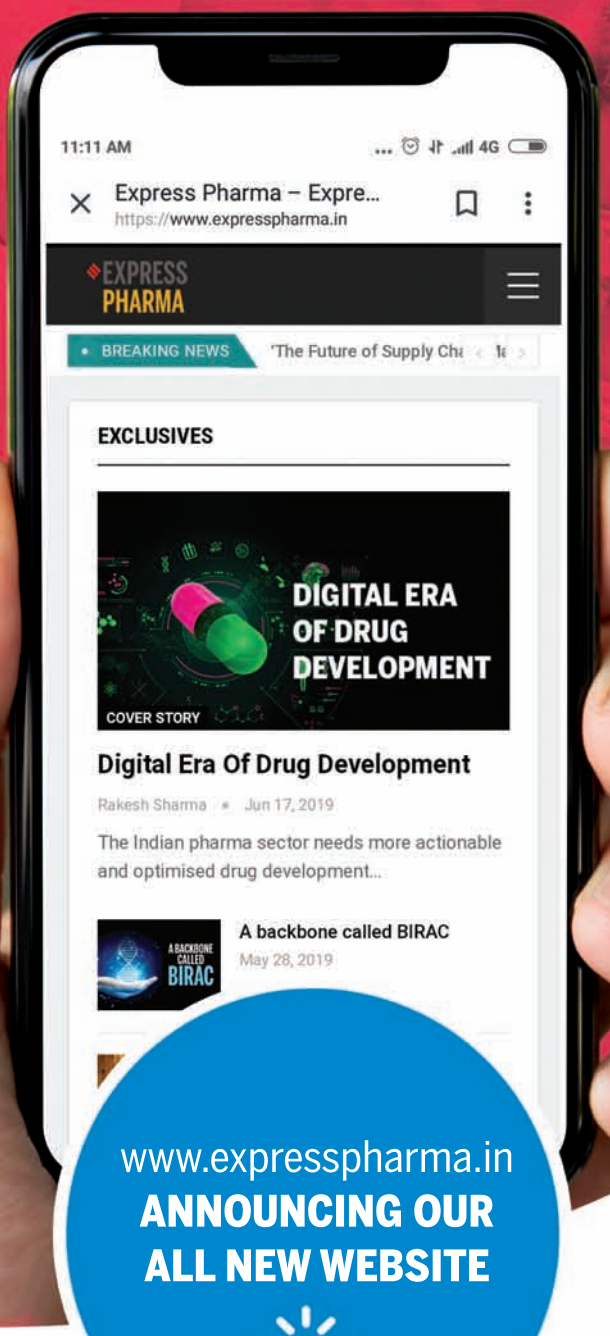

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Indian pharma and healthcare M&A: Why legal due diligence defines the deal

As India's pharma and healthcare M&A landscape enters a new phase of strategic consolidation, regulatory risk is becoming the defining factor in deal value and execution. **Biplab Lenin,** Partner, and **Pratiti Shah,** Senior Associate, at Cyril Amarchand Mangaldas examine why legal due diligence has become central to protect high-value acquisitions from costly liabilities

Biplab Lenin

Pratiti Shah

When a pharma acquisition goes wrong in India, it rarely fails because the financial model was wrong. It fails because something always visible, in the inspection record, the price control schedule, or the licensing register, was never examined closely enough. In Indian pharma and healthcare M&A, regulatory risk is operational risk. A single unresolved manufacturing observation can eliminate an export market, and the liabilities that determine deal value rarely sit on the balance sheet. Legal due diligence is not a closing formality. It is the deal itself.

India's pharma and healthcare M&A landscape is entering a sustained phase of strategic activity, driven by hospital network consolidation, portfolio rationalisation, increased API and CDMO investment, and renewed inbound interest. Transactions are increasingly capability-led, targeting complex generics, specialty portfolios, digital health integration, and regulatory track records. The pace has accelerated, but the underlying risk profile remains deeply regulatory and jurisdiction specific. The capital is there. And the legal instinct of deal teams should be to pause and look considerably harder.

In most sectors, legal due diligence is a compliance formality appended to a financial model. In Indian pharma and healthcare, it is categorically different, frequently the only place where real liabilities live. The balance sheet will not reveal the manufacturing inspection finding. The information memorandum will not volunteer the price control exposure. And the promoter will rarely lead with the regulatory gap that a change of control is about to trigger.

The sharpest and most underestimated risk remains manufacturing compliance. Data integrity deficiencies are cited in approximately 60 per cent of US FDA warning letters issued to Indian facilities, compared to around 10 per cent for US sites and 21 per cent for Chinese facilities. For export-driven businesses, an undisclosed regulatory finding is not a compliance footnote; it is an immediate revenue risk that must be quantified and reflected in price, indemnity structure, or both. Effective diligence must move beyond inspection histories to assess corrective action status, data systems integrity, and the underlying quality culture which permits data integrity lapses. Remediation costs can be modelled; deficiencies in quality culture are materially harder to remediate post-acquisition.

Licensing risk is equally structural. Licenses under the Drugs and Cosmetics Act are facility-specific and product-specific, with processes commonly taking three to six months. A share acquisition preserves the license on paper but may trigger a de facto regulatory review if CDSCO or the relevant state authority takes the view that effective control has changed. Counsel must map every license, understand its nuances, and build realistic timeline assumptions into the deal structure. A model assuming Day 1 revenue continuity without factoring regulatory lag risks a significant valuation gap.

Price control remains a persistent blind spot. The NPPA enforces ceiling prices for drugs in the essential medicines list under the DPCO framework and can recover overcharged amounts with interest. With the NLEM periodically revised, products outside price control at signing may be reclassified before or after closing, exposing portfolios to continuous margin compression. A rigorous DPCO exposure analysis mapping scheduled products, reclassification risk, retrospective liability, and revenue impact-is not a compliance check. It is a fundamental valuation question.

Transaction structuring introduces further complexity. Combinations exceeding thresholds require CCI approval, with increasing scrutiny of therapeutic overlaps. While 100 per cent FDI is permitted in greenfield pharma under the automatic route, brownfield acquisitions beyond 74 per cent require government approval, often with public health-linked conditions. Deal timelines and valuation assumptions must be calibrated to this regulatory stack at the outset.

The same diligence intensity applies in healthcare delivery assets. Hospital and diagnostics transactions must navigate fragmented state-level regulation, clinical establishment laws, labour compliance, and environmental norms-all creating execution risk if not mapped locally.

An emerging theme is digital health integration. India's digital health ecosystem—spanning telemedicine, AI diagnostics, and interoperable health records, is scaling rapidly, valued at over USD 14 billion in 2024 with projected growth exceeding 25 per cent CAGR. Digital assets bring new diligence questions: data ownership, consent architecture, cybersecurity resilience, software-as-a-medical-device classification, and compliance with the DPDP Act. In a sector built on trust, data governance failures create both regulatory exposure and reputational risk.

But 'sound strategy' and 'sound execution' are two different things. The difference between value creation and an inherited liability set is almost always visible in the data room, if legal due diligence is given the mandate, the time, and the sectoral expertise to interrogate it fully. Nor should diligence terminate at signing. Post-closing integration, from regulatory remediation to contract novation and workforce alignment, is where identified risks translate into realised value or loss. The acquirer who treats diligence as a pre-signing exercise will often find that liabilities surfaced in the data room mature into losses in the first operating year. In Indian pharma and healthcare M&A, the diligence file is the deal.

