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CONTENTS

RESILIENCE BY DESIGN
THE PACKAGING IMPERATIVE

Pg28

PRE EVENT

34 | EXPRESS PHARMA WORLD EXPO: THE PLATFORM FOR INDIA PHARMA INC'S NEXT LEAP

TECHNOLOGY

54 | THE SHIFT TO INTELLIGENCE DRIVEN PHARMA

STRATEGY

55 | THE INNOVATION LITMUS TEST

INTERVIEWS

P16
STEPHANIE ARMSTRONG
Regional President, Asia Pacific and Africa, Zoetis

P21
NANDAN KULKARNI
Senior Research Analyst, Healthcare, Bernstein (India)

P23
TONY QIU,
Head of APAC Region, Global Plant Operations, ISCO, Merck Life Science

P26
AJAY SINGH DASSUNDI
Secretary, MP Small and Medium Drugs Manufacturers Association

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The fine line between reform and risk

A couple of recent notifications, one a notified amendment and the second one, a proposed amendment, concerning medicines have good intentions, but could have quite the opposite outcomes. While regulators are playing their role to rationalise restrictions, with the mandate to improve Ease of Doing Business, they have to also balance patient safety and public good.

Let's first take a recent instance of authorities stepping in to investigate and if necessary, enforce anti-dumping duties on specialised packaging material. A recent LKS International Trade Team update informs about the Directorate General of Trade Remedies (DGTR) acting on a complaint from JPFL Films and initiating an Anti-Dumping Duty investigation concerning imports of Biaxially Oriented Polyamide (BOPA) film originating in and exported from China PR and Thailand.

As per the LKS International Trade Team update, BOPA films are high-performance specialised flexible packaging films manufactured from polyamide resin through biaxial orientation technology, known for its high mechanical strength, isotropic properties, odour and aroma resistance, hot and cold forming resistance, moisture and oxygen barrier properties, and puncture resistance.

BOPA film is used as specialised packaging material for food, liquids and pharma products. If the DGTR's investigation finds that the imports of BOPA film from China PR and Thailand are at dumped prices and impacting the business of the domestic industry/company, then it can recommend anti-dumping duty, to rectify the harm to JPFL Films' business. This case ties in directly to the crisis looming around pharma packaging, the theme of the cover story of Express Pharma's July edition. *(Resilience by Design: The Packaging Imperative)*

Let's now consider how some regulations could backfire. For instance, the Union Health Ministry has expanded the QR code-based drug traceability framework to include all vaccines, antimicrobials, narcotic and psychotropic drugs covered under the Narcotic Drugs and Psychotropic Substances (NDPS) Act, and anti-cancer medicines.

This notified amendment to the Drugs Rules, 1945 to expand the ambit of Schedule H2 is expected to "facilitate authentication of medicines at various stages of the supply chain and enable improved tracking and verification of drug products. The measure is expected to strengthen regulatory oversight and support efforts to curb the distribution of spurious medicines in the market."

But industry experts have pointed out that QR codes can be counterfeited, leading to a false sense of security among patients. *(https://www.expresspharma.in/how-counterfeiters-are-breaching-indias-qr-code-system/)*

Manufacturers of vaccines, narcotic and psychotropic drugs, and anti-cancer medicines have a year to comply with this mandate while the provisions relating to antimicrobials shall become effective a year later, from July 1, 2028.

One hopes that regulators use the interim period to ensure that they have the taskforce and systems in place to enforce these mandates. This would, at the very least, entail more frequent surprise inspections and raids of vulnerable touch points within the pharma supply chain to make this initiative as impactful as it needs to be.

Secondly, let's consider the Union Ministry of Health and Family Welfare's proposal to rationalise/reduce the required residual shelf-life for imported drugs. The draft amendment proposes to revise the current requirement of a minimum residual shelf life of more than 60 per cent for imported drugs to 12 months at the time of import. Biological products and radiopharmaceuticals are exempted from this revision "in view of their specialised nature and public health considerations."

Converting good intentions into impactful benefits for all stakeholders will need stringent implementation and enforcement

On the face of it, this amendment has many advantages. The amendment is "expected to optimise supply management, reduce costs, and strengthen the availability of essential medicines in the country." Patients are expected to get improved access to imported medicines, while importers of such medicines will get more time to distribute such medicines before expiry.

The proposed amendment is open for comments from industry till July 22, 2026. Industry response has been positive so far, as it seems to address supply chain issues and gives more time to sell imported medicines.

But from a patient safety point of view, how many patients in India are aware expired medicines could have health risks? How many patients check expiry dates? Are expired medicines indeed taken out of the pharma supply chain at all? Especially imported medicines, which would be more expensive? Would the Ease of Doing Business mandate result in compromised patient safety? Especially when it would be difficult to test the quality of such imported medicines as they near their expiry dates.

There have been many reports of expired medicines being re-sold to patients. In fact, the illegal sale and disposal of expired medicines was the topic of a Lok Sabha question in March 2026 (*Unstarred Question no. 4641*) from Jai Prakash of the Hardoi constituency of Uttar Pradesh, Bharatiya Janata Party.

His query was quite detailed and reveals the modus operandi of such scams: 'whether the Government has taken or proposes to take strict action to curb the illegal and dangerous practice of reselling expired medicines, which involves altering expiry dates and re-entering them into the supply chain'; whether the Central Drugs Standard Control Organization (CDSCO) has issued new guidelines on the safe disposal of expired/unused drugs to ensure that they are not diverted back into the market; and whether the Government has launched "Drug Take-Bank" programmes, where consumers can drop off expired medicine at designated locations.

In her reply, Anupriya Patel, Union Minister of State for Health and Family Welfare, informed that CDSCO, with the approval of the Drugs Technical Advisory Board (DTAB) had issued a guidance document (on May 26, 2025) on the disposal of expired/unused drugs. She also informed that State Licensing Authorities 'are legally empowered and take stringent actions against violation of provisions of the Act and Rules including the instances of reselling the expired medicines.'

This exchange proves that there is enough awareness among legislators and regulators on the extent and serious harm to consumer health posed by expired medicines, imported or manufactured in India. Whether these rules are implemented and enforced enough is another question.

There is no doubt that regulatory oversight has had some wins. The recent CDSCO advisory against 'promotional activities, including so-called "awareness campaigns," that function as a surrogate advertisement for prescription drugs including Glucagon-like peptide-1 (GLP-1) receptor agonists,' was a timely reminder that what may work in other markets, may not be aligned to Bharat's realities.

These recent amendments and reforms underline the fine line between reform and risk. Regulators like the CDSCO, Ministry of Health & Family Welfare have a tough balancing act: to bring in business efficiencies without compromising public health. Converting good intentions into impactful benefits for all stakeholders will need stringent implementation and enforcement.

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India is one of Zoetis' strongest markets in Asia for in-ovo vaccination

India is the world's second-largest egg producer, ranked fourth globally in overall meat production, with poultry accounting for nearly half of the country's meat output. Outbreaks like H5N1 are reminders that animal health and human health are deeply connected, points out **Stephanie Armstrong,** Regional President, Asia Pacific and Africa, Zoetis. In an email interaction with **Viveka Roychowdhury,** she details how more precise and adaptable vaccine science, combined with biosecurity, surveillance, training and technical support are essential to support India's poultry sector and the country's broader ambitions in food production, productivity and companion animal care

The recent H5N1 avian influenza resurgence in poultry farms in certain districts of Maharashtra and Karnataka once again reminds us that human health is connected to animal health. How has animal health science and research evolved to meet these challenges?

When we see outbreaks like H5N1, it is a very real reminder that animal health and human health are deeply connected. These are not abstract public health concepts. They affect farms, families, food systems, trade and livelihoods, often very quickly.

Highly Pathogenic Avian Influenza (HPAI) remains one of the most serious threats to global animal health. India has had experience with H5N1 since its first poultry outbreak in Maharashtra in 2006, so the current resurgence builds on a history that has already shown why vigilance, rapid response and coordination matter. According to the World Organisation for Animal Health's HPAI Situation Report 71 dated May 2025 (1), HPAI has led to the death or mass culling of more than 633 million poultry worldwide between 2005 and 2024, and the recent spread of H5N1 beyond poultry into other species, including mammals, reinforces why surveillance and scientific readiness matter.prediction, prevention, detection and rapid response - from biosecurity and genomic sequencing to faster diagnostics, better field-level

> What is encouraging is India's pace of modernisation, technical talent and growing recognition that prevention is far less costly than a serious outbreak. The poultry markets that will lead over the next decade will not simply be those that produce more, but those that grow responsibly and build resilience into the system

What has changed is the speed and precision of animal health science. The response is no longer only reactive. It is increasingly built around surveillance and data sharing.

At Zoetis, this aligns closely with how we think about innovation. With nearly 75 years of experience in animal health, our role is to support veterinarians, producers and public health systems with science that helps predict, prevent, detect and treat disease.

But science only delivers when the systems around it are strong. That means robust biosecurity, surveillance, rapid diagnostics, transparent reporting and collaboration across government, industry and the veterinary community. Where appropriate and permitted by local policy, vaccination can also be part of that broader disease-control strategy. That is One Health in practice.

What can be done to proactively detect and predict zoonotic spillover incidents, especially as industrial livestock farming intensifies?

The shift we need is from waiting for disease to appear, to building systems that help us prevent disease and detect risk earlier. That means stronger

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biosecurity, surveillance, better field-level sampling, faster diagnostics, genomic sequencing, and the ability to connect data across animal health, human health and the environment. Biosecurity remains fundamental, but it cannot stand alone. It needs to be supported by surveillance, diagnostics, responsible vaccination strategies where appropriate, and clear channels for rapid reporting and response.

The real opportunity is to make those systems more connected. If something is detected at farm level, that information should move quickly through veterinary, public health and government systems so that risk can be assessed and action taken earlier. Digital platforms, data analytics and AI can support this by helping identify patterns, prioritise risks and enable faster decisions.

At Zoetis, we have a long history with avian influenza beginning in the early 2000s when we developed a vaccine in response to outbreaks in SE Asia. Since then, we continue to monitor avian influenza as well as many other zoonotic diseases so we can be ready with updated solutions if warranted.

We are also investing in genomics, predictive analytics and digital tools, and our India Capability Centre is part of that global capability. As livestock systems become more complex, the most effective approach will be a connected One Health system: good farm practices, strong veterinary capacity, science-led surveillance and prevention and close collaboration across industry, government and public health authorities.

How is India's poultry sector evolving vis a vis other countries? Has it demonstrated the capability to tackle such public health challenges while balancing growth imperatives?

India's poultry sector is evolving quickly, and its importance goes well beyond agriculture. Poultry is one of the most accessible sources of animal protein, and India is now the world's second-largest egg producer. India also ranks fourth globally in overall meat production, with poultry accounting for nearly half of the country's meat output.

The opportunity is significant, but so is the responsibility. As the sector grows, strong animal health systems become even more important. Among larger integrated producers, we are seeing greater focus on biosecurity, veterinary oversight, housing, hygiene and disease prevention. That is encouraging because animal health is not only a welfare issue. It is a productivity, food security and public health issue. India has demonstrated the ability to respond to animal disease threats through national and state-level surveillance, reporting and containment systems. At the same time, recent avian influenza outbreaks show that the next step is consistency: ensuring good biosecurity, veterinary access, rapid reporting and preventive health practices across the full poultry ecosystem.

What is encouraging is India's pace of modernisation, technical talent and growing recognition that prevention is far less costly than a serious outbreak. The poultry markets that will lead over the next decade will not simply be those that produce more, but those that grow responsibly and build resilience into the system.

What are the latest technologies available in this space?

There is a great deal of innovation happening across poultry health, and I would group it into three areas: prevention, production systems and decision-making.

On prevention, vaccine science is becoming more precise and adaptable as disease threats evolve. Vector and recombinant vaccines are a fast-growing area, and approaches such as DIVA - Differentiating Infected from Vaccinated Animals - are increasingly important because they support surveillance, disease control and confidence in global trade.

The way vaccines are delivered is also changing. India has seen a remarkable shift from more conventional farm-level vaccination and treatment-led protocols toward hatchery vaccination and prevention-led health programmes. For Zoetis, our in-ovo vaccination technologies, including Inovoject and Inovoject NXT, are strong examples. They support vaccine delivery during incubation, helping hatcheries automate and standardise vaccination at scale. India has adopted this technology quickly and is one of Zoetis' strongest markets in Asia for in-ovo vaccination, reflecting how fast the sector is modernising.

Beyond vaccines, environment-controlled farming is another important advancement. Better control of temperature, ventilation, humidity and housing conditions can improve predictability, productivity and flock health.

On detection and decision-making, faster diagnostics, field-level sampling, genomic sequencing, environmental surveillance, digital platforms and AI are all changing what is possible. They can help identify risks, support faster decisions and strengthen the connection between farm-level signals and public health response.

That is the direction poultry health innovation is moving in: stronger prevention, more consistent production systems, faster detection and more connected decision-making.

How affordable and implementable are these technologies for India's poultry sector, given that each country would have localised situations linked to capex, labour available at poultry farms etc?

These are exactly the right questions, because technology only matters if it can be implemented in the system where it is needed. In a market like India, affordability and practicality are just as important as scientific sophistication.

The answer will not be the same for every part of the poultry sector. For larger integrated producers, many technologies - from improved vaccination systems and stronger biosecurity to digital monitoring and diagnostics - are increasingly viable because the business case for prevention is clear.

For smaller and medium-scale producers, the model has to be different. It cannot depend on every farmer making large capital investments. Shared infrastructure, veterinary extension services, practical farm-level training and partnership models become much more important.

This is where Zoetis can bring value beyond products alone. We bring both products and services - including technical knowledge, training, field support and experience from different markets - which can help producers of different sizes adopt solutions in a way that is practical for their operations.India also has an implementation advantage: people on the ground. Farm workers can observe changes in flock health, follow biosecurity protocols and escalate concerns quickly, but only if they are trained, supported and given clear protocols.

So the technologies are implementable, but not through a one-size-fits-all model. The right approach is tiered: advanced systems for larger integrated producers, shared access and support models for smaller producers, and strong basic biosecurity, surveillance and training across the sector. That is how we can partner in the industry's transition to become more efficient, resilient and sustainable.