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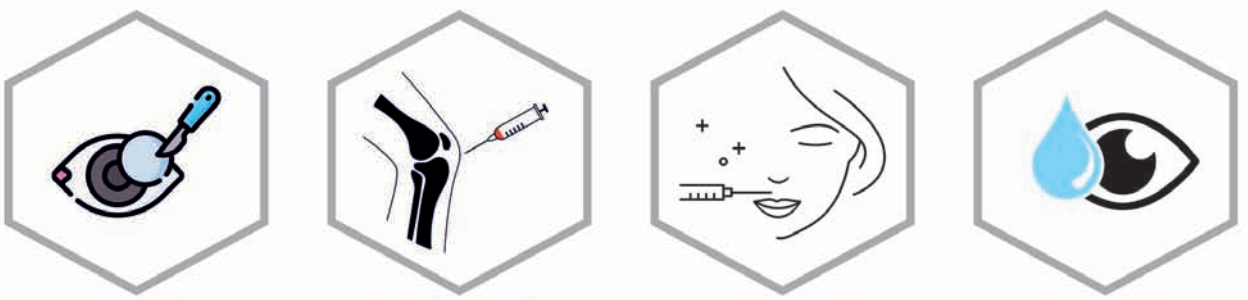

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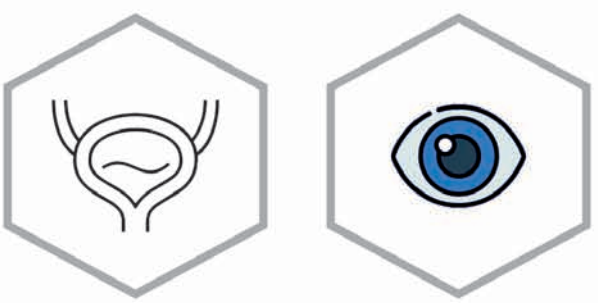

Interstital Cystis (Inflammation of the Urinary Bladder Wall) | **General Vision Disorders**

YASHAM

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Ami Polymer

Enabling Healthcare

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CLOSING THE GAP

HOW TRUE CLOSED SYSTEMS ARE REDEFINING CONTAMINATION CONTROL

In modern biopharmaceutical manufacturing, contamination prevention is no longer achieved through cleanrooms alone. True closed single-use systems are transforming fluid handling by minimizing human intervention and creating safer, more efficient aseptic processes.

KEY BENEFITS

- Reduced contamination risk
- Minimized operator intervention
- Faster batch changeovers
- Enhanced sterility assurance
- Improved manufacturing flexibility

CORE TECHNOLOGIES

- Sterile Connectors
- Single-Use Assemblies
- Automated Fluid Transfer
- Closed Sampling Systems
- SUS Bags & Manifolds

INDUSTRY IMPACT

- Biopharmaceutical Manufacturing
- Cell & Gene Therapy
- Vaccine Production
- mRNA Processing
- Personalized Medicine

INTERVIEW

OPTIMA India: Growth and commitment to the market

India is one of the fastest-growing pharmaceutical markets worldwide and is increasingly becoming a hub of innovation for biosimilars, injectables, cell and gene, ADC's and complex biologics. Optima India was founded in 2011 as a wholly owned subsidiary of the Optima Group. Since then, the site has developed from a pure sales organization into a comprehensively positioned unit with a strong focus on service and engineering. Against this backdrop, we spoke with **Akshay Chikodi,** Managing Director of Optima India, about market potential, growth, and the strategic direction of the company.

Mr. Chikodi, how is Optima India positioned within the Optima Group, and why is the Indian market so strategically important?
India is positioned to become the 3rd largest economy by 2030 hence it is imperative for Optima group be a part of this growth story. Optima India as a subsidiary offers the platform for cost optimization, speed & scale which can be leveraged for growth in the domestic market, and also open global avenues.

For us, India is not only a growth market, but also a market undergoing structural change. In addition to the strong generics business, we see a clear trend toward innovative therapies, complex biologics, cell and gene, ADC's, and modern, integrated fill-finish solutions. This is precisely where we can make a lasting contribution with our experience and technological expertise.

The location has developed significantly since its foundation. What does your local presence look like today?
Think global act local! What began in 2011 as a sales organization is now a broad-based unit with around 50 employees and growing further in sales, service, and engineering. We operate a sales and service office in Bangalore and an engineering center in Pune, which works closely with our global teams. In addition, we have established a service hub in Ahmedabad as the same has a huge install base of Optima machines in western India. Optima India also acts as a reseller for spares.

In your opinion, what are the most important drivers of this growth?
Our growth is closely linked to the dynamics of the Indian pharmaceutical market. Demand is rising significantly, particularly in the area of injectable drugs – both in the generics segment and for innovative products. At the same time, we are investing specifically in expanding our service and engineering capabilities. Today's customers expect not only high-quality machines, but also comprehensive support throughout the entire life cycle. This demand has played a key role in shaping our growth.

What sets Optima India apart in terms of expertise and service portfolio?
We see ourselves as an integrated solution provider

Akshay Chikodi
Managing Director
OPTIMA packaging machinery India Pvt. Ltd.

for filling and closing machines, isolators, and freeze dryers, not just a machine supplier. Our local service team has extensive expertise in installation, commissioning, maintenance, qualification, training, and automation for new machines, and also handle refurbishment and upgrades for existing lines.

In addition, we distribute spare parts directly in India through the reselling business and are expanding our range to include refurbished components. This enables shorter delivery times and significantly increases plant availability. At the same time, engineering and service team work closely together to develop cost-efficient and locally adapted solutions.

What role does service play in your market strategy?
Service is a central component of our value proposition. Our aim is not only to respond quickly, but also to create real added value and build long-term partnerships. We rely on regionally based service teams, modular service packages, and continuous training for our employees. Our goal is to be as close as possible to our customers' production lines.

What are your strategic priorities for the coming years?
Our focus is clearly on further expanding our local expertise. We want to establish a strong knowledge and engineering pool in India and gradually take on more responsibility locally. A significant step was the acquisition of engineering talent in Pune and starting a competence center for engineering that works closely with the HQ to have competitive solutions with speed and scale. An excellence center for services that caters not just Indian market but global needs.

Finally, what message would you like to convey to customers?
Optima India stands for long-term partnership, technological excellence, and sustainable growth. We continuously invest in innovation, digitalization, and local expertise. Our goal is to actively develop the Indian pharmaceutical market together with our customers. To develop a strategic reliable partnership.

A growing team, a strong presence: Optima India is continuously expanding its local expertise and, with a dedicated team, is strengthening its role as a strategic partner in India's rapidly growing pharmaceutical market

Ecocool®: A next-generation cooling agent for advanced formulations

Ecocool® supports patient-centric oral formulations with sustained cooling, taste masking and compatibility across multiple dosage forms to improve palatability and compliance.

Introduction

Oral drug delivery systems are broadly classified as nutraceuticals or pharmaceuticals. Both the approaches often face challenges leading to bitter/ chalky excipients or Active pharmaceutical ingredients, disturbing after taste, etc; which can negatively impact patient adherence. Thus, product palatability and patient compliance are critical factors in the success of formulations. Sensory traits such as taste and mouthfeel are often deciding factors.

Ecocool® is a novel cooling agent designed to address these challenges by delivering an immediate yet prolonged cooling sensation, setting it apart from traditional cooling compounds.

Conventional cooling agents are effective initially, but tend to dissipate rapidly, leading to incompatibility issues. Ecocool® has been developed to maintain the broad formulation compatibility.

Why choose Ecocool®?

Ecocool® is a versatile choice of modern drug delivery systems. It contributes to several functionalities. It is broadly available in various physical forms, enabling flexibility across dosage form and applications. They are as listed below:

Product Variant	Physical Form	Typical Applications
Ecocool® Pellets / Granules	Pellets / Granules	Dispersible tablets, instant anti-ulcer pellets, suspensions
Ecocool® MP	Solution	Syrups, gels, cough syrups, lotions, pain balms
Ecocool® HD	Solution	Medicated hair oils
Ecocool® TI	Solution	Medicated powders
Ecocool® DT	Powder	ORS, dispersible tablets, dry syrups
Ecocool® DP	Powder	Vitamin supplements, chewable tablets
Ecocool® FC	Powder	Film coating applications

Key attributes of Ecocool®

● Immediate and prolonged cooling sensation

The traditional cooling agent enables a short-lived sensory effect. The main advantage of Ecocool® is, that it is engineered to offer a sustained and long-lasting cooling experience, unlike the traditional cooling agent. This prolonged cooling sensation enhances the overall mouthfeel and plays a significant role in patient adherence to treatment and improvement of palatability, even in critical drug delivery system.

● Mechanism and sensory performance

Menthol is usually associated with sharp, aggressive cooling profile. Ecocool® is fabricated specifically to eliminate the same. Thus, the product results in smoother and more acceptable sensory experience that can be perceived as cooler than menthol without associated irritation.

Ecocool® is designed to deliver both immediate onset and extended cooling sensation. This sustained effect aids in modulating oral sensory perception, thus tackling the bitterness/ chalkiness associated with APIs or excipients.

● Taste masking and palatability enhancement

Ecocool® plays a very important role in tackling issues with palatability and after bitter taste, i.e. post administration. This characteristic is specifically useful for paediatric, geriatric and compliance sensitive patients.

● Formulation compatibility

Additional advantage of Ecocool® is that it is highly compatible with APIs and excipients, including flavours and sweeteners. It integrates effortlessly into systems without affecting flavour integrity or sweetness perception.

It also displays good compatibility with aqueous, alcoholic and hydroalcoholic systems. This aids in its use over a wide range of oral dosage forms, e.g. oral solutions, syrups, sprays, gels, ointments, reconstitute liquids, etc.

It also has no adverse impact on drug product stability.

● Multi-system applicability

Due to the exceptional functions of Ecocool®, it provides formulators with flexibility during product development. Its consistent sensory performance across different matrices supports its use in both immediate-release and controlled-release products, where post-administration sensory experience remains critical.

Applications of Ecocool®

Ecocool exhibits broad applicability across a range of dosage forms, as summarized in the table. With the pharmaceutical industry increasingly moving toward patient-centric formulations such as mouth-dissolving films, its importance becomes even more pronounced. Incorporating Ecocool into these advanced oral delivery systems can significantly enhance the patient experience by imparting an immediate and pleasant cooling sensation. This sensory attribute not only improves palatability and mouthfeel but also promotes better patient acceptability and compliance, particularly among pediatric and geriatric populations who are more sensitive to taste. A human volunteer study (n=10) was conducted to evaluate the respective sensory attributes.

Mouth dissolving films:

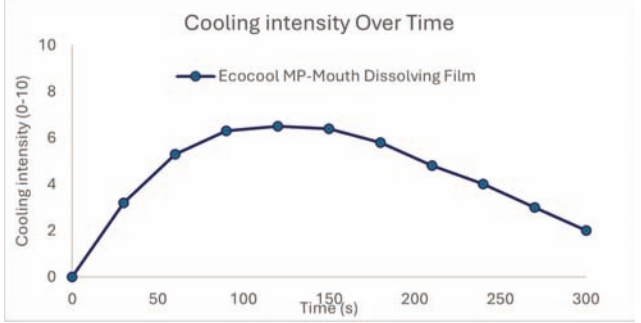
Ecocool MP was incorporated into a Mouth Dissolving Film (MDF) formulation to evaluate

Figure 1. Ecocool MP-Mouth Dissolving Film

its performance and its ability to impart a refreshing cooling sensation. This study aimed to assess not only the intensity of cooling, but also to further understand its cooling journey, i.e. onset and duration of the sensory effect, a detailed sensory evaluation was designed to track the progression of the cooling effect over time—from the moment of film placement, through dissolution, to peak sensation and eventual decline.

Cooling Characteristics Summary (Mean ± SD)	
Parameters	**Ecocool MP MDF**
Onset time (s)*	4.2 ± 2.8
Time to Peak (s)**	64.7 ± 14.2
Peak Intensity (0-10)	5.8 ± 0.6
Duration (s)***	214.3 ± 22.1

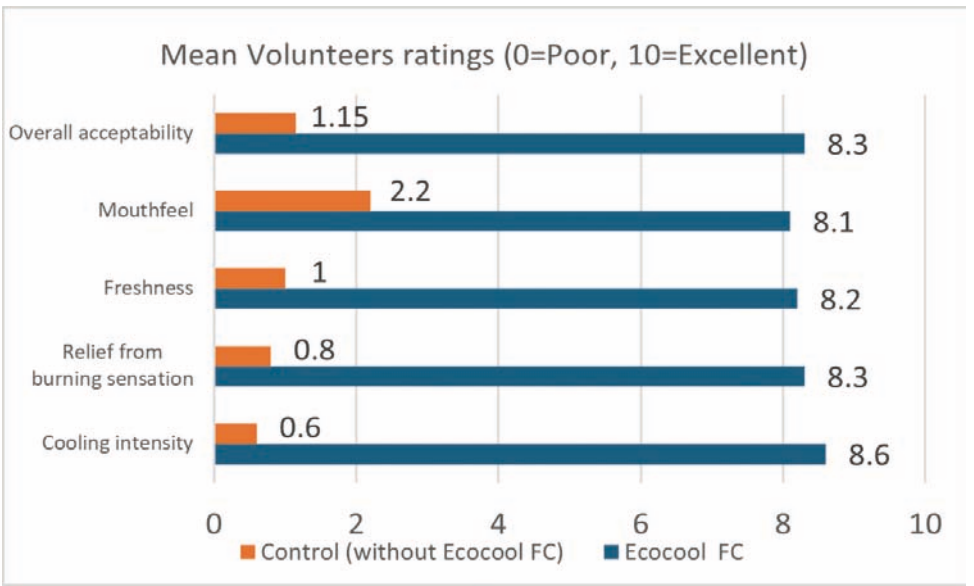
* Time to first perceived cooling
** Time to reach maximum cooling intensity
*** Time during which intensity remains



Chewable tablets:

Ecocool FC was incorporated into the chewable film coating of sodium bicarbonate-based cores intended for acidity regulation. Its inclusion provided an immediate and pronounced cooling sensation, which volunteers perceived as soothing and associated with rapid relief from the burning discomfort of acidity. Beyond reinforcing the perception of efficacy, the formulation offered a refreshing mouthfeel and no aftertaste. The cooling sensation was reported to persist for up to five minutes, demonstrating a sustained sensory effect. Overall, the addition of Ecocool FC enhanced the sensory attributes of the dosage form supporting improved patient acceptability.

Figure 2. Ecocool FC-Chewable Film Coated Cores



Note: Data represents mean value, n=10 human volunt

Conclusion

Ecocool® is a robust sensory aid for modern drug delivery systems. It has a sustained cooling effect, and broad system compatibility, thus making it a valuable additive for pharmaceutical research and development teams. It aids in enhancing palatability, improving taste masking, formulation differentiation and patient acceptability; without compromising formulation design.

Written By-
Ms. Tanvi Sawant,
Ms. Priya Patwa &
Ms. Mahima Yadav

Enhance Cold Chain Integrity with Gandhi Automations Cold Storage Doors

Discover How Gandhi Automations Pvt Ltd- India's No. 1 Entrance Automation and Loading Bay Equipment Company, Delivers Advanced Cold Storage Doors for Optimal Temperature Management

Maintaining precise temperatures is critical for cold storage operations, particularly in industries such as food and beverages, pharmaceuticals, and biotechnology, where even slight temperature fluctuations can result in significant losses. At Gandhi Automations Pvt Ltd, we understand the challenges of maintaining the cold chain, where frequent door openings allow heat to enter and inadequate door sealing can lead to energy loss, spillage, and product wastage.

To address these issues, we offer advanced cold storage doors engineered to minimize heat infiltration and enhance sealing, ensuring that your temperature-sensitive goods remain safe and fresh.

Our range includes cold storage Sliding Doors, Hinged Doors, and Semi-Insulating To & Fro Doors, all designed for superior insulation and durability.