A key feature of preventive strategies is vaccination, be it human or animal health. What are the latest offerings in this space for animal health and the advantages over traditional methods?

Vaccines are one of the most important tools we have in preventive animal health. Across livestock, poultry and companion animals, they help protect animal welfare, support more reliable food production, and reduce the need to use antimicrobials to manage disease. That is why vaccines should be seen as part of core health infrastructure, not just as a response during an outbreak.

What is changing is the precision of vaccine science and the consistency of delivery. Compared with more traditional approaches, newer vaccine technologies can be more targeted, more adaptable to changing disease threats, and easier to deliver consistently at scale. In areas such as avian influenza, they can also support surveillance through strategies like DIVA, which we discussed earlier.

Delivery is advancing too. Zoetis in-ovo vaccination technologies, including Inovoject and Inovoject NXT, help hatcheries automate and standardise vaccine delivery at scale, which is especially relevant for modern poultry systems.For India, the opportunity is to make prevention practical across different production systems. That means combining strong vaccine science with biosecurity, surveillance, training and technical support, so that innovation works not only in theory, but in the day-to-day reality of farms, hatcheries and veterinary practice.

What is Zoetis' annual spend on R&D as a percentage of overall revenues? Give us an idea of the projects in the animal health research pipeline to watch out for in this space.

R&D is central to who we are as a company. Since our IPO, Zoetis has invested more than $6 billion in research and development, reflecting our sustained commitment to science-led innovation.

What matters is not only the level of investment, but where it is focused. Our pipeline includes 12 potential blockbuster candidates across areas of significant unmet need, including chronic kidney disease, oncology, cardiology, anxiety and obesity in companion animals. We are also continuing to advance

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One area to watch is precision animal health. Zoetis has announced an agreement to acquire Neogen's animal genomics business, which would strengthen our capabilities in genomic technologies and data-led insights for livestock producers, subject to closing and regulatory approvals.

More broadly, the future of animal health will be increasingly integrated. It will not be medicines, vaccines, diagnostics or data in isolation, but these capabilities working together to help veterinarians and producers predict, prevent, detect and treat disease earlier and more effectively. That is where we see the next wave of innovation.

Besides industrial livestock, the One Health philosophy includes the pet and companion animals. What is the current share of global revenues coming from India and what is predicted growth of the overall animal health market in India?

India sits within our International segment, which remains an important growth driver for Zoetis. In our most recent quarter, our International segment delivered 10% organic operational growth, and India is an active part of that broader story. The market itself is very promising. Public estimates vary, but India is widely expected to be a high-growth animal health market, driven by the continued importance of livestock and poultry, as well as the rapid evolution of companion animal care.

On the companion animal side, we are seeing a clear shift. Urbanisation, rising incomes, changing family structures and the growing role of pets in households are changing expectations of veterinary care. Pet owners are becoming more aware of prevention, diagnostics, parasite protection, dermatology and chronic disease management - not just treatment when something goes wrong.

For Zoetis, the opportunity is to support that transition across both livestock and companion animals: helping producers improve health, productivity and disease prevention, while supporting veterinarians and pet owners with innovative solutions that improve quality of life for pets.

That is One Health in practice - stronger animal health, stronger veterinary capacity and better preventive care contributing to healthier animals, people and communities.

What are Zoetis' plans for India? Where does it fit into the company's overall strategy, besides being a huge market?

India is an important market for Zoetis, and not simply because of its size. What makes India distinctive is the combination of commercial opportunity, scientific capability and technology talent.We have a strong commercial presence in India, a Veterinary Medicine Research and Development presence in the Mumbai-Thane area, and our Zoetis India Capability Center in Hyderabad, which has become an important part of our global digital and technology capability. That gives India a role beyond local market growth - it contributes to how we innovate for customers globally.

On the ground, our focus is to expand access to our portfolio across livestock and companion animals, while bringing global innovation to Indian veterinarians, producers and pet owners in a way that fits the market. That includes preventive care, productivity, diagnostics, dermatology, pain management and digital tools that support better decision-making.

More broadly, we want to be a long-term partner in strengthening India's animal health ecosystem. As India's ambitions in food production, productivity and companion animal care continue to grow, strong animal health infrastructure will be a critical enabler. What gives me confidence is the depth of talent we see in India - across our teams, our customers, and the veterinary and technology communities we work with.

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Why India's biopharma value shift could unlock an additional $125-bn opportunity

Contrary to the initial hype, Bernstein's view on India's overall GLP-1 market is modest and borderline neutral, borne out by recent reports of moderation in sales after the initial frenzy. Instead, **Nandan Kulkarni,** Senior Research Analyst, Healthcare, Bernstein (India) explains to **Viveka Roychowdhury** that Indian biopharma's volume-value transition will come from niche asset areas that require process and engineering depth and global market presence rather than pure patent-expiries. These include peptides, complex injectables, 505(B)(2) NDAs, orphan drugs, bio-betters and supplementary biologics, high-potency APIs, drug-device combinations

What are the broad global consumer health trends driving the global biopharma sector this decade?
We believe that global consumer health is moving towards a continuum of care in chronic disease pools. The continuum is increasingly being shaped by the lifestyle, pollution, and aging population as the key drivers. These pools are concentrated mainly across metabolic health, anti-ageing, skin and cosmetics, women's health, gut health, sleep, immunity and preventive care. The scale is already material. We estimate the global wellness opportunity in Over-The-Counter (OTC) drugs at about $200 billion while dietary supplements another ~$210 billion.

The clinical backdrop is also supportive to this trend: we

acknowledge that clinically it is estimated that globally every one in six adults is obese, and about one in eight has diabetes.

For Indian biopharma, we believe the key strategic pivot is that consumer health is becoming more science-led, with better opportunities in Rx-adjacent products where efficacy, trust and medical credibility matter. To simply put, it is pivoting from FMCG play to more a science/value play.

How are biopharma companies in India converting these trends into new revenue strategies?
Our report on India healthcare highlights that Indian biopharma is increasingly building higher-value franchises across chronic therapies, derma, nutrition,

women's health, metabolic adjacencies, complex dosage forms, biologics, sterile manufacturing and CDMO. We believe India's domestic pharma market at about $25-27 billion will nearly double to about $60 billion over the next decade and chronic therapies form the largest part of this growth story in our view.

India also supplies roughly 20 per cent of global generic medicines by volume. The revenue strategy is gradually shifting from adding more SKUs to owning patient conditions through HCP education, differentiated delivery, point of care diagnostic, adherence support, and regulatory simplification in new product/therapy launches.

How much impact will geopolitical disruptions like various US tariffs (e.g. USTR Section 301, Section 232) various conflicts etc. have on the long term profitability of India's pharma companies?
We believe that geopolitics should be treated mainly as a margin, supply-chain and working-capital risk. In our view, global demand for prescription drugs, particularly in chronic therapies as well as in the OTC segment is relatively resilient, and India remains structurally important to global generics supply. The current pressure points in our view are reliable procurement channels,

We believe India's domestic pharma market at about $25-27 billion will nearly double to about $60 billion over the next decade and chronic therapies form the largest part of this growth story in our view

compliance to highest quality standards for these global supplier bases, and higher logistic costs.

We estimate that India's pharma exports are around $30-31 billion, with regulated markets contributing roughly half of these exports. On the import front for the sector, we estimate that the API, bulk drug and intermediate imports are about $4.5- 5 billion in the last financial year with China continuing to dominate at nearly 74 per cent of this import basket. In our view, the recent geopolitical pressures from regional conflicts stretches this import burden while delaying realisation of exports in the short term. In the medium to long term we believe that the redrawn supply chains will increasingly put Indian biopharma in the global sweet-spot and thus improve sector profitability. Furthermore, we estimate that the global sales prices realised (ASP) for majority drugs are nearly bottoming with early signs of reversal, and this in our view will boost industry margins and volumes materially.

In summary, we believe that in the short term the overhang on US tariffs, Section 232 or equivalent probes in regulated markets, China-linked supply disruptions and conflict-led freight volatility will pressurise margins. Longer term, we estimate Indian biopharma to be an integral part of redrawn supply chains in the global healthcare spend.

Specifically, what are the niche areas where India's biopharma players are positioning themselves to transition from a volume to value, generics to innovation model?
We believe Indian biopharma is pivoting from quantity driven to quality led innovation. Our report suggests that the strongest value migration for Indian biopharma is in niche asset areas that require process and engineering depth and global market presence rather than pure patent-expiries. We believe these include peptides, complex injectables, 505(B)(2) NDAs, orphan drugs, bio-betters and supplementary biologics, high-potency APIs, drug-device combinations. We also believe this is moving (from) a typical CDMO space towards Pharma as a Service (Paas). Our report suggests that this volume-value transition will potentially unlock additional $120-125 billion in revenues over the next decade and will be global in its reach.

We believe that the global regulatory and policy backdrop supports this shift. Biosimilars are also becoming mainstream, with the global market around $30–33 billion in 2024 and more than 75 biosimilars approved by the US FDA by late 2025. Similarly, 505(B)(2) and new drug development guidelines (are) increasingly conducive for the industry, and Indian policy makers (are) unlocking sectoral measures such as Bioshakti, PLI and PRIP schemes.

Will the GLP-1 opportunity turn out to be lower than initial forecasts, as the increasing competition reduces profit margins? How are the leading players planning to retain consumers/patients, given the CDSCO's close watch on promotional vs educational content?
Our view on India's overall GLP-1 market is modest and borderline neutral. We expect the India market to peak at about $2–2.5 billion with a high competitive intensity, despite the global excitement around the category. We acknowledge that the Indian population has a large addressable patient pool, with estimated ~100mn people living with diabetes and around 136mn with prediabetes. However, we believe that the monetisation and actually serviced market in India is limited due to affordability, India's socio-cultural patterns on food habits and lifestyle, limited reimbursement and social perception.

Our research suggests that barring higher income strata and certain metropolitan markets, obesity is still not widely viewed as a disease in India, so awareness education will (be) required to precede treatment. Against the backdrop of regulatory watch on promotional versus educational content, patient retention will depend on compliant HCP-led initiation, nutrition counselling, titration support, side-effect management, refill reliability and affordability, rather than aggressive consumer-led promotion.

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India has emerged as a strategically important hub for Merck

As the Asia-Pacific region emerges as a key growth engine for the global life sciences industry, companies are increasingly investing in localized manufacturing, resilient supply chains, and innovation ecosystems. Merck's expanded Peenya facility in Bengaluru reflects this shift, strengthening the company's ability to support biopharmamanufacturing, advanced filtration technologies, and regional customer needs. **Tony Qiu,** Head of APAC Region, Global Plant Operations, ISCO, Merck Life Science, discusses the strategic importance of the Peenya site, the evolving life sciences landscape in APAC, and how Merck is leveraging technology, talent, and infrastructure to drive future growth in an exclusive interview with **Swati Rana**

Since its expansion, how has the Peenya facility contributed to strengthening Merck's manufacturing footprint in the Asia-Pacific region?

Peenya is one of the key manufacturing locations for the APAC region, particularly for Life Science operations, and over time, it has established itself as a benchmark for operational excellence. Following its recent expansion, the Peenya facility in Bengaluru has significantly strengthened Merck's manufacturing footprint in APAC, evolving into a strategic hub for life science production.

The site consistently demonstrates high standards in safety, quality, efficiency, and compliance, positioning it as a model facility within Merck's global manufacturing network. With this expansion, the facility is expected to play an even larger role in the production of advanced filtration technologies.

The development also supports the Government of India's 'Make in India' initiative by strengthening regional

biotech manufacturing capabilities and enhancing the reliability of global life science supply chains.

What role does the Peenya site play in enhancing supply chain resilience for global life sciences customers?
The expansion of the Peenya facility has significantly strengthened Merck's ability to manage and supply filtration products to global markets. With new production lines for both hardware and consumables, the site now has greater capacity to support a more consistent and reliable supply of critical filtration solutions used in bioprocessing.

The facility is evolving into an integrated hub that supports multiple stages of the bioprocessing workflow in a single location. This transformation enhances operational flexibility and enables the site to respond more effectively to changing customer needs.

Its location in India provides access to a strong engineering talent pool and a well-established supplier ecosystem, helping maintain efficiency while upholding Merck's global quality standards. These strengths position Peenya as an increasingly important site for supporting growth across APAC while contributing to greater resilience and stability in the global supply chain.

With biologics, cell and gene therapies gaining traction, how is Merck adapting its manufacturing capabilities to support these next-generation modalities?
Merck is continuously adapting its manufacturing operations to support next-generation therapies through investments in advanced technologies and specialised infrastructure.

The expansion of the Peenya facility includes capabilities for filtration hardware and systems that play a critical role in biologics manufacturing, particularly in purification and separation processes. These technologies support the scalable and high-quality production of complex therapies, including biologics as well as emerging cell and gene therapies.

Aligned with our "in-region for-region" strategy, the site leverages India's skilled workforce and economies of scale while maintaining global quality standards, enabling Merck to support innovation, reliability, and supply resilience across APAC markets.

Can you elaborate on how platforms like M Lab at the Peenya facility are enabling process innovation and faster scale-up for customers?
Merck's M Lab Collaboration Centers, located across APAC including Bengaluru, Singapore, Shanghai, Seoul, Tokyo, and Taipei, play an important role in accelerating pharmaceutical innovation.

Designed as non-GMP simulated environments, these centres allow customers to test processes, optimise workflows, and receive hands-on technical training. This helps them scale up production faster while reducing technology transfer risks and development costs.

The centres also bridge the gap between research and commercial manufacturing by supporting process optimisation and providing specialised expertise in emerging areas such as cell and gene therapy production.

How is AI being integrated into day-to-day operations at the Peenya facility to improve manufacturing efficiency and consistency?
Merck integrates AI across its operations to enhance efficiency and accelerate innovation. Sites in APAC, including Peenya, are currently in the pilot phase of implementing AI-driven solutions for manufacturing and operational processes.

As these initiatives evolve, AI is expected to play a growing role in improving efficiency, consistency, and decision-making across manufacturing operations.

How is Merck leveraging local talent in India to support its global manufacturing and innovation goals?
As global manufacturing and innovation become increasingly complex and technology-driven, India has emerged as a strategically important hub for Merck.

The country offers not only a deep pool of skilled technical

talent but also the operational agility and advancing digital capabilities needed to support global ambitions.