Sliding Doors: Our sliding doors are highly favoured in industrial manufacturing plants and cold storage facilities for their ability to maximize operational space and ease of use. We offer both single-leaf and double-leaf versions, suitable for various cold storage needs, including cold rooms and quick-freezing rooms. With thicknesses ranging from 70 mm to 150 mm, our sliding doors handle temperatures as low as -40 degrees Celsius. Manufactured using the mono-block door leaf technology, they offer exceptional durability and resistance, even against chemical disinfectants. Available in both manual and motorized options, they are engineered to meet the highest standards. These doors are available in both Manual as well as Motorised versions.

Hinged Doors: For smaller passage areas where sliding doors might not be practical, our hinged doors are ideal. They facilitate the movement of pallet trucks and personnel in spaces with limited room. We provide a range of hinged doors with single and double-leaf options, suitable for cold rooms with door thicknesses from 70 mm to 150 mm. Featuring an aluminium-leaf edge and features an external lockable handle and an internal luminous push button for quick emergency exit, our hinged doors ensure reliable performance across various cold storage applications.

Semi-Insulating To & Fro Doors: Known for their sturdiness and precise design, our semi-insulating doors are versatile and cater to a range of applications, from small hatches to large openings. They are particularly suitable for areas with minimal temperature differences, such as manufacturing, processing, and handling areas. Commonly used in agro-industrial settings, dairy plants, fishing industries, logistics, nurseries, and meat processing facilities, these doors offer a "turnkey" service to meet diverse needs across various industries.

All our cold storage doors are tailor-made to fit the clear opening of your entrance facility and meet the specific temperature requirements of your establishment, ensuring optimal performance and efficiency.

To know more about our advanced cold storage solutions and how they can meet your specific needs, Contact:

For further information on our high-speed doors offering, contact:
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Fax : +91 22 66720201
Email : sales@geapl.com
Website : www.geapl.com

Romaco launches Tecpharm 400 tablet coater and VENTILUS Lab processor at interpack

Romaco introduces the Tecpharm 400 tablet coater and VENTILUS Lab fluid bed processor for pharmaceutical coating, granulation, drying and laboratory-scale applications at interpack

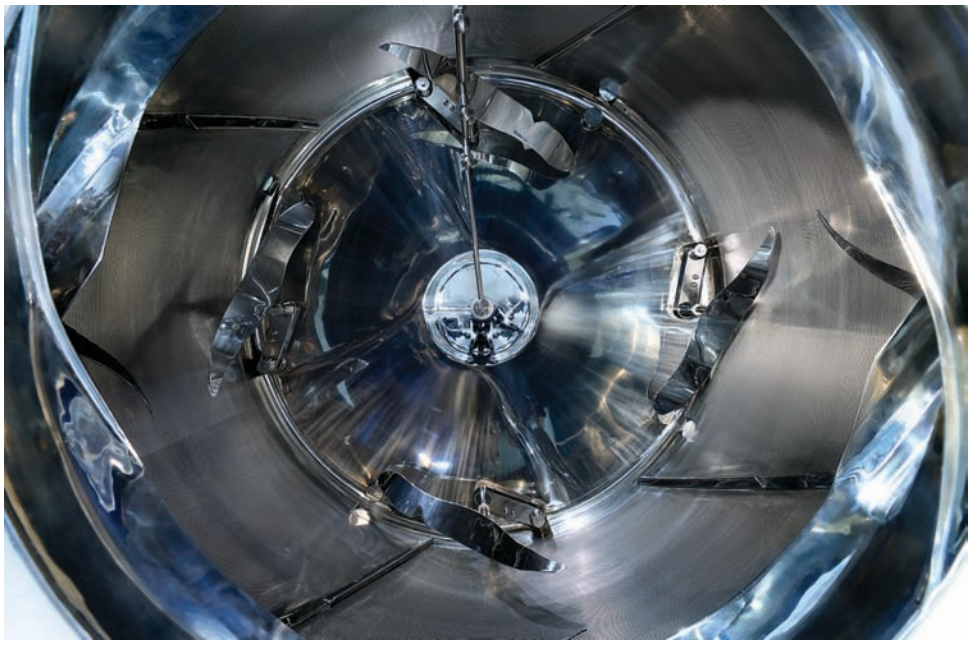
At interpack, Romaco celebrated the world premiere of its Tecpharm 400 tablet coater. This highly automated technology offers special advantages for a coating with pharmaceutical ingredients that often add a lot of weight to the tablets. The one stop solutions supplier for processing and packaging also presented its VENTILUS® Lab fluid bed processor for laboratory applications.

Tecpharm 400 tablet coater

Romaco's highly automated Tecpharm 400 tablet coater specialises in the coating of pharmaceutical ingredients that cause the product to gain considerable weight. This is often the case with combinations of ingredients containing Metformin, which cannot be formulated as bi-layer tablets due to their size. Therefore, the second layer of the formulation is sprayed on, to enable these medicines to be swallowed easily.

In conventional systems, this process can take well over 20 hours, during which time the tablets keep on increasing in weight and size. As this happens, the movement of the tablet bed and the spray conditions inside the drum change continuously. The Tecpharm 400 has been equipped with special features to handle the demands of this highly variable process environment. It is the first ever tablet coater to automatically adapt the geometry and position of the baffles in line with the tablet bed's increasing volume during the process. Its baffles make sure the tablets move in the drum in such a way that uniform spraying is achieved. The position and angle of the baffles in the tablet bed must be adjusted regularly as the volume changes, to create the ideal conditions for tablet coating. As its baffles are controlled automatically, there is no need to stop the Tecpharm 400 in order to adjust or replace components manually. This saves a great deal of time, as the machine does not need emptying during operation. What's more, the fully automated system ensures safer working for operating personnel, because at no time do they come into contact with potentially high-potency products. Thanks to its flexibly adjusting baffles, the Tecpharm tablet coater can tackle batch sizes ranging from 5 to 100%, all with the same drum.

Tecpharm 400 tablet coater



Flexibly adjusting baffles of the Tecpharm400

The optimum balance between quality, yield and processing time

The Tecpharm 400 boasts a fully automated air distribution system that steers the process air with precision through the tablet bed using exhaust flaps that open steplessly. It also features Tecpharm's innovative PCA spray arm. The smart technology continuously measures the distance from the tablet bed using radar, and constantly adjusts both the distance and the spray angle. Mechanically, this is achieved by the three-pivot-point design of the spray arm. For enhanced process reliability, the machine also includes a system that detects blocked spray nozzles by accurately identifying the affected nozzles, and even has a self-cleaning function. The advanced level of automation results in an ideal balance between product quality, yield and duration of the coating process.

User-friendly and sustainable

The Tecpharm 400 also sig-

nificantly improves ease of use, thanks to its spray arm that automatically extends from the machine. This brings major benefits in terms of ergonomics, particularly with large machines on which the spray arm is above chest height for the operator. Furthermore, sampling is a closed process, which protects operating personnel from toxic medicines, because the drum coater does not have to be opened manually to remove samples during production.

To considerably reduce the carbon footprint of energy-intensive coating processes, the Tecpharm 400 can optionally be fitted with an energy recovery system (ERS). This system allows energy consumption to be cut by up to 50%. To achieve this, a cross-flow heat exchanger is installed in the air handling unit (AHU), which feeds the energy from the process outlet air directly into the ongoing coating process. The technology is ideal for production processes that take several hours to complete and entail high power consumption. The new Tecpharm 400 therefore excels on all fronts – with its outstanding product quality and process efficiency, but also its ease of use and excellent environmental credentials.

Correction: In the previous issue, Vol. 21 NO. 6, the “Tecpharm 400” tablet coater was introduced with the name “Maximus 400”. Romaco has changed the name of this tablet coater, because the product name “Maximus 400“ had, without Romaco’s knowledge, infringed the trademark rights of third parties. As soon as Romaco became aware of this issue, the name was changed to “Tecpharm 400”. The change applies solely to the product name. All product characteristics and specifications remain unchanged.

VENTILUS® Lab fluid bed processor by Romaco Innojet

Designed for laboratory-scale applications, the VENTILUS® Lab fluid bed processor from Romaco Innojet is used for granulating, drying and coating particles of any size from 10 ❁m to 2 mm. To showcase its broad and varied portfolio of laboratory machines, Romaco will be presenting the VENTILUS® Lab fluid bed processor from Innojet at interpack. This exceptionally versatile all-rounder is used for granulating, drying and coating particles of any size from 10 ❁m to 2 mm. This multipurpose lab unit is intended for batch sizes from 0.7 to 7.0 liters. With its innovative process air distribution system inside the cylindrical product container, the required energy can be used far more efficiently, enabling the VENTILUS® Lab to cut batch processing times by up to 25%. The process air is introduced through the circular ORBITER® booster, ensuring homogeneous flow conditions and gentle intermixing of the batch. In combination with a bottom spray nozzle located in the center, the booster plate forms a unique functional unit enabling much simpler scale-up processes. When it comes to nozzle technology, users can choose between the tried-and-tested ROTOJET® and the new FLEXIJET®, which was specifically developed for granulation processes and is both very easy to handle and quick to clean. The patented fluid bed components invented by Dr. h. c. Herbert Hüttlin are behind the remarkably accurate application of the spray liquid, with a precisely defined droplet size. With controlled release formulations, for instance, the modified release profiles are achieved using 10 to 15% less material. This targeted reduction in the amount of spray liquid used also means less power consumption, so that the VENTILUS® Lab substantially reduces CO2 emissions from fluid bed processes. Moreover, the rotating SEPAJET® filter system minimises general product loss by returning particles retained by the filter to the process rather than discharging them.

VENTILUS® Lab fluid bed processor

Romaco’s Tecpharm 400 and VENTILUS® Lab technologies focus on improving pharmaceutical coating, granulation and laboratory processing through automation, process control, energy management and reduced operator intervention

Romaco Group

Romaco is a leading international supplier of processing and packaging equipment specialising in engineering technologies for pharmaceutical products. The Group provides individual machines, lines and turnkey solutions for manufacturing, filling and packing powders, granulates, pellets, tablets, capsules, syringes, liquids and medical devices. The company also serves the food and chemical industries. Through its various technologies, Romaco is committed to sustainable production and to systematically reducing CO2 emissions.

The Romaco Group has its headquarters in Karlsruhe (Germany) and is part of Truking Technology, a globally operating high-tech enterprise based in Changsha (China). Truking’s core competency is handling and filling pharmaceutical liquids.

Romaco operates from six production sites worldwide, with a broad portfolio comprised of seven established product brands. Noack and Siebler (Karlsruhe, Germany) supply blister, heat-sealing and rigid tube filling machines. Macofar (Bologna, Italy) markets technologies for filling sterile and non-sterile powders and liquids. Promatic (also Bologna, Italy) specialises in cartoners, track & trace systems and case packers. Kilian (Cologne, Germany) is a leading manufacturer of tablet presses. Innojet (Steinen, Germany) is in the business of granulating and coating fine solid particles. Tecpharm (Barcelona, Spain) offers tablet coating technologies.

More than 930 highly skilled and committed Romaco employees are dedicated to the development of future product technologies and to the continuous implementation of internal improvement processes. The Romaco Group’s multibrand system solutions are sold worldwide through ten Sales & Service Centers and a dense network of local agent organisations. Over 12,000 installations delivered by Romaco are currently in use in more than 180 different countries.

Closing the gap: How true closed systems in Single-Use liquid handling are redefining contamination control

For decades, the biopharmaceutical industry has pursued a single ambition in aseptic manufacturing: eliminate contamination risk without compromising agility. Yet despite billions invested in cleanrooms, HVAC systems, sterilization infrastructure, and operator training, contamination events continue to occur. The uncomfortable reality is that most contamination does not originate from equipment failure alone—it emerges at the interface between process, people, and environment.

Single-use liquid handling technologies promised to change that equation. Disposable bags, tubing, connectors, manifolds, and pre-sterilized assemblies dramatically reduced cleaning validation burdens and accelerated manufacturing flexibility. But early single-use adoption often replicated the same vulnerabilities found in traditional stainless-steel operations. Systems were called "closed," while still depending on multiple aseptic manipulations, manual interventions, open transfers, or exposed connection points.

Today, the industry is entering a more mature phase. The conversation is no longer about whether single-use systems reduce contamination. The focus is now on what constitutes a truly closed system—and how that distinction is fundamentally reshaping contamination control strategy (CCS), facility design, regulatory expectations, and operational economics.

The future of aseptic processing will not belong to facilities with the largest cleanrooms. It will belong to organizations capable of minimizing human interaction with sterile product pathways.

The hidden illusion of "Closed"

The term "closed system" has historically been used too loosely across bioprocessing operations. A process may appear closed because product flows through tubing and disposable assemblies, yet critical manipulations still occur during sampling, filter integrity testing, bag changes, aseptic connections, venting, aliquoting, transfer line integration, sensor installation, and media addition, etc.

Every intervention introduces opportunity for microbial ingress, particulate contamination, operator error, or process deviation.

The industry is increasingly recognizing that contamination risk is not defined merely by whether a process uses disposable components. Risk is determined by whether the sterile fluid path remains physically and functionally isolated from the external environment throughout the process lifecycle.

This distinction is becoming critically important under modern regulatory frameworks such as revised EU GMP Annex 1, which places contamination control strategy at the center of sterile manufacturing.

The shift is philosophical as much as technical. Historically, facilities relied on environmental control to protect products from people. True closed processing reverses that dependency: the process itself becomes the primary contamination barrier.

Human intervention remains the largest risk vector

Numerous aseptic processing studies continue to identify human operators as the dominant source of contamination in sterile manufacturing environments. Even the best gowning practices cannot eliminate microbial shedding, glove contamination, motion-generated particulates, or procedural inconsistency.

Traditional contamination control strategies attempted to compensate for this reality through increasingly complex cleanroom classifications and environmental monitoring programs. But complexity itself creates operational fragility.

Dr. Priyabrata Pattnaik
Chief Executive Officer (CEO)
Ami Polymer Pvt. Ltd.

A truly closed single-use liquid handling architecture changes the paradigm by reducing dependence on operator behavior altogether.

This is why isolators, robotic filling systems, automated sterile connectors, and fully integrated single-use fluid paths are gaining rapid adoption. The strategic objective is clear – (a) reduce interventions, (b) reduce exposures, and (c) reduce uncertainty. In contamination control, simplicity is not convenience. Simplicity is robustness.

Moving beyond disposable components

Many organizations mistakenly assume that implementing single-use assemblies automatically creates a closed process. In reality, disposability and closure are not synonymous.

A true closed system requires integration across the entire process ecosystem:

1. Closed fluid transfer

Sterile-to-sterile connectors and aseptic disconnect systems are becoming foundational technologies in modern facilities. These systems enable fluid transfer without exposing product pathways to the surrounding environment.

The industry is increasingly replacing open pouring, laminar flow transfers, manual hose welding, and clamp-based temporary integrations with genderless sterile connectors, thermal fusion technologies, automated welding systems, and closed sampling devices, respectively.

This evolution is especially critical in cell and gene therapy, mRNA manufacturing, high-potency biologics, personalized medicine, and multi-product facilities - where batch sizes are smaller but contamination consequences are significantly higher.

2. Integrated automation

Automation is no longer merely a productivity tool. It is now a contamination control tool. Modern closed liquid handling systems integrate automated venting, closed-loop pressure monitoring, in-line integrity testing, digital recipe execution, automated filling, real-time leak detection, electronic batch records, etc. These capabilities dramatically reduce manual intervention points and improve process reproducibility.