Through continued investments in talent development, digital infrastructure, and specialised capabilities, Merck is strengthening India's role within its global manufacturing and innovation ecosystem. We firmly believe that local excellence, when connected to global purpose, becomes a powerful engine for sustainable innovation.

What are the key challenges in building a robust and agile life sciences supply chain across diverse APAC markets?

The life sciences supply chain across APAC is operating in an increasingly complex environment shaped by regulatory scrutiny on API sourcing and traceability, geopolitical uncertainties, and concentrated manufacturing dependencies.

These are no longer isolated challenges but interconnected pressures that require a fundamentally more agile and resilient approach.

For Merck, supply chain resilience means proactively anticipating risks, embedding compliance throughout the supply chain, and maintaining the flexibility to adapt to changing global conditions. The reliability of our supply chain is directly linked to our commitment to patients and healthcare systems worldwide.

Do you see APAC evolving as a global hub not just for manufacturing, but also for innovation in life sciences? What will drive this shift?

We see APAC undergoing a significant transformation from being primarily a manufacturing destination to becoming a major innovation hub for life sciences.

The region is making substantial progress in areas such as cell and gene therapy, antibody-drug conjugates, mRNA technologies, and biologics. Growing R&D investments, supportive policy environments, and expanding scientific talent pools are creating ecosystems where innovation can thrive.

Markets such as China, Singapore, India, South Korea, and Japan are establishing increasingly sophisticated positions within the global biopharmaceutical landscape.

For Merck, this evolution presents both an opportunity and a responsibility to contribute scientific expertise, global capabilities, and innovation partnerships that help strengthen the regional life sciences ecosystem.

Looking ahead, what strategic priorities will define Merck's growth in APAC over the next 3-5 years?

APAC will remain one of the most important growth regions for Merck's Life Science business over the next three to five years. The region's rapid growth and increasing importance in the global life science ecosystem make it a key focus for capacity expansion.

Our priorities include strengthening regional capabilities, supporting growth in biopharmaceutical manufacturing, and helping customers scale more efficiently, particularly in areas such as single-use bioprocessing.

India will continue to play a central role in this strategy. At our Peenya site, manufacturing of products such as the Pellicon Holder Family and MVP Icon® Swab directly supports customers across APAC, while the site's expanding product portfolio through 2028 reinforces India's role as a localized manufacturing hub for filtration and device-related capabilities.

Sustainability will also remain a core pillar of our manufacturing strategy through initiatives focused on renewable energy, water optimisation, and packaging recycling, aligned with our broader ESG commitments and customer expectations.

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Future of MP Pharma lies in quality manufacturing, exports and contract development

As Madhya Pradesh strengthens its position as an emerging pharma manufacturing destination, the state's MSME sector is playing an increasingly important role in driving production, exports, and investment. Backed by the growing Pithampur pharma cluster, supportive government policies, and expanding opportunities in contract manufacturing, the ecosystem is poised for significant growth. **Ajay Singh Dassundi,** Secretary, MP Small and Medium Drugs Manufacturers Association, shares his views on the state's growth trajectory, the challenges faced by MSMEs, the impact of revised Schedule M, and the roadmap for making Madhya Pradesh a leading pharma manufacturing hub, in an exclusive interview with **Swati Rana**

Madhya Pradesh is steadily emerging as a pharma manufacturing hub. How do you assess the current growth trajectory of the state's pharma MSME sector?

Madhya Pradesh has witnessed significant growth in pharma manufacturing over the last decade, particularly in and around Indore-Pithampur, which has emerged as the state's strongest pharma ecosystem. The state offers a strategic central location, comparatively lower operating costs, availability of industrial land, and a supportive manufacturing environment.

The pharma cluster around Indore-Pithampur today houses a large number of formulation, API, herbal, nutraceutical, and contract manufacturing units, ranging from MSMEs to globally regulated facilities. The presence of major companies alongside hundreds of MSME units has created a strong industrial ecosystem, generating employment and supporting ancillary industries.

From an MSME perspective, there is increasing investment in quality systems, export readiness, and product diversification. The sector is moving from being primarily a domestic supplier to becoming an important contributor to regulated and semi-regulated international markets.

How important is the Pithampur pharma cluster in positioning Madhya Pradesh as a preferred manufacturing destination?

Pithampur is undoubtedly the backbone of Madhya Pradesh's pharma manufacturing sector. It has developed into one of India's important pharma production centres, with the presence of domestic and multinational companies manufacturing for both Indian and international markets.

The cluster provides economies of scale, availability of skilled manpower, logistics advantages, supplier networks, packaging support, engineering services, and regulatory expertise. It has also enhanced investor confidence in Madhya Pradesh as a reliable manufacturing destination.

The upcoming infrastructure developments, including improved connectivity and industrial corridors, are expected to further strengthen Pithampur's position in the coming years.

What are the biggest challenges currently faced by small and medium drug manufacturers in Madhya Pradesh?

The biggest challenge remains cost competitiveness. MSME manufacturers are facing rising costs of raw materials, packaging materials, utilities, logistics, and skilled manpower. Working capital pressure has also increased due to delayed payments from institutional buyers and government procurement agencies.

Another challenge is maintaining profitability while complying with

increasingly stringent regulatory requirements. Smaller manufacturers often operate with limited financial resources, making investments in technology upgrades, automation, validation, and documentation systems difficult.

Availability of trained technical manpower, particularly in quality assurance, regulatory affairs, and validation functions, is also becoming a concern for many MSME units.

What kind of policy support or incentives are most urgently needed to strengthen the pharma manufacturing ecosystem in the state?
The sector would benefit significantly from dedicated support for Schedule M compliance, technology modernisation, and infrastructure upgrades. Interest subsidies, capital investment subsidies, and low-cost financing mechanisms can help MSMEs transition smoothly to higher quality standards.

The government should also strengthen common facilities such as advanced testing laboratories, stability chambers, training centres, and regulatory support cells that can be shared by smaller manufacturers.

Faster reimbursement of industrial incentives, prompt payment mechanisms in government procurement, and export promotion initiatives would further improve the competitiveness of MSME pharma companies.

The revised Schedule M guidelines are expected to significantly impact manufacturing practices. How prepared are MSME pharma companies in Madhya Pradesh to comply with the new requirements?
The industry understands the importance of revised Schedule M because it will strengthen product quality, patient safety, and global acceptance of Indian medicines. Many medium-sized companies have already initiated infrastructure improvements, documentation upgrades, training programmes, and quality system enhancements.

However, preparedness varies significantly across the MSME segment. While some units have made substantial progress, smaller companies are still assessing the investments required for full compliance. The intent to comply is strong, but implementation timelines and financial capability remain important factors.

What are the major concerns of smaller manufacturers regarding Schedule M implementation, especially in terms of infrastructure upgrades and compliance costs?
The primary concern is the substantial capital expenditure required for facility modifications, HVAC systems, water systems, equipment qualification, computerised documentation, and validation activities.

For many MSMEs, these investments can run into several crores of rupees. In addition to infrastructure costs, there are recurring expenses related to training, documentation, audits, consultants, and quality management systems.

Most small manufacturers are not opposed to quality improvements; their concern is ensuring that compliance requirements are implemented in a practical manner with adequate transition time and financial support.

Are MSME pharma companies in MP increasingly exploring opportunities in exports, nutraceuticals, and contract manufacturing?
Yes, this trend is clearly visible. MSME companies are actively exploring export opportunities in Africa, Asia, Latin America, and other emerging markets. Many companies are also diversifying into nutraceuticals, wellness products, herbal formulations, and food supplements due to growing consumer demand.

Contract manufacturing and third-party manufacturing have become important growth drivers. Brand owners increasingly prefer asset-light models, creating opportunities for quality-focused manufacturing companies. This shift is helping MSMEs improve capacity utilisation and expand their business beyond traditional markets.

Looking ahead, what is your vision for the growth of Madhya Pradesh's pharma MSME sector over the next five to ten years?
Madhya Pradesh has emerged as one of the most attractive destinations for pharma manufacturing in India. The State Government's industrial and MSME policies offer a strong combination of capital incentives, infrastructure support, and ease of doing business.

Under the latest industrial promotion and MSME policies, pharma and medical device manufacturing units are eligible for substantial capital assistance on investments in land development, buildings, plant and machinery, along with interest subsidies on term loans. In several cases, incentives can range from approximately 40 per cent to over 50 per cent of eligible investments, particularly for priority sectors and MSME units. The state also provides support for laboratory infrastructure, quality certifications, and export-oriented initiatives.

Apart from financial incentives, Madhya Pradesh offers competitively priced industrial land, excellent road connectivity through national corridors, reliable power availability, and abundant water resources, which are critical for pharma manufacturing operations. The development of industrial ecosystems such as Pithampur, Indore, and Mandideep has further strengthened the state's attractiveness for investors. Recent government initiatives to expand industrial land banks and improve logistics infrastructure are expected to accelerate industrial growth even further.

Apart from financial incentives, Madhya Pradesh offers competitively priced industrial land, excellent road connectivity through national corridors, reliable power availability, and abundant water resources, which are critical for pharma manufacturing operations. The development of industrial ecosystems such as Pithampur, Indore, and Mandideep has further strengthened the state's attractiveness for investors

As a result, Madhya Pradesh is witnessing growing investment interest from leading pharma companies as well as small and medium-sized manufacturers across the country. The combination of investor-friendly policies, strategic location, lower operating costs, and strong infrastructure is positioning the state as a preferred destination for pharma manufacturing and healthcare-related industries.

I believe Madhya Pradesh has the potential to become one of India's leading pharma manufacturing states over the next decade. The combination of strong industrial infrastructure, strategic location, expanding pharma clusters, and supportive policies creates a strong foundation for growth.

My vision is to see Madhya Pradesh emerge as a centre for quality pharma manufacturing, exports, nutraceutical production, and contract development and manufacturing services. With continued government support, successful implementation of quality standards, and investment in innovation and skill development, the state's pharma MSME sector can significantly increase its contribution to employment, exports, and healthcare manufacturing.

Pithampur hosts manufacturing facilities of leading companies such as Cipla, Lupin, Glenmark, Torrent, Alkem, Aurobindo and others, making it one of Central India's most important pharma manufacturing hubs.

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RESILIENCE BY DESIGN THE PACKAGING IMPERATIVE

Global uncertainties are accelerating a strategic shift in pharma packaging, with resilience emerging as a critical driver of continuity, competitiveness, and long-term growth

By **Kalyani Sharma**


Rx Only
500 mg
Film-Coated
Tablets
30 Tablets
PHARMACEUTICAL
TABLETS
SCAN TO
LEARN MORE

For a long time, pharma packaging was treated as a back-end function something that got done after the formulation work was complete. The focus was on cost, compliance, and timelines. That view is changing. As geopolitical tensions affect shipping routes, energy prices, and raw material supply, packaging has moved into sharper focus for procurement, supply chain, and leadership teams across the Indian pharmaceutical.

The triggers are well known: Pritam Shimpi, General Manager-Supply Chain, ACG Packaging Materials explains, “Geopolitical risks are now directly influencing pharma packaging operations. Tensions in the Middle East, uncertainty around key trade routes, freight disruption, energy volatility, war risk and insurance premiums, currency movement, and potential trade restrictions, sanctions, or sudden regulatory changes are creating pressure across the packaging value chain. For Indian pharma packaging, the implications are significant because several packaging inputs are linked to global supply networks, crude derivatives, metals, polymers, films, additives, energy, and international logistics. Any disruption in raw material flow, port operations, shipping routes, container and vessel availability or insurance availability can affect lead times, landed costs, and production planning.”

“Pharma packaging has therefore moved from being a cost focused support to a critical supply continuity enabler for pharma customers.”

These are not new developments, but their combined effect on pharma packaging like a function that depends on polymers, aluminium, glass, specialty films, and stable logistics has been meaningful.

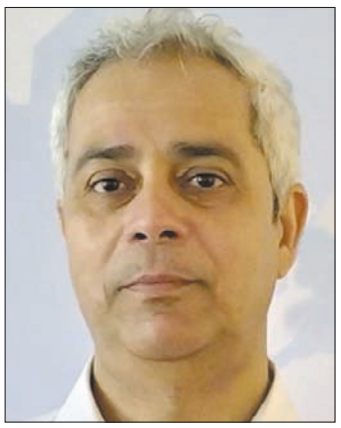
Manish Jain, Director, Naprod Life Sciences, says the impact extends beyond logistics. "Escalating geopolitical tensions, including conflicts in the Middle East and disruptions to critical maritime chokepoints, are creating volatility in global freight, crude and petrochemical markets, directly affecting the availability and pricing of packaging raw materials, increasing transit times, and exposing supply chains to greater risk of delay or interruption. Geopolitical risk also intersects with trade policy shifts, tariffs and export restrictions that can complicate cross-border movement of packaging supplies while amplifying cost pressures and compliance burdens across global markets."

Pharma packaging has moved from being a cost focused support to a critical supply continuity enabler for pharma customers

Pritam Shimpi
General Manager-Supply Chain,
ACG Packaging Materials

India's advantage as the world's pharmacy will, over the next decade, be defended less at the chemistry bench and more in the packaging hall, where physical integrity and digital traceability meet

Siddharth Reddy
Co-Founder,
AltiusHub



Indian pharma is being squeezed by higher costs, shipping delays, and stricter compliance. Short-term resilience comes from buffer stocks, agile logistics, and supplier diversification, while long-term stability requires local manufacturing, smart packaging, and trade alliances

Shivaji Chakraborty
Head-Packaging Development, Fresenius Kabi Oncology

Future-proofing will come from validated localisation, not basic import substitution

Ankush Kapoor
Founder,
PharmNXT

Jitendra Srivastava, CEO, Triton Logistics and Maritime, offers a view from the logistics side, "One of the biggest lessons from this year's geopolitical disruptions is that the most critical risks in pharma are often invisible until they affect continuity. What appears to be a shipping issue quickly becomes a manufacturing issue. Extended transit times, rerouting through the Cape of Good Hope, and changing vessel schedules influence production planning, packaging availability, and inventory cycles."

What has changed on the ground

Giving a market analysis, Ankush Kapoor, Founder, PharmNXT said, “While India's pharma exports grew by over 5 per cent to $28.29 billion during April-February FY26, the industry's $32 billion FY26 export target is considered challenging due to tariff uncertainties and geopolitical risks. Achieving this would require exports of nearly $3.7 billion in March 2026, compared to about $1.6 billion in March 2025.”

Dhananjay M. Chaudhari, DGM-Packaging Development(Formulations), Indoco Remedies notes, “India’s pharma exports is rising upto almost by 10 per cent year-on-year, showing the broader export momentum behind generics. More than 60 per cent of exports go to stringent regula-

tory markets, which strengthens India's reputation as a reliable supplier of affordable medicines. The recent Middle-East geopolitical crisis raises packaging material costs, tighten supply and increase logistics risk for India's pharmaceutical packaging."

The industry's ability to supply these markets reliably depends, in part, on a packaging supply chain that has historically been built around cost efficiency and single-source procurement. That approach is now showing its limits.

The most visible impact has been on input costs.

Urvee Garg, Director, HAB Pharma, shares what the organisation has seen directly, "Prior to the conflict, PVC was being procured at approximately Rs 115 per kilo; currently, prices have increased to nearly Rs 150 per kilo, although we expect them to stabilise at around Rs 135 per kilo. Similarly, aluminium foil (Alu) prices have surged from around Rs 480 per kilo before the conflict to nearly Rs 650 per kilo now. These are just small examples highlighting the increase in tablet packaging material costs."

Rajendra Prasad A, AGM-Packaging Development, Maiva Pharma provides a wider view of cost movement, "The Iran–US–Israel conflict and disruptions in the Hormuz have emerged as one of the most critical risks in 2026. This has impacted energy supplies (oil, gas), petrochemical feedstocks (critical for plastics and polymers) and global shipping routes. India imports a significant portion of crude oil via this region, and disruptions have caused raw material cost increases significantly in some cases and plastic resin prices from 50 per cent to 60 per cent.

He also notes that, "Recent tariff escalations particularly from the US and EU have introduced higher input costs (metals, polymers, components), uncertainty in export markets and supply chain reconfiguration pressures. Tariffs of 20–40 per cent (potentially up to 200 per cent) on pharmaceutical-related goods are expected to increase cost burdens and force relocation strategies."

Just-in-time inventories with only weeks' cover are vulnerable — shortages are forcing production slowdowns, product reformulation, or use of inferior substitutes that may affect regulatory compliance or shelf-life

Dhananjay M. Chaudhari
DGM-Packaging Development,
Indoco Remedies

Dual-route sourcing strategies, diversified ports of entry, and multimodal flexibility are increasingly standard expectations rather than exceptional measures

Jitendra Srivastava
CEO,
Triton Logistics and Maritime

Pharma companies are increasingly adopting multi-vendor sourcing strategies and expanding partnerships with domestic packaging suppliers to reduce overdependence on single geographies or suppliers

Urvee Garg
Director,
HAB Pharma

Since packaging materials from PVC and HDPE to aluminium and specialty films are tied to petrochemical and energy markets, any disruption in feedstock supply or energy pricing tends to move through the entire packaging value chain.

The feedstock connection

To understand why pharma packaging is affected, it helps to look upstream. Many packaging materials are manufactured from petrochemical feedstocks such as naphtha, ethylene, and propylene. India imports a significant share of these from the Middle East region.

Chaudhari explains, "Feedstocks such as naptha, ethylene, propylene and other derivatives which India is mainly exporting from Middle-East region is hampered due to Middle-East crisis. Many primary packaging materials such as bottles, blister films production is constrained due to reduced supply or shipping of feedstock causing tightened supply and price hike affects almost all pharmaceutical sector in India."

On the logistics side, route disruptions have added to the challenge. Shivaji Chakraborty, Head of Packaging Development, Fresenius Kabi Oncology notes, "Attacks in the Red Sea and tensions in the Strait of Hormuz force vessels to reroute around Africa, adding weeks to transit times and sharply increasing the freight costs forcing Indian farms to rethink sourcing strategies."

For temperature-sensitive products, longer transit times also raise questions around product integrity.

Chaudhari points out, "Just-in-time inventories with only weeks' cover are vulnerable — shortages are forcing production slowdowns, product reformulation, or use of inferior substitutes that may affect regulatory compliance or shelf-life."

Dr Sufi Roomi, Medical Spokesperson, Jolly Healthcare shares, "One of the main risks today is overdependence on limited geographies for all packaging inputs, well specialised materials, polymers and other allied suppliers. Any kind of disruption in shipping routes, customs movement, cost of energy and directly impact timelines of packaging and in turn product dispatches schedule. For all pharma companies, even a slight delay in availability of packaging can impact market commitments, and patient access."

Availability is as much a concern as cost

Rising costs are one issue. The other and in some situations the more pressing one is availability. When supply is tight, materials can go to buyers who pay a premium or commit to advance payments, leaving others with longer lead times or gaps in supply.

Jain says the current environment has exposed structural dependencies in packaging sourcing. "Packaging material availability is being stressed by supply chain dependencies on foreign petrochemical inputs and long

logistics corridors, while shipping route disruptions cause lead time volatility and higher insurance and freight costs; this, combined with heavy reliance on imports of specialised materials such as polymers and barrier components, can impede operational continuity and force firms to reallocate inventory, change carriers, or resort to costly expedited shipping."

Garg describes a specific situation her organisation has faced, "We have one product that is an extremely important brand for us. To prevent counterfeiting, we use a holographic film on the PVC sheet for its packaging. We currently have two approved vendors for this material, both of whom are very large listed companies specialising in high-security packaging solutions. However, even these suppliers are facing difficulties in maintaining consistent supply during the current conflict situation. This, in turn, has a significant impact on our operational continuity."

The regulatory structure of the pharma industry means that supplier changes are not quick. An alternate source needs to go through qualification, documentation, and change control before it can be used. When even established, approved suppliers face supply issues, companies have limited immediate options.

Shimpi frames the implication for how the industry needs to think about suppliers, "Supplier reliability is no longer measured only by price and quality; it must also include continuity capability, feedstock risk management, early communication, and compliance support."

Srivastava puts the same point in the context of logistics planning, "The challenge today is less about whether packaging materials are available and more about whether they arrive with the predictability that pharmaceutical operations require. Inputs that once moved through stable freight cycles are now exposed to disruptions that can alter timelines with little warning, creating uncertainty across production schedules and supplier commitments."

Geopolitical risk also intersects with trade policy shifts, tariffs and export restrictions that can complicate cross-border movement of packaging supplies while amplifying cost pressures and compliance burdens across global markets

Manish Jain
Director,
Naprod Life Sciences

For all pharma companies, even a slight delay in availability of packaging can impact market commitments, and patient access

Dr Sufi Roomi
Medical Spokesperson,
Jolly Healthcare

For Indian pharma companies, packaging functions must evolve from a transactional role to a strategic pillar of supply chain resilience

Rajendra Prasad A
AGM-Packaging Development,
Maiva Pharma

A different kind of risk: Compliance and serialisation

Beyond materials and logistics, there is a dimension of the geopolitical impact that tends to get less attention: the effect on compliance and serialisation. As trade relations between countries shift, destination markets are introducing their own data and traceability requirements, and these are not always aligned with each other.

Siddharth Reddy, Co-Founder, AltiusHub mentions, "The risk most operators underestimate is not material scarcity but regulatory fragmentation. As trade blocs harden, every major destination market is mandating its own serialisation and reporting regime, and they are diverging rather than converging. India exports to over 50 regulated markets, each with its own data format, reporting cadence and national portal. A packaging line that was compliant for one corridor can be non-compliant for another overnight when a regulator updates a mandate. The geopolitical story for packaging is increasingly a data-sovereignty story, not just a logistics one."

Reddy also highlights an aspect of the hardware supply chain that many quality teams have not had to consider before, "The industry's dependence on a narrow set of geographies for specialty films, foils, aluminium, and crucially the electronic components inside vision systems and print-and-apply hardware, means a single export control or port disruption can idle a line even when the drug substance is available. We have seen lead times on serialisation-grade printers and cameras stretch precisely when shipping lanes get politicised. Packaging continuity now depends on hardware supply chains that most quality teams have never had to think about."

This points to a broader reality. The packaging function today has more dependencies on materials, logistics, hardware, and data infrastructure than it did even five years ago. Each of these can be affected by geopolitical developments, and they do not all respond to the same mitigation strategies.

How companies are responding

Across the industry, the response to these pressures has broadly moved in a few directions: building buffer stocks, qualifying more suppliers, diversifying sourcing geographies, and investing in supply chain visibility.

Chakraborty outlines the near-term actions being taken: "Build safety stock of imported packaging materials, viz., aluminium foils, polymers, and inks to absorb shipping delays... use multimodal transport (air, sea and rail) and reroute via Europe or Central Asia to avoid Red Sea bottlenecks... Source packaging materials/raw materials from other countries including Europe to reduce dependency on China and Gulf countries."

Garg describes the broader pattern she has observed: "Pharma companies are increasingly adopting multi-vendor sourcing strategies and

expanding partnerships with domestic packaging suppliers to reduce overdependence on single geographies or suppliers. Vendor qualification programs are also being strengthened to build flexibility and ensure continuity during disruptions. Many organisations are maintaining higher safety stocks for critical packaging materials and investing in better forecasting and supply chain visibility tools."

Kapoor identifies the shift in thinking this is prompting: "There is a shift away from the lowest cost supply chain philosophy to that of lowest risk qualified supply. This is evident in firms making safety stocks for critical components, qualifying alternative suppliers, regionising critical raw material supplies as well as getting packaging and process containment vendors involved early on in the manufacturing design."

Srivastava describes this same shift from the logistics side: "The most significant change we are witnessing is a move away from efficiency-only models toward resilience-by-design. Pharma companies are no longer treating alternate routes as contingency plans; they are becoming part of the network architecture from the outset. Dual-route sourcing strategies, diversified ports of entry, and multimodal flexibility are increasingly standard expectations rather than exceptional measures."

He also highlights what visibility can do for companies during periods of disruption: "Real-time shipment intelligence allows disruptions to be identified early and responses to be activated before they escalate into operational challenges. The invisible journey of a resilient supply chain lies in its ability to adapt quietly in the background so that manufacturers, healthcare providers, and ultimately patients experience continuity rather than disruption."

An important context comes from Shimpi: "Alternate sourcing requires quality checks, documentation, validation, customer approval, qualification, change control, and regulatory discipline. For customers, resilience must not mean uncontrolled substitution. It must mean pre qualified, compliant, and approved alternatives."

The pharma supply chain operates within a regulatory framework that does not allow for quick substitutions, even under pressure. Companies that move too fast on alternate sourcing without following the required steps may create compliance problems that are harder to resolve than the original supply issue.

Sustainability amid disruption

The industry was already working through sustainability commitments when the geopolitical pressures intensified. For pharma packaging, the two objectives: supply continuity and reduced environmental impact do not always point in the same direction.

Dr Roomi reflects, "The industry also needs to balance both sustainability and continuity. Eco friendly packaging is very significant, but it should be practical, compliance and scalable during the essential conditions of supply. Future ready pharma packaging also requires those material which are safe, cost efficient and adaptable to continuous changing regulations."

Garg is straightforward about the specific challenge pharma faces: "When it comes to sustainability goals, the answer is slightly more complex for the pharma industry. In many other sectors, it is comparatively easier to reduce or eliminate the use of single-use plastics. However, in pharma, where sterility and minimal exposure are critical requirements, it becomes far more difficult to completely move away from plastic-based packaging materials."

Srivastava notes that sustainability and logistics are now being looked at together rather than separately: "We are also seeing a meaningful shift in sustainability thinking. Packaging design, weight optimisation, emissions, and transport modes are no longer being evaluated independently. Companies are increasingly viewing them as interconnected decisions that influence both environmental performance and long-term supply chain resilience."

The longer-term picture

The current disruptions have brought to the surface a structural issue: India's domestic packaging material manufacturing capacity has not kept pace with the country's pharmaceutical ambitions. This gap is something companies are now more directly aware of.

Garg points to the plastics sector as a specific area that needs attention: "India needs to improve both the quality and availability of pharmaceutical-grade plastics. I believe this is one area where the industry is still lacking. At present, there is one major corporation manufacturing high-quality plastic materials, but even they are not always able to meet the volumes required by the market. Apart from them, very few players can consistently match the same quality standards. There is a strong need for greater investment in the plastics manufacturing sector, along with government support to encourage the growth of more companies in this space."

Shimpi points to the role of digital systems: "Digital tools and digital manufacturing will play a major role in building early risk visibility and faster response capability. Stronger systems for demand sensing, inventory visibility, supplier monitoring, logistics tracking, scenario planning, real time operational visibility, advanced quality systems, and data led decision making can help companies respond before disruption reaches the customer."

Kapoor frames the investment case in terms of India's next growth opportunity: "Estimates show that 118 biologics will lose patent protection between 2025 and 2034, opening a $232 billion to $234 billion biosimilar opportunity. It has also been reported that biologic drugs with more than $300 billion in global sales are set to lose patent protection over the next decade. India has recognised this shift through Biopharma SHAKTI, a Rs 10,000 crore, five-year initiative to strengthen biologics and biosimilars, with an ambition to capture 5 per cent of the global biopharma market. To make this real, India must localise the critical enabling layer: specialty films, sterile bags, tubing, connectors, filters, cold-chain systems and traceable packaging formats. Future-proofing will come from validated localisation, not basic import substitution."

Prasad highlights, "For Indian pharma companies, packaging functions must evolve from a transactional role to a strategic pillar of supply chain resilience. Proactive diversification, localisation, innovation, and long-term planning will be essential to ensure uninterrupted supply, regulatory compliance, and product integrity in an increasingly uncertain global environment."

The road ahead

The geopolitical pressures affecting pharma packaging are unlikely to ease quickly. Supply chain dependencies built over many years will take time to reconfigure. Regulatory frameworks in destination markets will continue to evolve. Input costs will remain linked to global energy and commodity markets.

Srivastava is clear about what the long-term response needs to look like: "Looking ahead, resilience must become a built-in capability rather than an emergency response mechanism. Diversifying sourcing geographies for critical packaging inputs, strengthening regional supply networks, and reducing dependency on single trade corridors will be essential for long-term stability. We are already seeing companies reassess traditional supply models and create greater redundancy across both procurement and logistics functions."