The most advanced systems are beginning to combine robotics, disposable flow paths, and AI-assisted process monitoring into unified aseptic ecosystems. This represents the transition from "single-use equipment" to "autonomous contamination control platforms."

3. Functional closure across the entire process

One of the industry's largest blind spots is assuming closure exists only during production. In reality, contamination risk emerges during setup, assembly, sampling, transportation, storage, changeover, disposal, and many more.

A process cannot truly be considered closed if sterile exposure occurs at any stage of the operational lifecycle. This is pushing manufacturers toward pre-configured manifolds, gamma-irradiated assemblies, factory-tested flow kits, modular fluid transfer skids, single-use sensor integration, and closed waste handling systems. The goal is operational continuity without aseptic disruption.

Redefining facility economics

The implications of true closed systems extend far beyond sterility assurance. They are fundamentally altering facility economics. Historically, contamination control depended heavily on infrastructure, such as large Grade B cleanrooms, extensive HVAC systems, pressure cascades, cleaning validation, water-for-injection systems, CIP/SIP infrastructure, etc. None the less, true closed processing reduces dependence on these environmental controls by shifting sterility assurance directly into the process architecture itself.

The economic consequences are profound:

- Smaller cleanrooms and simplified utilities reduce facility construction costs, leading to reduced capital expenditure.
- Single-use assemblies eliminate lengthy cleaning validation cycles and enable faster changeovers.
- Facilities can switch products more rapidly without extensive decontamination downtime leading to increased manufacturing flexibility.
- Improved contamination control can directly protects manufacturing yield by reducing batch failure risk
- Modular closed systems can enable distributed and flexible manufacturing strategies offering accelerated scale-out models

This is especially important as the industry moves toward decentralized manufacturing, personalized therapies, smaller batch productions, and rapid-response biologics. The stainless-steel mega facility model is no longer universally optimal.

The regulatory shift is accelerating

Regulators are increasingly encouraging technologies that minimize contamination risk through process design rather than procedural dependence.

The revised Annex 1 guidance strongly reinforces closed processing, barrier technologies, risk-based contamination control, reduced interventions, automation, and scientific process understanding. The expectation is no longer simply compliance. The expectation is proactive contamination prevention by design and this distinction matters.

Historically, environmental monitoring often functioned as retrospective evidence of contamination control. Modern regulators increasingly expect manufacturers to engineer contamination risk out of the process before monitoring even becomes necessary. That is a major philosophical evolution.

The emerging challenge: false confidence

Ironically, the success of closed systems introduces a new risk: complacency. As processes become more automated and physically isolated, organizations may assume contamination risk has been eliminated. In reality, it has not. True closed systems still depend on - proper connector design, material compatibility, extractables and leachables control, assembly integrity, robust gamma sterilization validation, operator trainings, pressure boundary management, supply chain quality, and many more.

Even microscopic failures in tubing welds, seals, membranes, or connector interfaces can compromise sterility. Additionally, the increasing complexity of integrated single-use assemblies creates new quality assurance demands, i.e., leak testing, pressure decay validation, packaging integrity verification, transportation qualification, shelf-life studies, and

real-time integrity monitoring. The future contamination battle may not occur in the cleanroom. It may occur within the supply chain.

Sustainability: The contradiction the industry must solve

Single-use systems reduce contamination risk and operational complexity—but they also increase disposable material consumption. This creates a difficult tension between sterility assurance, manufacturing agility, and environmental sustainability.

The industry is now confronting difficult questions.

- Can recyclable polymers meet biopharmaceutical sterility requirements?
- Will PFAS regulations disrupt current single-use materials?
- Can closed systems remain economically viable under sustainability pressure?
- How should lifecycle analysis be incorporated into contamination control strategy?

The next generation of single-use systems will likely be judged not only by sterility performance, but also by environmental impact. Sustainability is no longer a separate conversation from contamination control. It is becoming part of process design itself.

The strategic reality

The companies that will lead the next decade of biopharmaceutical manufacturing are not simply buying more disposable technology. They are redesigning manufacturing philosophy around functional closure, process integration, automation, reduced human dependency, real-time quality assurance, modular manufacturing, and digitally connected fluid handling ecosystems.

The contamination control strategy of the future will not rely primarily on detecting contamination after it occurs. It will focus on architecting processes where contamination opportunities are systematically eliminated before production even begins. That is the true promise of closed single-use liquid handling systems. Not better clean-up, but better prevention. And ultimately, in sterile manufacturing, prevention is the only contamination strategy that truly scales.

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Advancing biopharma excellence: Precision humidity control and capability building

As biopharma manufacturing evolves, capability building, contract manufacturing, and precision humidity control are becoming central to quality and compliance

The rapid evolution of the biopharmaceutical industry highlights the growing importance of capability building and efficient contract manufacturing as key enablers of success. As companies work within a landscape shaped by continuous innovation and strict regulatory expectations, strengthening operational capabilities and improving manufacturing processes becomes essential. This not only supports adherence to stringent quality requirements but also enables the development of advanced therapies.

Contract manufacturing: A pillar of biopharma operations

For many biopharma companies, outsourcing production to specialised contract manufacturing partners has become an important strategic approach. It provides flexibility, cost efficiency, and access to advanced manufacturing technologies. By collaborating with experienced manufacturing experts, biopharma organisations can focus more effectively on core priorities such as research and development, while ensuring that products are manufactured to high quality standards. Such partnerships also help accelerate the availability of new therapies and support smoother scalability.

The crucial role of humidity management

Strict environmental control is critical in pharmaceutical manufacturing, with humidity management playing a particularly important role. Excess moisture can contribute to challenges such as equipment corrosion, biochemical degradation, and microbial growth, all of which may compromise product quality. Processes including powder milling, tablet compression, storage, and packaging require precise humidity regulation to maintain product integrity, stability, and efficacy.

Bry-Air: The benchmark for pharmaceutical humidity control

Bry-Air's desiccant dehumidifiers are designed to maintain optimal relative humidity levels, with the capability to achieve conditions as low as 1 per cent RH, regardless of ambient challenges. Built with precision using CNC technology and finished with a durable powder-coated surface, these systems incorporate advanced Metal Silicate Fluted media. This bacteriostatic and non-toxic solution aligns with GMP requirements and helps safeguard product quality across different stages of pharmaceutical production.

With Bry-Air, biopharma companies can address regulatory expectations with greater confidence while supporting innovation, process reliability, and excellence in therapy development.

Ensuring pharma compliance with testo data measurement technology

Testo highlights the importance of end-to-end climate monitoring, data compliance, and calibration systems in helping pharmaceutical companies maintain controlled storage, transport, and production environments for medicines, vaccines, laboratory samples, and blood products

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

Ensuring end to end climate monitoring – Testo Data Loggers

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

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

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

Data compliance for audits and inspections

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

Service & Calibration made easy

Testo also has an established state-of-the-art NABL accredited service & calibration LAB in accordance with the standard ISO/IEC 17025:2017, that takes care of the after sales support locally from Pune. Testo service & calibration facility is highly cost effective as it delivers international standards very conveniently within a week's time. Instruments of any brand/make can be calibrated and serviced locally maintaining necessary standards.

The accredited parameters include Humidity, Pressure, Absolute Pressure, Contact Type Temperature, Non-Contact Type Temperature (Infra Red Thermometer, Thermal Imager). In fact, ours is the First and Only Lab in India to get NABL Accreditation for Dew Point Temperature as well.

For more details, login to our website www.testo.com or write back to us on info@testo.in

Driving a new era of logistics excellence with Armstrong Dematic

As pharma supply chains grow more complex, Armstrong Dematic is enabling faster, compliant, and automated logistics operations through advanced intralogistics solutions.

Today, pharmaceutical organisations require seamless integration of compliance, traceability, temperature control & security in their supply chains. In this endeavour, they must modernise the intra-logistics at both the manufacturing unit and the distribution centre, which are areas long neglected in favour of ramping up production.