Chakraborty summarises where the industry stands: "Indian pharma is being squeezed by higher costs, shipping delays, and stricter compliance. Short-term resilience comes from buffer stocks, agile logistics, and supplier diversification, while long-term stability requires local manufacturing, smart packaging, and trade alliances."

Shimpi puts the collaboration agenda plainly: "Pharma companies and packaging partners must work more collaboratively. Early demand visibility, faster approvals for alternate sources, transparent cost discussions, and joint risk planning will be essential to protect medicine availability in an increasingly uncertain world."

Reddy makes the case for treating packaging as a strategic function: "Standardise internal master data so you are mandate-agnostic; insist on interoperable, exportable serialisation data so no single portal or vendor can strand you; wargame disruptions the way other industries run continuity drills; and elevate compliance from a cost centre to a board-level resilience function. India's advantage as the world's pharmacy will, over the next decade, be defended less at the chemistry bench and more in the packaging hall, where physical integrity and digital traceability meet."

The current situation has made clear that packaging is not just a downstream activity. It carries supply risk, cost risk, compliance risk, and in the longer run, competitive risk. How the industry responds to that reality including how much it invests in building domestic capacity and better supply chain structures will shape its ability to meet export commitments and grow in regulated markets over the years ahead.

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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.

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FDD Conclave 2026: Charting the future of formulation science and drug delivery

The conclave served as a platform for conversations on leadership, innovation, advanced drug delivery systems, manufacturing excellence and the future of pharma research

By Lakshmipriya Nair

L-R: Dr Vellaian Karuppiah, COO, Shilpa Medicare; Dr Pavan Bhat, MD and CEO, Inventia Healthcare; Ms Viveka Roychowdhury, Editor, Express Pharma; Vijay Doshi, MD, Pioma Chemicals; Dr Praveen Khullar, ED, VerGo Pharma; AVPS Chakravarthi, Chairman, FOPE Andhra Pradesh and Telangana; Manish Jain, MD, Cilicant; Sreehari Babu P, CEO, HyCON Labs; and Jayanta Kumar Mandal, CEO and MD, APDM Pharmaceuticals.

The pharma industry is entering an era where scientific innovation must move faster, scale smarter and remain affordable. Against this backdrop, Express Pharma's FDD Conclave 2026 brought together formulation scientists, R&D leaders, technology providers and industry experts to discuss the evolving landscape of formulation development and drug delivery. Hosted by Express Pharma, presented by Cilicant and powered by Pioma Chemicals, the conclave served as a platform for conversations on leadership, innovation, advanced drug delivery systems, manufacturing excellence and the future of pharmaceutical research.

The event commenced with a welcome address from Express Pharma, followed by the traditional lamp-lighting ceremony attended by Viveka Roychowdhury, Editor, Express Pharma; Manish Jain, MD, Cilicant; Vijay Doshi, MD, Pioma Chemicals; AVPS Chakravarthi, Chairman, FOPE Andhra Pradesh and Telangana; Dr Vellaian Karuppiah, COO, Shilpa Medicare; Dr Pavan Bhat, MD and CEO, Inventia Healthcare; Dr Praveen Khullar, ED, VerGo Pharma, Sreehari Babu P, CEO, HyCON Labs; and Jayanta Kumar Mandal, CEO and MD, APDM Pharmaceuticals. The ceremony symbolised the industry's collective commitment to innovation, scientific excellence and better healthcare outcomes.

Leadership lens: The business of FR&D amid global shifts

The opening session, "The Business of FR&D: Global Shifts, New Pressures", set the tone for the day. Moderated by Viveka Roychowdhury, the discussion featured Dr Praveen Khullar, Executive Director, VerGo Pharma Research Laboratories; Sreehari Babu P, CEO, HyCON Labs; and Jayanta Kumar Mandal, CEO and Managing Director, APDM Pharmaceuticals.

The panel examined how formulation research and development is being reshaped by rising development costs, increasing regulatory scrutiny, global competition and the need to shorten development timelines. The speakers emphasised that FR&D can no longer function as a standalone scientific activity. Instead, it must align closely with business objectives, market requirements and evolving patient needs.

The discussion highlighted the growing importance of agility, cross-functional collaboration and strategic decision-making in ensuring that R&D investments translate into commercial success.

From lab to market: Scaling formulation science

A key panel discussion of the conclave focused on the journey from laboratory innovation to commercial manufacturing.

Moderated by Dr Ravikumar N, President – Formulations R&D, MSN Laboratories, the panel included Dr Pavan Bhat, MD and CEO, Inventia Healthcare; Dr Vellaian Karuppiah, COO, Shilpa Medicare; Dr Pankaj Mandpe, EVP-R&D, Micro Labs; Dr Madhusudhan Bommagani, President, FR&D, Cadila Pharmaceuticals; Dr Vasanthakumar Ramu, Head – R&D (Peptides and Complex Generics), Alembic Pharmaceuticals; Dr Saurabh Gupta, VP and Delivery Manager – Integrated Product Development, Dr Reddy's Laboratories; and Dr Ratnakar P Mehendre, Director, Shuban Pharmaceuticals.

The discussion explored the challenges involved in translating promising scientific concepts into commercially viable products. Panellists stressed the importance of integrating formulation development, process understanding, regulatory planning and manufacturing readiness early in the development cycle.

The speakers also highlighted the growing role of complex generics, peptide-based therapies and platform technologies in shaping future development strategies. A recurring theme was the need to reduce technology transfer risks and ensure scalability from the earliest stages of product development.

Tackling nitrosamine risks

Nitrosamine mitigation emerged as a major theme throughout the conclave.

In an insightful presenta-

L-R: Viveka Roychowdhury, Editor, Express Pharma (Moderator); Dr Praveen Khullar, ED, VerGo Pharma Research Laboratories; Sreehari Babu P, CEO, HyCON Labs; Jayanta Kumar Mandal, CEO & MD, APDM Pharmaceuticals

L-R: Dr Ravikumar N, President – Formulations R&D, MSN Laboratories (Moderator); Dr Pavan Bhat, MD & CEO, Inventia Healthcare; Dr Vellaian Karuppiah, COO, Shilpa Medicare; Dr Pankaj Mandpe, EVP-R&D, Micro Labs; Dr Madhusudhan Bommagani, President, FR&D, Cadila Pharmaceuticals; Dr Vasanthakumar Ramu, Head R&D (Peptides & Complex Generics), Alembic Pharmaceuticals; Dr Saurabh Gupta, VP & Delivery Manager-Integrated Product Development, Dr Reddy's Laboratories; Dr Ratnakar P Mehendre, Director, Shuban Pharmaceuticals

tion, Dr Vivek Jha, Head – R&D, Cilicant, and Dhairy Sharma, Manager – Business Development (Healthcare Division), Cilicant, discussed the role of their Frexil technology in minimising nitrosamine risks.

The session focused on practical approaches to mitigating nitrosamine formation and contamination, highlighting the need for proactive risk assessment, packaging innovations and collaborative strategies across the pharmaceutical value chain.

Complementing this discussion, Dr Prafulla S Chaudhari, VP – Technical, Nitika Pharmaceutical Specialities, delivered a presentation on controlling nitrosamine impurities through low-nitrile excipients.

He explained how excipient selection can significantly influence nitrosamine risk management and shared insights into material design strategies that can help manufacturers meet evolving regulatory expectations.

Excipients as innovation enablers

Excipients are increasingly playing a strategic role in formulation development, and this theme was explored through multiple technical sessions.

Jaynil Doshi, Director – Techno Commercial, Pioma Chemicals, presented "Hydrocel: Multi-functional Cellulose Technologies for Modern Formulators". He highlighted how multifunctional cellulose technologies can simplify formulation development while enhancing product performance and process efficiency.

The session demonstrated how advanced excipients are moving beyond traditional functionality to become key

Dr Vivek Jha, Head - R&D, Cilicant

Dhairy Sharma, Manager - Business Development (Healthcare Division), Cilicant

Jaynil Doshi, Director – Techo Commercial, Pioma Chemicals

Dr Jayant Karajgi, CEO, FTF Pharma

Manoj Bansal, Business Development Head - India & South Asia, Thermo Fisher Scientific

Dr Jitendra Amrutkar, Head – Process Technology and Support, APT Shirwal, ACG Engineering

Dr Prafulla S Chaudhari, VP- Technical, Nitika Pharmaceutical Specialities

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

L-R: Dr Manikandan R, Sr VP, Granules India (Moderator); Dr Rakesh Bhasin, Head-Generic Formulations R&D, Biocon Pharma; Mr Girish Achliya, CSO, Novapharm Healthcare; Dr Ganeshchandra Sonavane, CSO, Umedica Laboratories; Debjani Singh, VP - Formulation & Development, Zydus Lifesciences; Dr Sandhya Shenoy, VP - Formulation R&D, MSN Laboratories; Dr Abhay Joshi, VP - Formulation Development, Dr. Reddy's Laboratories • Dr Dinesh Shinde, AVP & Head; Formulation Development and Tech Transfer, Wockhardt; Preeti Raut, Technical Consultant, Cipla

L-R: Dr Sukhjeet Singh, CSO, Acme Formulations (Moderator); Dr Ravindra Agarwal, Sr VP, Mankind Pharma; Dr Syed Moinuddin, Head Global R&D, Wockhardt

enablers of innovation across dosage forms.

Similarly, Krutik Prajapati, Manager (Techno Commercial), Vikram Thermo (India), discussed drug release modulation through DRUGCOAT RSPO/RLPO technologies. His presentation illustrated how advanced coating systems can provide greater control over drug release profiles while improving therapeutic outcomes and patient compliance.

Building future-ready research infrastructure

As India seeks to strengthen its position in global pharmaceutical innovation, research infrastructure is becoming increasingly important.

Addressing this topic, Dr Jayant Karajgi, CEO, FTF Pharma, spoke about building world-class FR&D laboratories in India.

He outlined the infrastructure, talent and technology investments required to create globally competitive research environments. The session underscored that innovation ecosystems require more than scientific expertise; they also depend on advanced facilities, digital capabilities and collaborative networks.

Process optimisation and manufacturing excellence

The link between formulation science and manufacturing outcomes was another major focus area.

Manoj Bansal, Business Development Head – India and South Asia, Thermo Fisher Scientific, discussed advancements in hot melt extrusion technology, highlighting instrumentation considerations and methodological approaches needed for successful implementation.

He explained how hot melt extrusion is becoming an increasingly valuable platform technology for improving solubility, bioavailability and product differentiation.

Dr Jitendra Amrutkar, Head – Process Technology and Support, APT Shirwal,

Vinod Vilas Kenekar, Subject Matter Expert- Process Technology, ROMACO India (ROMACO Group)

Dr Suruchi Vishwasrao, Sr Scientist, R&D, Merck Life Sciences

S Mukherjee, GM - Marketing, Dhara Lifescience

L-R: Dr Vijayendrakumar Redasani, CEO & MD, DelNova Healthcare (Moderator); Vinod Arora, Principal Advisor, IGMPI; Dr Ashok Omray, Pharma Consultant

L-R: Dr Pirthi Pal Singh, President & Group R&D Head, Tirupati Group (Moderator); Shrenik Kole, VP and Head-Sterile Product Development, Micro Labs; Dr Sachin Mundade, VP - R&D, Micro Labs; Dr Krishna Murthy Bhavanasi, VP - R&D, Lotus Pharmaceutical; Yogesh Joshi, Associate Director & Head (Formulation Development)/Head – Clinical Manufacturing, Piramal Pharma Solutions; Dr Arindam Halder, GM, Sun Pharmaceutical Industries; Sandipan Roy, GM, Hetero

L-R: Dr Vaibhav Dubey, AVP, Kashiv BioSciences (Moderator); Mr Rakesh Kumar Sinha, Sr VP, Biological E; Dr Jaby Jacob, Sr President, R&D, BSV (A Mankind Group Company)

ACG Engineering, expanded the conversation through his presentation on connecting formulation science, process understanding and manufacturing outcomes.

His session emphasised that successful process optimisation requires an integrated understanding of product design, process parameters and manufacturing performance. He highlighted how data-driven process understanding can improve consistency, quality and scalability.

Further strengthening the manufacturing focus, Vinod Vilas Kenekar, Subject Matter Expert – Process Technology, ROMACO India, explored the integration of fluidised bed granulation and tablet coating technologies.

His presentation demonstrated how combining advanced granulation and coating platforms can enhance efficiency, product quality and operational flexibility.

Advanced drug delivery takes centre stage

Innovation in drug delivery remains one of the most exciting areas of pharma development.

A panel discussion on "Advanced drug delivery: From oral to injectables and beyond" brought together leading experts from across the industry.

Moderated by Dr Manikandan R, Sr VP, Granules India, the panel featured Dr Rakesh

Bhasin, Head – Generic Formulations R&D, Biocon Pharma; Girish Achliya, CSO, Novapharm Healthcare; Dr Ganeshchandra Sonavane, CSO, Umedica Laboratories; Debjani Singh, VP – Formulation and Development, Zydus Lifesciences; Dr Sandhya Shenoy, VP – Formulation R&D, MSN Laboratories; Dr Abhay Joshi, VP – Formulation Development, Dr Reddy's Laboratories; Dr Dinesh Shinde, AVP and Head – Formulation Development and Tech Transfer, Wockhardt; and Preeti Raut, Technical Consultant, Cipla.

The panel explored innovations across oral delivery systems, injectables and emerging modalities. Discussions centred on improving bioavailability, enhancing patient convenience and developing next-generation delivery platforms capable of addressing increasingly complex therapeutic challenges.

The speakers noted that future drug delivery innovation will require a combination of formulation expertise, device integration and patient-centric design.

Affordable innovation as a strategic imperative

A deep-dive discussion titled "Affordable Innovation: The New FR&D Mandate" addressed one of the industry's most pressing challenges.

Moderated by Dr Sukhjeet Singh, CSO, Acme Formulations, the session featured Dr Ravindra Agarwal, Senior Vice President, Mankind Pharma, and Dr Syed Moinuddin, Head – Global R&D, Wockhardt.

The speakers discussed how pharma companies can balance scientific ambition with affordability and accessibility. They argued that innovation should not be measured solely by scientific breakthroughs but also by its ability to improve patient access and healthcare outcomes.

The discussion highlighted the growing need for cost-efficient development models, smarter resource allocation and scalable innovation strategies.

Peptide delivery and emerging modalities

Peptide therapeutics continue to attract significant attention across the pharmaceutical industry.

Addressing this opportunity, Dr Suruchi Vishwasrao, Senior Scientist – R&D, Merck Life Sciences, presented on overcoming the challenges associated with oral peptide delivery.

She outlined the scientific barriers that have traditionally limited oral peptide administration and discussed emerging technologies designed to improve stability, absorption and bioavailability.

The session highlighted the considerable potential of peptide-based therapies and the innovations required to unlock broader patient access.

Leadership lessons for the next generation

Beyond technology and science, the conclave also focused on leadership development.

In a session titled "The Mentorship Exchange: What FR&D leaders must learn and unlearn", Dr Vijayendrakumar Redasani, CEO and MD, DelNova Healthcare, moderated a discussion featuring Vinod Arora, Principal Advisor, IGMPI, and Dr Ashok Omray, Pharma Consultant.

The speakers reflected on evolving leadership expectations within pharmaceutical organisations. They discussed the importance of adaptability, continuous learning and challenging traditional assumptions in an industry undergoing rapid transformation.

The conversation reinforced that leadership remains a critical driver of innovation, talent development and organisational success.

Navigating the R&D reset

The concluding panel discussion addressed the changing realities facing pharma R&D organisations.

Moderated by Dr Pirthi Pal Singh, President and Group R&D Head, Tirupati Group, the panel featured Shrenik Kole, VP and Head – Sterile Product Development, Micro Labs; Dr Sachin Mundade, VP – R&D, Micro Labs; Dr Krishna Murthy Bhavanasi, VP – R&D, Lotus Pharmaceutical; Yogesh Joshi, Associate Director and Head (Formulation Development) and Head – Clinical Manufacturing, Piramal Pharma Solutions; Dr Arindam Halder, GM, Sun Pharmaceutical Industries; and Sandipan Roy, GM, Hetero.

The discussion examined how organisations are responding to regulatory changes, market volatility and increasing scientific complexity. Panellists emphasised the need for flexible development models, stronger risk management frameworks and greater collaboration across functions.

Biologics: India's next scientific frontier

The final session of the conclave focused on one of the most promising opportunities in healthcare.

Moderated by Dr Vaibhav Dubey, AVP, Kashiv BioSciences, the fireside chat featured Dr Jaby Jacob, Senior President – R&D, BSV (A Mankind Group Company), and Dr Rakesh Kumar Sinha, Senior Vice President, Biological E.

The discussion explored India's growing capabilities in biologics, biosimilars and advanced biological therapies. The speakers highlighted the investments, talent and infrastructure required for India to emerge as a global biologics powerhouse.

They noted that while significant progress has been made, continued investment in scientific capabilities, manufacturing infrastructure and regulatory readiness will be essential to unlock the full potential of the biologics sector.

Looking ahead

Across every session, a common message emerged: the future of pharmaceutical innovation will be defined by collaboration, scientific excellence and the ability to translate complex research into accessible healthcare solutions.

From nitrosamine mitigation and advanced excipients to peptide delivery, biologics and affordable innovation, FDD Conclave 2026 showcased the breadth of innovation shaping pharmaceutical development today.

More importantly, it highlighted the evolving role of FR&D as a strategic function that must balance science, business, manufacturing and patient needs. As the industry continues to navigate new challenges and opportunities, the insights shared at the conclave provided a valuable roadmap for the next chapter of pharma innovation.

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FDD Leadership Awards spotlight FR&D excellence

The awards recognised outstanding contributions to formulation research, innovation and scientific leadership, reports **Lakshmipriya Nair**

Continuing its tradition of recognising excellence, the FDD Leadership Awards 2026, held alongside the FDD Conclave 2026, celebrated scientists, innovators and organisations driving advances in formulation research and development (FR&D).

The evening opened with a welcome address by Viveka Roychowdhury, Editor, Express Pharma, Express Healthcare and Express Nutra, who spoke about the vision behind the awards and the need to celebrate the people shaping the future of pharmaceutical FR&D.

The event also comprised a very interesting fireside chat, 'The New Playbook: What will define winning FR&D teams in 2030?', with jury members Suresh Pareek, Angel and Growth Investor (Pharma); Dr Sumedha Nadkar, Pharmaceutical Strategy and Technology Consultant; and Dr Manish Grover, Director, Healthcare Technologies, Mangrove Creations. The discussion explored the evolving FR&D landscape, emerging innovation priorities and the leadership needed to drive the next phase of pharmaceutical development.

Following the session, the jury members present at the conclave were felicitated for their contribution to the evaluation process. Roychowdhury also acknowledged the efforts of the entire jury in identifying this year's winners.

L-R: Suresh Pareek, Angel and Growth Investor (Pharma) (Moderator); Dr Sumedha Nadkar, Pharmaceutical Strategy and Technology Consultant; Dr Manish Grover, Director, Healthcare Technologies, Mangrove Creations

The awards were then presented by the jury members and Roychowdhury, joined by Manish Jain, MD, Cilicant, and Vijay Doshi, MD, Pioma Chemicals, representing the presenting and co-presenting partners.

The honours were presented across four categories.

Rising Stars: The next generation of FR&D innovators

This category recognised emerging professionals making an early impact in pharma formulation research and development.

- Dr Ankit Anand Kharia
- Mr Anirudha Kute
- Mr Arjunarao Panchada
- Ms Chitra Varma
- Dr Kashyap Nagariya
- Dr Mukesh Kumar
- Dr Nandkishore Yadav
- Mr Pankaj Soni
- Mr Prabhat Shrivastava
- Dr Rajiv Khurana
- Dr Shailesh Vishwanath Bisaradar

Leaders: Driving excellence through scientific leadership

This is a category that honored professionals whose vision and sustained contributions continue to strengthen pharma FR&D.

- Dr Alagumurugan Alagarswamy
- Dr Ravindra Agarwal
- Mr Sandipan Roy
- Mr Shrenik Kole
- Dr Syed Shah Moinuddin Husaini
- Dr Tathagata Dutta

Entrepreneurs: Turning research into real-world impact

This Editor's Choice category recognised scientist-entrepreneurs who have successfully translated research into impactful businesses.

- Jayanta Kumar Mandal, CEO & MD, APDM Pharmaceuticals
- Vijayendra Kumar Redasani, CEO & MD, DelNova Healthcare

Special Citation: Recognising breakthrough innovation

A Special Citation was presented to Team Wockhardt for the development of Zaynich, recognising the team's breakthrough contribution to antibiotic innovation and the fight against antimicrobial resistance.

The ceremony was followed by a networking dinner and cocktails. Bringing together researchers, industry leaders and innovators, the FDD Leadership Awards 2026 once again underscored the importance of celebrating excellence and fostering innovation across India's pharma FR&D ecosystem.

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All winners of FDD Leadership Awards 2026

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Injectable Innovations Conclave: Ahmedabad Connect maps the future of sterile manufacturing

From complex injectables and contamination control to advanced analytics, regulatory preparedness and manufacturing excellence, the Injectable Innovations Conclave 2026: Ahmedabad Connect brought together industry leaders to discuss how India's injectable ecosystem is preparing for the next phase of global growth, reports **Swati Rana**

As the global pharma industry witnesses an unprecedented shift towards biologics, complex injectables, long-acting formulations, specialty therapies and personalised medicines, India's injectable manufacturing sector is undergoing a transformation of its own. Manufacturers are increasingly moving beyond conventional sterile production to embrace advanced technologies, integrated quality systems, digital manufacturing and collaborative innovation to remain globally competitive.

L-R: Prem Mevada, Director, NKP Pharma; Shaunak J Dave, CEO & MD, Antares Vision Group India; Rajesh Bhatkal, GM, Express Pharma; Shirish G Belapure, Sr Technical Advisor, IPA; Rajiv Gandhi, CEO & MD, Hester Biosciences; Parag Swadia, CEO & Executive Director, Otsuka Pharmaceutical India; and Sandeep Raktate, President – Operations India & Ireland, Amneal Pharmaceuticals

These emerging trends were the focus during discussions at the Injectable Innovations Conclave 2026, organised by Express Pharma in Ahmedabad.

The conclave commenced with a ceremonial lamp lighting led by Rajesh Bhatkal, GM, Express Pharma, along with Shirish G Belapure, Sr Technical Advisor, Indian Pharmaceutical Alliance (IPA); Rajiv Gandhi, CEO & MD, Hester Biosciences; Parag Swadia, CEO & Executive Director, Otsuka Pharmaceutical India; Sandeep Raktate, President – Operations India & Ireland, Amneal Pharmaceuticals; Shaunak J Dave, CEO & MD, Antares Vision Group India; and Prem Mevada, Director, NKP Pharma. The inauguration symbolised the collective commitment of industry leaders towards strengthening India's position as a global hub for advanced injectable manufacturing.

The conference began with the leadership panel discussion, 'Leadership Lens – The new injectable ecosystem: Partnerships, platforms and possibilities,' moderated by Shirish G Belapure, with Rajiv Gandhi, Parag Swadia, and Sandeep Raktate sharing their perspectives on the changing dynamics of injectable manufacturing.

The discussion highlighted that the industry's future extends far beyond expanding manufacturing capacity. The rapid growth of biologics, biosimilars, peptide therapies, depot injections, oncology products and other specialised formulations is fundamentally changing the way pharma companies approach product development, manufacturing and commercialisation.

One of the strongest themes emerging from the session was the growing importance of partnerships. The panelists agreed that no single organisation can independently build all the capabilities required for the next generation of injectable products. Instead, closer collaboration between innovators, contract manufacturers, technology providers, packaging companies, equipment suppliers and regulators will be essential to accelerate innovation while ensuring uncompromising quality and compliance.

The panel also discussed the increasing need for flexible manufacturing platforms capable of handling multiple product types and smaller commercial batches. Digitalisation, automation and data-driven manufacturing were identified as important enablers for improving operational efficiency, reducing variability and strengthening regulatory readiness.

Another important takeaway was India's growing opportunity to become a preferred destination for complex injectable manufacturing. While the country has established itself as a reliable supplier of generic medicines, future global leadership will increasingly depend on scientific capabilities, advanced manufacturing technologies, skilled talent and robust quality systems. The speakers concluded that organisations capable of combining innovation with manufacturing excellence will be well positioned to capitalise on emerging global opportunities.

Sterility & quality: Heart of injectable manufacturing

Quality and contamination control remained among the most extensively discussed topics throughout the conference.

The panel discussion titled 'Sterility under pressure: Are current systems strong enough?', moderated by Hitesh Bhatt, Former Sr VP and Head – India Quality Management, Amneal Pharmaceuticals, brought together Vinay Jathar, CEO & Founder, Aditi Advisory Services; Dr Tarun Chugh, Founder and CEO, SIMco Pharma Consultancy; Nitish Chakravarty, Site Director, Centrient Pharmaceuticals; Digambar Nigade, VP, Quality – Injectable Division, Amneal Pharmaceutical; Santosh Jadhav, Associate VP, Head of Quality - India operation, Kashiv Biosciences; Chetan Majmudar, Technical Director and Partner, Clesta Lifesciences; and Pinak Kumar Patel, Assistant Division Head - Production, Otsuka Pharmaceutical India to examine the evolving challenges of sterile manufacturing.

The discussion reflected how contamination control has evolved from a quality function into an organisation-wide responsibility. The panelists observed that increasing product complexity and tightening global regulatory expectations demand significantly stronger contamination control strategies than ever before.

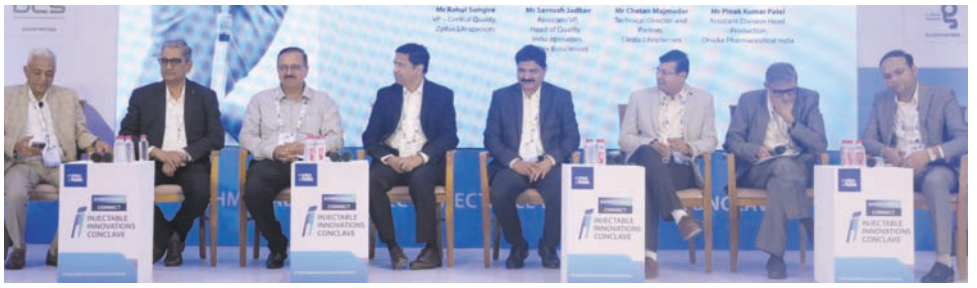
Rather than relying solely on end-product testing, manufacturers today must build integrated quality systems that combine environmental monitoring, aseptic process control, equipment qualification, personnel training, automation and data-driven investigations. The panel repeatedly emphasised that sterility assurance begins with process design rather than final product inspection.

Another major theme was quality culture. The speakers stressed that sustained compliance cannot be achieved through documentation alone. Organisations must foster cultures where every employee understands their role in maintaining product quality and patient safety. Data integrity, risk management and continuous improvement were identified as equally important pillars of modern sterile manufacturing.

The discussion also explored the increasing role of digital technologies in contamination control. Automated monitoring systems, real-time analytics and predictive quality tools are helping manufacturers identify risks earlier while improving process consistency and regulatory confidence.

Regulatory expectations formed another important dimension of the conference.

L-R: Shirish G Belapure , Sr Technical Advisor, IPA (MODERATOR); Rajiv Gandhi, CEO & MD, Hester Biosciences; Parag Swadia, CEO & Executive Director, Otsuka Pharmaceutical India; Sandeep Raktate, President, Operations India, and Ireland, Amneal Pharmaceuticals



L-R: Hitesh Bhatt, Former Sr VP, Head - India Quality Management, Amneal Pharmaceuticals (MODERATOR); Vinay Jathar, CEO & Founder, Aditi Advisory Services; Dr Tarun Chugh, Founder and CEO, SIMco Pharma Consultancy; Nitish Chakravarty, Site Director, Centrient Pharmaceuticals; Digambar Nigade, VP, Quality – Injectable Division, Amneal Pharmaceutical; Santosh Jadhav, Associate VP, Head of Quality - India operation, Kashiv Biosciences; Chetan Majmudar, Technical Director and Partner, Clesta Lifesciences; Pinak Kumar Patel, Assistant Division Head - Production, Otsuka Pharmaceutical India

Delivering an insightful session on 'The new frontier in injectable excellence,' Dr Hemant Koshia, former Commissioner, FDA Gujarat and Drug Regulatory Expert, explained that regulatory agencies worldwide are increasingly moving towards science-based and risk-based inspections. Compliance, he noted, should no longer be viewed as a periodic activity undertaken during inspections but as an organisational culture embedded across manufacturing operations.