For decades, the industry focused on aligning manufacturing capabilities with global good manufacturing practices; however, the disruptions triggered by COVID-19 exposed deep vulnerabilities in distribution networks. The backlog in supply chain innovation has accelerated investments in digital tracking, cold chain infrastructure, and e-pharmacy integrations while complying with evolving regulatory mandates. End-to-end traceability has also emerged as a significant challenge, particularly for high-value drugs requiring stringent temperature controls.

Simultaneously, the rapid ascent of quick commerce is reshaping expectations, as consumers and healthcare providers demand near-instant access to critical medicines. Balancing speed, security, and compliance remains a delicate act, with logistics providers increasingly expected to offer solutions that integrate automation with rigorous oversight.

Addressing these complexities requires specialised automation solutions that ensure regulatory adherence while optimising speed and efficiency, and Armstrong Dematic offers just that.

An intralogistics and warehouse automation solutions provider, the company specialises in the design and implementation of advanced solutions that optimise storage, sorting, and order fulfilment processes across various industries. From pharmaceutical methods handling high volume, variety, and value of SKUs to mid-sized organisations forming consortiums of 10 to 15 companies to establish shared distribution channels, its solutions offer three core benefits.

Visibility, velocity & space optimisation

The company's advanced automation systems ensure real-time product tracking at every stage of the supply chain. Beyond traditional QR codes and barcodes, Armstrong Dematic integrates AI-driven monitoring, capturing images or short video clips when products are transferred between locations. This provides verifiable proof of movement, particularly critical in sensitive environments such as pharmaceutical supply chains. The company's solutions adhere to stringent industry standards, including 21 CFR Part 11 and GMP compliance, ensuring regulatory alignment. Pharmaceutical organisations can confidently monitor their supply chains, reducing the risks associated with counterfeit drugs and ensuring product authenticity from production to delivery.

Furthermore, Armstrong Dematic is one of the leaders in intralogistics automation where 'velocity' plays a vital role. "We have successfully increased operational speeds by four to five times within the same space while reducing manpower requirements to just one-fourth of previous levels," says Vinit Majgaonkar, Chairman, Armstrong Dematic.

While manual loading remains prevalent in India, the company also offers automated truck loading systems to further optimise efficiency.

When it comes to storage capacity, traditional warehouses, with their 10 to 12-meter storage height, limit the scalability of pharmaceutical distribution centres. Armstrong Dematic's automated storage systems extend up to 40 meters, reducing the overall footprint required for storage by 75 percent. In addition, its high-density storage solutions maximise efficiency in temperature-controlled warehouses, doubling storage density compared to standard automated systems and achieving up to four to eight times the capacity of manual storage. This conserves warehouse space and reduces energy costs associated with climate-controlled storage.

Beyond storage & retrieval

The company offers a comprehensive end-to-end order fulfilment solution, far beyond the conventional automation of storage and retrieval. While many pharmaceutical organisations have adopted storage and retrieval systems (ASRS) in isolated pockets, Armstrong Dematic integrates every stage of the fulfilment process, from the end of the production line to final dispatch, much like e-commerce logistics.

The process begins at the packaging stage, where primary packs such as capsule strips or bottles are placed into secondary cartons, labelled, and recorded for traceability. These cartons are then transported to its proprietary robotic palletising system, which meticulously arranges and maps their position on a pallet for complete SKU traceability. The company's autonomous mobile robots (AMRs) transport these pallets either directly to dispatch for cross-docking or to ASRS for optimised storage.

Its systems ensure strict adherence to FIFO (First-In-First-Out) protocols, preventing expired inventory from being overlooked. As pioneers in ASRS technology, the company, through its partnership with Dematic, the global inventor of ASRS, offers unmatched storage density and visibility.

Beyond ASRS, Armstrong Dematic's patented software solutions drive intelligent order fulfilment, enabling precise sequencing for optimised dispatch. Instead of merely moving full pallets, the system dynamically picks and compiles mixed orders based on route efficiency, ensuring that trucks are loaded in a logical LIFO sequence for streamlined last-mile delivery.

The company's orchestration software seamlessly integrates AMRs, robotic palletizers, high-speed sorters, and other automated systems, ensuring synchronised operations. At the core of this orchestration is Dematic iQ, globally recognised as the industry's most advanced order fulfilment software.

Compliant & sustainable solutions

Armstrong Dematic's approach to automation encompasses both hardware and software, ensuring a seamless, compliant, and data-driven solution for its clients. As an end-to-end consultant, the company begins by analysing customer data and forecasts with its in-house data science team to develop solutions that incorporate compliance standards from the conceptualisation stage itself.

The Systems Engineering Department ensures adherence to global regulatory frameworks, including cGMP, FDA, EU GDP guidelines, 21 CFR Part 11, and ISO certifications, while also maintaining international safety standards in automation and robotics. On the software front, the company provides a robust regulatory trail with stringent data security, high visibility, and advanced traceability features.

It also understands that automation in pharmaceutical logistics is not just about efficiency; it is about sustainability. With the growing emphasis on reducing carbon footprints and optimising energy consumption, Armstrong Dematic is introducing green logistics solutions.

Its automated warehouses incorporate energy-efficient technologies such as smart lighting, solar-powered operations, and AI-driven climate control to minimise waste and emissions. By integrating sustainability with automation, the company helps pharmaceutical firms align with global environmental goals while enhancing their bottom line.

The future of pharmaceutical logistics will likely see even greater integration of robotics. The differentiation between leading brands is no longer solely based on product quality but on the efficiency and reliability of their supply chains, an area where Armstrong Dematic plays a pivotal role.

The shift toward automation has been further fuelled by the consolidation of warehouses following the introduction of GST, with companies moving from fragmented, state-level facilities to centralised hubs serving multiple regions. This shift has created economies of scale, making automation investments more viable and necessary.

"While five years ago, a typical investment in warehouse automation ranged around ?10 crore, the market has now escalated to ?25–50 crore, with projections indicating a rise to ?50–100 crore in the next three years," says Vinit Majgaonkar.

Armstrong Dematic is one of the few companies in India equipped to handle such large-scale, complex projects, leveraging its global expertise in automation, where project sizes often exceed ?500–1,000 crores. With a quarter century experience in the Indian market and access to world-class technology, it can deliver solutions tailored to the unique needs of Indian businesses, setting a new benchmark in supply chain efficiency.

PROSOLV® SMCC 50 - A high-functional excipient from JRS Pharma

The development of co-processed, multi-functional excipients has enabled formulators to address multiple challenges with a single excipient, resulting in enhanced production and better finished product quality.

Why PROSOLV® SMCC?

Attaining good hardness at low compaction forces is quite essential while considering suitability of excipient for tablet formulation. Microcrystalline cellulose is one of the widely used and accepted excipients in tablet dosage form. Compactability of microcrystalline cellulose (MCC) is of prime importance during compression.PROSOLV® SMCC is a novel high-functionality tablet-ing excipient. The material is manufactured by co-processing MCC with colloidal silicon dioxide (CSD) and can be used to improve flow, lubricant sensitivity and tablet strength. The addition of CSD in MCC helps to improve compactability [1][2].

It has been reported that silicification appears to have no apparent effect on the primary chemical and polymorphic characteristics of MCC. This suggests that bulk modification of MCC does not occur during silicification and that the CSD, either by providing surface modification or by modifying strengthening interactions, is primarily responsible for the improvements in functionality, in particular tablet strength. This may be solely due to a morphological property or some other silicon dioxide MCC interfacial interaction. Based on scanning electron microscopy studies together with electron microprobe analysis, it was stated that silicon dioxide is primarily located at the surface of the SMCC particles. While certain amounts of silicon dioxide were detected in the internal regions of some particles, the colloidal silicon dioxide particles present at the surfaces of the SMCC particles are shown to be uniformly distributed[2][4].