Complementing this perspective, Swapnil Pawar, Business Unit Director – West India, Lindstrom India, highlighted the changing regulatory expectations surrounding contamination control strategies. His session on environmental monitoring and contamination control systems explained that modern manufacturing facilities require integrated systems where environmental monitoring, cleanroom behaviour, cleaning validation and contamination prevention work together rather than as isolated compliance activities.

Adding another technological dimension, Kalidas Verma, Regional Technical Sales Manager, Ergoclean, introduced delegates to FAR-UVC UV222 technology for continuous decontamination. He explained how next-generation ultraviolet technologies can strengthen contamination control programmes while supporting safer manufacturing environments and improving operational efficiency within sterile production facilities.

Collectively, these sessions reinforced that quality is no longer merely a regulatory requirement, but a strategic differentiator influencing patient safety, business continuity and global competitiveness.

Technology and science reshape injectable manufacturing

Technology-led innovation emerged as another defining theme of the conference. Presenting on the successful implementation of Visual Inspection (VI) and Container Closure Integrity Testing (CCIT) technologies, Shaunak J Dave, CEO & MD, Antares Vision Group India, shared practical insights into deploying automated inspection systems for injectable manufacturing.

He explained that visual inspection technologies have evolved significantly from conventional manual inspection methods to intelligent automated systems capable of improving defect detection, reducing variability and strengthening compliance. Container Closure Integrity Testing similarly provides greater confidence in product sterility by identifying packaging defects before products reach patients. As regulatory scrutiny continues to increase, automated inspection technologies are becoming indispensable components of modern injectable manufacturing.

Packaging innovation formed another important pillar of the conference.

Speaking on 'NKP Pharma – Your trusted Indian partner for advanced injectable packaging,' Prem Mevada, Director, NKP Pharma, explained how packaging has evolved into a key contributor to product stability, patient safety and regulatory compliance. As injectable formulations become increasingly sophisticated, packaging systems must provide enhanced protection against contamination while ensuring compatibility throughout the product lifecycle.

Scientific development also received significant attention as Dr Ravichandra BV, GM & Head – Global Toxicology & Nonclinical Development, Amneal Pharmaceuticals, discussed the role of preclinical research in de-risking complex injectable drug development. He highlighted how comprehensive toxicological evaluation enables companies to identify potential safety risks early in development, thereby reducing uncertainty during clinical and commercial stages.

Shaunak J Dave, CEO & MD, Antares Vision Group | India

Prem Mevada, Director, NKP Pharma

Dr Ravichandra BV, GM & Head - Global Toxicology & Nonclinical Development, Amneal Pharmaceuticals

Swapnil Pawar, Business Unit Director West India, Lindstrom India

Kalidas Verma, Regional Technical Sales Manager, Ergoclean

Dr Hemant Koshia, Former Commissioner, FDCA Gujarat

Dr Rohit Jadav, Sr GM, Amneal Pharmaceutical

L-R: Naresh Kumar Gaur, Consultant – Pharma Manufacturing Operations (MODERATOR); Dhananjay Dwivedi, VP - Analytical Research and Development, Amneal Pharma; Dayanand More, Head Site - Operation, Alembic Pharma; Dr Bhaskar Chauhan, Head R&D and Quality Management, Puniska Injectable; Dr Pramod Gupta, DGM - R&D, Troikaa Pharma; Bhavin Kachhiya, Sr Manager, DPD – Packaging Development, Kashiv Biosciences; Dr Ajinath Shirsat, Technical Lead – Complex Product Development, Formulation Development, Baxter Pharma India

L-R: Dr Mayur Parmar, Dy Collector & Sub-Divisional Magistrate, Anand; CEO, AVKUDA; NLMT ECI (MODERATOR); Dr Madhusudan Bommagani, President, FR&D,Cadila Pharmaceuticals; Dr Arvindkumar Thakker, Technical Director, Stallion Laboratories; Dr Jayesh M Wankhade, GM - Formulation Development (Sterile Products), FTF Pharma; Sandip Deshpande, R&D Tech Transfer, Amneal Pharmaceuticals; Pradip Som, Head -Packaging Development, Aculife Healthcare; Dr Kashyap Nagariya, Assistant Division Head, Otsuka Pharmaceutical India

Highlighting the importance of scientific excellence, Dr Rohit Jadav, Sr GM, Amneal Pharmaceuticals, delivered a presentation on advanced analytical characterisation for complex injectables from development to commercialisation. He explained how sophisticated analytical tools now play a critical role in understanding molecular behaviour, ensuring product consistency, supporting regulatory submissions and facilitating successful technology transfer.

These presentations demonstrated that future competitiveness in injectable manufacturing will depend on combining scientific expertise with advanced manufacturing technologies.

Manufacturing must evolve with product complexity

The panel discussion, 'The complexity challenge: Can manufacturing keep up with advanced injectables?', moderated by Naresh Kumar Gaur, Consultant – Pharma Manufacturing Operations, brought together Dhananjay Dwivedi, VP - Analytical R&D, Amneal Pharmaceuticals; Dayanand More, Head Site - Operation, Alembic Pharmaceuticals; Dr Bhaskar Chauhan, Head R&D and Quality Management, Puniska Injectable; Dr Pramod Gupta, DGM - R&D, Troikaa Pharma; Bhavin Kachhiya, Sr Manager, DPD – Packaging Development, Kashiv Biosciences; and Dr Ajinath Shirsat, Technical Lead – Complex Product Development, Formulation Development, Baxter Pharmaceuticals India

Panelists agreed that advanced injectables require integrated capabilities spanning formulation development, analytical sciences, process engineering, packaging, technology transfer and commercial manufacturing.

The discussion highlighted the importance of Quality by Design principles, digital manufacturing systems and continuous process verification in delivering consistent product quality. Speakers also stressed that increasing product complexity demands closer collaboration between R&D, manufacturing, engineering and quality functions from the earliest stages of product development.

Packaging development also emerged as a critical success factor, particularly for sensitive formulations requiring specialised delivery systems and enhanced protection against contamination. The panel concluded that manufacturing organisations must invest in technology, infrastructure and talent if they are to remain competitive in an evolving injectable market.

Ahmedabad: An injectable manufacturing hub

The conference concluded with a panel discussion titled 'Making Ahmedabad a Preferred Destination for High-Value Injectables,' moderated by Dr Mayur Parmar, Deputy Collector & Sub-Divisional Magistrate, Anand; CEO, AVKUDA.

Joining him were Dr Madhusudan Bommagani, President, FR&D,Cadila Pharmaceuticals; Dr Arvindkumar Thakker, Technical Director, Stallion Laboratories; Dr Jayesh M Wankhade, GM - Formulation Development (Sterile Products), FTF Pharma; Sandip Deshpande, R&D Tech Transfer, Amneal Pharmaceuticals; Pradip Som, Head -Packaging Development, Aculife Healthcare; and Dr Kashyap Nagariya, Assistant Division Head, Otsuka Pharmaceutical India, who explored Ahmedabad's growing prominence within India's pharma landscape.

The panel highlighted Gujarat's long-standing strengths in pharma manufacturing, strong industrial infrastructure, skilled workforce, research capabilities and export-oriented ecosystem. These advantages have positioned Ahmedabad as one of the country's most important pharma clusters.

The speakers emphasised that sustaining future growth will require continued investments in advanced sterile manufacturing, specialised talent development, industry-academia collaboration, technology adoption and innovation ecosystems. The panel also discussed the importance of supportive regulatory frameworks, infrastructure development and collaborative initiatives in positioning Ahmedabad as a preferred destination for advanced injectable manufacturing.

Way forward

India's injectable industry stands at a defining moment. The transition from conventional sterile manufacturing to complex, innovation-driven injectable products is reshaping every aspect of pharma operations—from R&D to manufacturing, quality assurance, packaging and regulatory compliance.

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The shift to intelligence driven pharma

Dr Pradeep Kumar Vishwakarma, Associate Director - Manufacturing Science and Technology, Cipla explains hat AI is transforming the pharma industry from a one-size-fits-all model to intelligence-driven, patient-centric healthcare by accelerating drug discovery, optimising manufacturing, and enabling personalised therapies

Pharmaceutical companies are experiencing a substantial transformation compared to how they operated in prior decades. Previously, medications were developed with an approach that targeted large populations. While this produced medications for mass distribution, there wasn't always an ideal response from every patient. The reason is that different patients respond to medication differently due to variables like genetics, lifestyle choices, age, etc. The beginning of Artificial Intelligence (AI) is enabling pharmaceutical companies to analyse large data sets to determine how various patients may respond to the same medication. As a result, the industry is gradually moving to a more tailored approach, as evidenced by new treatments (e.g., CAR T and other targeted therapies). That is where data and AI are playing crucial role for future to set the approaches and horizons.

Historically, AI has primarily been used for automating business processes. Increasingly, AI has become a critical component of drug discovery, development, manufacturing, and regulatory processes. As a result, scientists are making faster, more informed decisions, thus reducing the time required to complete a particular project. As a result, the attention of pharma companies is shifting from the development of general treatments to the development of treatments that focus specifically on individual patients. Also, the data driven analysis and automation guide various cross function departments to easy their task with insightful guide.

Faster drug discovery and better formulation

The time and expense involved with drug discovery has always been significant, but companies today can utilise AI technology to streamline chemical experimentation, clinical trials plan, execution and monitoring. For instance, usually, many pharma companies perform thousands of tests to identify viable targets for drug development. With AI, however, they have access to sophisticated computational predictive tools that allow them to determine which molecules will potentially work before ever synthesising them, resulting in reduced time spent (and costs incurred) on testing many different varieties of molecules and enabling the focus to only be placed on those that are most promising. Ultimately, the time saved on traditional testing can greatly improve your chance for success.

Within formulation development as well, the cost associated with trial-and-error testing has also been reduced significantly using AI based tools. Using an AI system allows for the simulation of how various ingredients will perform as part of a given drug formulation, leading to quicker selection of raw materials and composition of an optimal drug combination. AI-based technology is also extremely effective in developing biologic and complex pharmaceutical products due to their inherent sensitivity and handling requirements. By having an indication of how long a given drug product will maintain its stability, AI will also allow researchers to determine appropriate storage conditions and minimise risk to patient safety using stable drug formulations.

Smarter clinical trials, manufacturing and quality

Clinical trials are often lengthy processes that require extensive planning and selection of appropriate participants. AI can aid in this process by helping to identify suitable participants as well as predicting their pharmacokinetic and pharmacodynamic responses; it can also facilitate better designs for clinical trials and reduce delays while improving overall success rate. However, it is important to emphasise that although AI can support clinical trial decision-making, it cannot displace clinical trials; test-based, regulatory requirements are still being reinforced by the regulators.

In production, AI enhances operational efficiency and product quality. One of the significant areas of pharma is technology transfer; that is, the step of moving a process from the laboratory to commercial scale is extensive with potential challenges. AI can help mitigate these problems by allowing how a process will behave at a commercial scale before we initiate technology transfer; this significantly reduces the potential for error and enhances the probability of success. Furthermore, digital models (CFD/DEM, etc.) of pharma processes can be built and simulated to test various parameters before initiating any manufacturing work; again, this greatly reduces the potential for error and increases the probability of success. Additionally, predictive maintenance can be enabled through constant monitoring of machinery and equipment, allowing companies to determine the cause of equipment failure prior to actually failing. Companies are then able to limit their production downtime due to machine failures or other production-related process breakdowns; thus, increasing productivity. And, through data analysis and early detection of quality issues, AI can help assure that problems are prevented prior to occurrence rather than later. Overall, these improvements contribute to higher product quality and compliance levels.

India's opportunity and the road ahead

The Indian pharma industry has a strong reputation as one of the world's leading pharma producers with an estimated value of over $75 million. This reputation is due to India being known as one of the largest producers of generic drugs globally (approximating 40 per cent of global generic drug production), having a large number of approved manufacturing sites and also the existing large domestic and export market size of generic drugs manufactured in India; therefore these factors are establishing the foundation for a very successful future for growth within the industry.

The pharma industry is currently transitioning from Pharma 4.0 to Pharma 5.0. Pharma 4.0 primarily focuses on automation and digital technologies versus Pharma 5.0, which extends beyond automation and digital technologies, leveraging human intelligence and artificial intelligence to create new healthcare solutions that are smarter, faster, and tailored than anything we have experienced previously.

Companies in India have already begun utilising AI technologies within their research and manufacturing processes. However, significant improvements will be needed to realise the full benefits of AI integration in the industry. These include improving both the quality and availability of data used to develop AI algorithms, investing in digital infrastructures that allow for AI research to be performed, and training people on newly developed digital technologies is essential. The final, and arguably most important, requirement for the successful integration of AI into the industry is to change and promote an accepting 'mindset' among the employees about their contributions to the AI development process.

In conclusion, AI will allow for quicker, smarter, and efficient development of pharmas. AI will also allow for the development of less expensive, higher quality, and better focused products to meet the needs of patients. Companies successfully utilising appropriate AI technologies combined with appropriately designed systems and compliant processes will lead the pharma industry over the next several years.

"By identifying and acting upon these opportunities, India will be able to make the transition from a volume-based supplier to a leader in innovation. If the right actions are taken today, India can become not only 'the pharmacy of the world', but also a center for personalised and cutting-edge healthcare."

The innovation litmus test

India has built the scientific capability to move beyond manufacturing. But as global pharma searches for its next innovation partners, the real test is whether India's ecosystem is predictable enough to inspire long-term confidence, writes **Neha Aathavale**

Every industry eventually reaches a point where yesterday's biggest strength is no longer tomorrow's biggest differentiator. For India's pharma industry, that moment seems to have arrived. India's manufacturing prowess has taken the country to the global stage. The next chapter, however, may rest less on what India can manufacture and more on what the world believes it can help create.

If recent conversations across the industry are any indication, it has already begun to take shape. The aspiration is no longer limited to manufacturing the world's medicines, but to becoming a destination for innovation itself.