PROSOLV® SMCC is available in following grades[3]

Grade	Functionality
PROSOLV® SMCC 50 LD	Best in class binder (improves tabletability)
PROSOLV® SMCC 50	Formulas in which optimal compaction and decent flow are required
PROSOLV® SMCC 90	Formulas in which a balance of flow and compaction are required
PROSOLV® SMCC HD 90	Formulas in which optimal flow and consolidation are required
PROSOLV® SMCC 90 LM	Equivalent to PROSOLV® SMCC 90, with lower moisture content

PROSOLV® SMCC provides solutions to the problems often encountered by formulation scientists while using conventional diluents having low bulk density (BD), poor flow, low compactability or loss of compactability during processing, sticking and sensitivity to lubricant(s). This article will focus on physico-chemical properties, applications and advantages of PROSOLV® SMCC 50 & PROSOLV® SMCC 50 LD.

PROSOLV® SMCC 50 LD is the Low density grade from PROSOLV® family of excipients having below characteristics –

Particle size (d50)	Bulk density
Around 50 µm	0.20-0.30 g/cc

PROSOLV® SMCC 50 is the grade from PROSOLV® family of excipients having below characteristics –

Particle size (d50)	Bulk density
Around 65 µm	0.25-0.37 g/cc

These grades offers several benefits to formulation development scientist(s) during development and production at later stage. These benefits along with a few case studies will be elaborated in next section of this article –

Benefits of PROSOLV® SMCC 50 and PROSOLV® SMCC 50 LD in Roller Compaction Applications [3][4]:

As stated above,Silicification of Microcrystalline cellulose results in an increase in surface area. This increase in surface area increases binding interaction between the individual particles by reducing the interparticulate cohesion. As a result, silicification improves both the flowability and re-compaction properties of compacts.

PROSOLV® SMCC 50 LD is a low-density PROSOLV® SMCC grade, it is having benefits like it improves the tablet hardness and re-compactability issues after roller compaction. PROSOLV® SMCC 50 LD can be first choice.

PROSOLV® SMCC 50 can be useful when both tablet hardness and powder flow are required.

Following are the case studies to evaluate the effect of physiochemical properties of PROSOLV® SMCC 50 and PROSOLV® SMCC 50 LD on tablet dosage form.

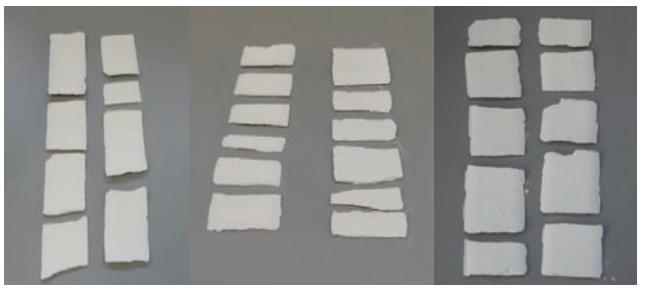
Roll compaction is necessary to improve bulk density, flowability, compactability & to improve content uniformity in the tablet dosage form.

In this study the comparison of MCC 101, PROSOLV SMCC 50 & PROSOLV SMCC 50 LD was studied & evaluated in roller compaction. The Powder blends used consisted of 75% of the Cellulosic compound (either MCC or SMCC) and 25% Dicalcium phosphate dihydrate.Material were blended for 10 mins.Different roller compaction forces were adjusted and the compacts were milled. The resulting powder was tested for particle size distribution and flowability. Furthermore, placebo tablets containing 0.5% of the lubricant, Sodium Stearyl fumarate (PRUV®), were compressed (Tablet weight- 400 mg, round, 13mm diameter) and hardness as well as disintegration time of compressed tablets was analyzed.

Ingredients	Percentage
PROSOLV® SMCC or MCC	75 %
DCP (EMCOMPRESS®)	25 %
PRUV® (Extra granular)	0.5 %

Compacts comparison:

In this study, the comparison of compacts at 25 KN was evaluated. After roller compaction compacts density plays an important role to get desired Granules: Fines ratio. This is important step for the flow & content uniformity point of view.

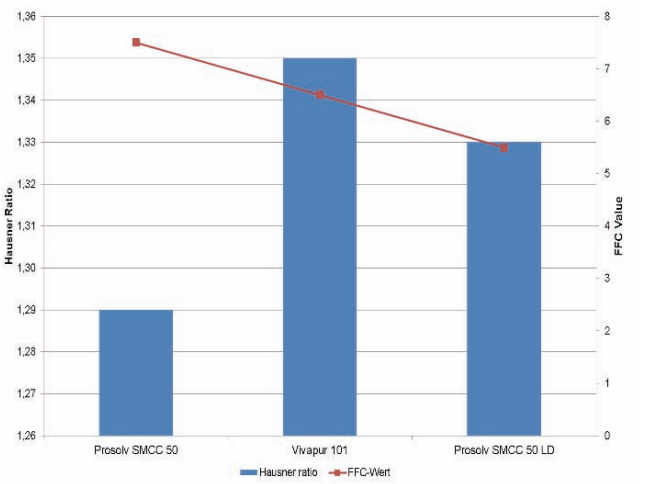


MCC 101 PROSOLV® SMCC 50 PROSOLV® SMCC 50 LD

Observation: MCC 101, PROSOLV® SMCC 50 and PROSOLV® SMCC 50 LD yield nicely shaped hard compacts at 25kN compaction force. From above picture we can conclude that PROSOLV® SMCC 50 LD yields dense compacts compare to Microcrystalline cellulose.

Flowability

In this study the flow of milled compacts was evaluated.



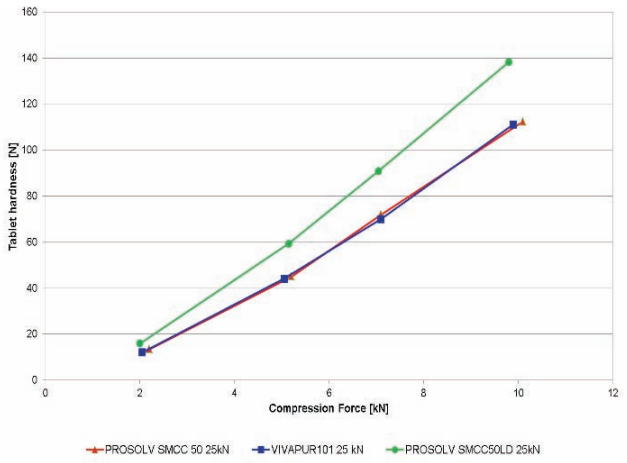
Observation:
Compacts were milled. It was found that PROSOLV® SMCC 50 exhibit best flowability followed by PROSOLV® SMCC 50 LD and MCC 101.

Conclusion:

The silicification of MCC has been shown to significantly influence the hardness and the flowability of compacts in roll compaction process, as well as the hardness of tablets made from granules obtained from the milled compacts. If the overall target in tablet production is

Tablet Hardness

In this study the effect on Tablet harness of roller compacted granules was evaluated.



Observation: Tablets were manufactured by using lubricant sodium stearyl fumarate (PRUV®) & compressed in to tablets.
Compacts based on PROSOLV® SMCC 50L D yield 30% harder tablets. Compacts based on MCC 101 and PROSOLV® SMCC 50 have nearly identical tablet hardness profiles over the entire range of compression forces.

the highest possible tablet hardness, the use of PROSOLV® SMCC 50 LD recommended [3][5][6].

If both, the particle flow and the tablet hardness is the target PROSOLV® SMCC 50 is the best choice [3].

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- High efficiency at low use level
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- Effective in various manufacturing methods viz. direct compression, wet granulation & dry granulation
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- No burst effect for highly soluble drugs
- No chance of dose dumping
- Excellent reproducibility
- Pharmacopoieal status available
- Works as efficient binder, no need to use additional binder

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