That ambition is also reflected in the EY Parthenon–Organisation of Pharmaceutical Producers of India (OPPI) report, *Fueling innovation, advancing equity: The power of partnerships and digital-first strategies driving Indian pharma's global dominance*. Where it states that India's pharma industry is entering precisely this next phase: One that calls for a transition from a cost-driven model to one anchored in innovation and value creation.

However, it also makes an important distinction. Innovation partnerships are rarely won on manufacturing scale, cost or capacity alone. Drawing on insights from industry CXOs, the report notes that attracting early-stage research and co-development programmes will increasingly depend on regulatory agility, intellectual property protection, sustained R&D investment and talent development.

It captures this shift in a single line: 'Partnerships follow predictability.' In other words, the question is no longer simply whether India can innovate, but whether its ecosystem offers the certainty global innovators seek before placing their next big bet.

That naturally leads to the next question. Has India already begun building the kind of ecosystem that inspires that confidence?

India's rise in the pharma value chain is driven by a powerful combination of scientific capability, regulatory maturity, integrated CDMO models, and cost-speed advantage. Together, these factors are redefining India's role—from a manufacturing base to a trusted partner for innovation-led drug development and co-creation

Yogesh Joshi
Associate Director and Head – Formulation Development (CDMO vertical)/ Head Clinical manufacturing, Piramal Pharma Solutions

Consistency and reliability are the foundation of successful global partnerships. Scientific excellence may initiate a conversation, but sustained trust is built through predictable execution

Dr Sandhya Shenoy
VP - Formulation R&D, MSN Laboratories

Companies invest where they have confidence in the regulatory framework and intellectual property protection. Equally important is the availability of skilled scientific talent, which ultimately drives innovation and long-term growth

Dr Syed Shah Moinuddin Hussaini
Head, Global Pharma R&D, Wockhardt

After the 'Pharmacy of the World'

India's appeal today stems from more than its manufacturing credentials. Over the past decade, the country has strengthened the building blocks that global innovators look for. Investments in R&D infrastructure, scientific talent, specialised technology platforms and integrated development capabilities have gradually expanded India's role from an execution partner to a development partner.

As global pharma companies increasingly look for collaborators who can contribute across the product lifecycle rather than simply manufacture at the end of it, India's proposition has evolved accordingly.

Validating this shift, Yogesh Joshi, Associate Director and Head – Formulation Development (CDMO vertical)/Head Clinical manufacturing, Piramal Pharma Solutions says, "Over the past decade, India has undergone a significant transformation—from being a cost-driven manufacturing hub to emerging as a credible and strategic partner for innovation and co-development in the global pharma landscape." He also highlights that Indian CDMOs have moved well beyond traditional generics manufacturing and are now supporting early-stage development, new chemical entities (NCEs), complex formulations and lifecycle management, signalling a broader shift from execution-focused services to innovation-led collaboration.

Joshi further attributes this evolution to sustained investments in R&D, advanced technology platforms and integrated CDMO capabilities spanning pre-formulation, development, clinical manufacturing and commercial supply.

Dr Sandhya Shenoy, VP - Formulation R&D, MSN Laboratories, believes this transition has also been driven by stronger scientific capabilities. "Global pharma companies are increasingly seeking agile, scientifically capable partners who can contribute meaningfully throughout the development journey. India's unique combination of scientific expertise, operational agility, speed, and scale has positioned it as a preferred destination for co-development and innovation-led partnerships rather than purely transactional outsourcing relationships."

Echoing a similar view, Dr Syed Shah Moinuddin Hussaini, Head, Global Pharma R&D, Wockhardt, adds, "India has developed strong R&D capabilities over the last two decades while serving regulated markets across the world. Today, many Indian companies have experienced scientists, modern R&D infrastructure, and expertise in complex product development. As a result, global companies are increasingly seeing India not just as a manufacturing destination but also as a capable development and innovation partner."

The global checklist

Yet, becoming an attractive innovation destination is only half the equation. Innovation partnerships are rarely won on a single strength. Instead, global pharma companies evaluate potential partners against a checklist of capabilities. Scientific expertise, regulatory maturity, quality systems, intellectual property protection, execution excellence and talent all carry weight. The question is not whether a country excels in one area, but whether it inspires enough confidence across all of them to become a long-term innovation partner.

According to Joshi, that evaluation begins with a partner's ability to solve complex scientific problems while delivering consistently at a global standard. He states organisations look for expertise in complex products and advanced drug delivery systems, supported by robust quality systems, data integrity and a proven regulatory track record across pathways such as IND, NDA, ANDA and 505(b)(2). Beyond scientific capability, he highlights integrated end-to-end CDMO services, seamless technology transfer, reliable supply chains, project management and execution excellence as factors that increasingly influence partnership decisions.

> India's next challenge may not be proving that it can innovate. It is ensuring that its policies, institutions and collaborations evolve at the same pace as its scientific ambitions. Because if partnerships follow predictability, predictability is built long before the partnership begins

Shenoy on the other hand believes scientific capability alone is only one part of the equation. "Organisations seek partners with strong capabilities in formulation science, process understanding, and advanced technology platforms. Equally important is an innovation-oriented mindset—the ability to solve complex technical challenges, generate scientific insights, and contribute to critical development decisions." She further points out that robust intellectual property management, governance frameworks, execution excellence and proactive regulatory compliance are equally critical to building long-term confidence.

Summing up the industry's priorities, Dr Moinuddin Hussaini says, "The most important factors are scientific talent, quality of R&D infrastructure, regulatory environment, IP protection, and the ability to consistently deliver high-quality outcomes. Cost remains important, but today companies are looking for capable partners who can contribute scientifically and accelerate development timelines."

Taken together, these perspectives suggest that attracting innovation partnerships is no longer about competing on cost or manufacturing scale alone. Increasingly, it is about demonstrating that every box on global pharma's checklist can be ticked, consistently and predictably.

Mind the gap

If India's scientific capabilities have strengthened and global interest is growing, what still prevents it from capturing a larger share of innovation-led partnerships? The experts suggest the answer lies less in capability itself and more in the ecosystem surrounding it.

One challenge, they point out, is perception. Despite significant progress in research and development, India is still widely associated with generics and cost-efficient manufacturing. Dr Shenoy believes this perception no longer reflects reality. According to her, India's scientific capabilities often exceed global perceptions because many organisations invest far more in programme delivery than in showcasing their scientific achievements through publications, patents, conference presentations and thought leadership.

At the same time, Joshi believes deeper structural gaps remain. While India has made significant strides, he notes that fewer companies are engaged in early research, new drug development and advanced technologies than their global counterparts. He also points to limited capabilities in areas such as biologics, gene therapies and complex drug-device combinations, alongside the need for greater consistency in quality, regulatory readiness and specialised scientific expertise. Joshi adds that stronger collaboration between academia, startups and industry, coupled with better research infrastructure, will be essential if India is to move beyond its image as a manufacturing destination and establish itself as an innovation leader.

For Dr Moinuddin Hussaini, the ecosystem itself holds the key. "They are extremely important. Companies invest where they have confidence in the regulatory framework and intellectual property protection. Equally important is the availability of skilled scientific talent, which ultimately drives innovation and long-term growth." He believes stronger collaboration between academia, research institutes, startups and industry could have the single biggest impact on India's ability to become a preferred global innovation partner.

Ultimately, India's next challenge may not be proving that it can innovate. It is ensuring that its policies, institutions and collaborations evolve at the same pace as its scientific ambitions. Because if partnerships follow predictability, predictability is built long before the partnership begins.

The final mile

If there is one thread running through the industry's vision for the future, it is that capability alone will not secure India's place in the next phase of pharma innovation. Sustaining that momentum will require an ecosystem that evolves as quickly as the science itself.

The EY Parthenon– OPPI report outlines three priorities to accelerate this transition. The first is regulatory agility, including aligning Indian GMP standards with global benchmarks, creating a dedicated regulatory pathway for CRDMOs and strengthening Regulatory Data Protection (RDP) to encourage early-stage research and co-development. The second is greater investment in innovation through public-private funding, higher industry spending on R&D and stronger collaboration between academia, startups and pharmaceutical companies. Finally, the report calls for a renewed focus on talent, urging academia and industry to work together to build capabilities in areas such as artificial intelligence, bioinformatics and regulatory science while linking research more closely to commercial outcomes.

Dr Shenoy believes Indian R&D teams must also deepen their scientific capabilities to remain competitive. According to her, future programmes will increasingly demand mechanistic understanding, digital and data-driven development, and closer collaboration between formulation scientists, engineers, data scientists, regulatory specialists and clinical teams. She adds that building a stronger culture of scientific curiosity, publications, patents and global thought leadership will be equally important in positioning India as an innovation-led ecosystem.

The direction, therefore, is becoming increasingly clear. India's manufacturing success created the foundation. Its scientific capabilities have strengthened the proposition. The next phase will depend on how effectively industry, academia and policymakers can work together to build an ecosystem that global innovators do not just recognise, but repeatedly choose.

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The GLP-1 effect: How weight-loss drugs could reshape India's FMCG playbook

Sounak Chatterjee, Management Consultant, Avalon Consulting, outlines how GLP-1 drugs could reshape not just healthcare, but the FMCG industry by changing how consumers eat, snack and choose food. As appetite-driven consumption evolves, brands will need to compete on nutrition, portion control and health value, not just volume

Everyone is talking about GLP-1 as the next big healthcare disruptor. That is only half the story.

If a drug can make people feel full faster, the impact is not limited to hospitals, pharmacies or weight-loss clinics. It enters the kitchen, the grocery basket, the office snack drawer and eventually, the P&L of FMCG companies.

GLP-1 drugs, used for diabetes and weight management, work partly by increasing satiety and reducing appetite. That does not mean consumers will stop eating. But it could mean some eating occasions become smaller, fewer and more conscious.

Think of the post-lunch sweet craving, the evening namkeen break, the impulse bakery purchase, or the sugary beverage top-up. Many of these are not planned meals. They are habits, cravings, boredom, or social cues. If appetite reduces, the economics of these occasions changes.

That is why GLP-1 is different from the usual health-food trend. The earlier health-food wave was about consumers choosing better products within the same routine. GLP-1 can go one step further. It can change the routine itself.

A recent report framed GLP-1 as a potential ?2.5 lakh crore FMCG opportunity, with companies preparing low-calorie foods, protein-rich products, zero-calorie beverages and healthier snacking options. This is not a market made only of GLP-1 users. It is better understood as the broader "build health" and "better-for-health" foods universe — estimated at around ?1 lakh crore today and projected to grow at 15–20 per cent to reach ?2.5 lakh crore by 2030.

Why can this market become so large? First, India's metabolic-health problem is already massive. The ICMR-INDIAB study estimated 101 million people with diabetes and 136 million with prediabetes in 2021. Second, GLP-1 itself is expected to scale. CareEdge estimates India's GLP-1 market at ₹1,000–1,200 crore in 2025, rising nearly fivefold to ₹4,500–5,000 crore by 2030, with patent expiry and generic competition improving access. This does not make GLP-1 mass-market overnight. But it does mean a premium, urban, medically guided consumer base may start shaping food choices earlier than expected.

Evidence from more mature markets shows the direction. GLP-1 users are reportedly spending less across several food categories, with sweet snacks, salty snacks and baked goods facing sharper pressure. Many users are also eating smaller portions and choosing healthier foods. The point is not just that consumption falls. Every eating occasion has to justify itself better.

So, which categories should worry?

The obvious ones are sweet snacks, salty snacks, bakery products and sugary beverages. These categories are built on impulse, repetition and calorie-dense reward. But the answer is not straightforward decline. A consumer may buy fewer large packs, but still pay for a smaller, better-quality indulgence. A sugary drink may lose relevance, but a zero-sugar, hydration-led or functional beverage may gain. A namkeen brand need not become a protein brand overnight, but it may need smaller packs, baked formats, cleaner ingredients or credible portion control.

This also changes the old pack-price logic. Indian FMCG has historically won through affordability, availability and pack-size laddering. But if a consumer is trying to eat less, "more grams for the same price" may not always be the winning promise. The new value equation may be: smaller quantity, but better nutrition; lower sugar, but still good taste; higher protein, but not medicinal; a smaller pack, but with a clearer benefit.

This is where brands can get the response wrong. Adding "high protein" to a few SKUs is not a strategy. Nor is creating a separate "GLP-1 friendly" shelf. The better approach is to map eating occasions. Which occasions may shrink? Which may shift to healthier alternatives? Which new occasions can be created around protein, fibre, hydration, gut health or portion control?

Early movers are already reacting. Nestlé's Vital Pursuit range in the US is positioned for GLP-1 users and weight-management consumers, with products designed around protein, fibre, essential nutrients and smaller appetites. In India, Marico has spoken about GLP-1-led behaviour shifts while strengthening its wellness portfolio across Saffola Foods, True Elements, Plix, Cosmix and 4700BC. The common thread is not "diet food." It is convenience, nutrient density, trust and a credible health promise.

There are risks too. India's GLP-1 adoption will not look like the US immediately. Cost, prescription access, adherence and side effects will matter. Brands also need to avoid medicalising food or making claims that sound too close to drug benefits. The safer route is to build around understandable nutrition claims: low sugar, high protein, fibre, gut health, hydration, satiety and portion control.

GLP-1 is unlikely to create a separate FMCG universe. Its bigger impact may be to change the rules inside existing categories. The brands that win will understand which occasions are changing, which benefits matter more, and how to make each eating occasion feel more useful. That is the real shift: from calorie-led volume to nutrition-led value.

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CATEGORY EXPOSURE AND OPPORTUNITY MAP

Category/Occasion	Likely GLP-1 impact	Strategic implication for FMCG players
Sweet/Salty snacks	Higher exposure	Move from volume-led impulse to portion-controlled, baked, protein/fibre-led snacking
Bakery/Indulgence	Higher exposure	Reframe as smaller, premium and permissible indulgence
Sugary beverages	Higher exposure	Accelerate zero-sugar, hydration and functional beverage formats
Dairy/Protein foods	Likely beneficiary	Build high-protein yoghurt, shakes, paneer snacks and meal complements
Nutraceuticals/functional foods	Likely beneficiary	Expand fibre, gut-health, protein and micronutrient-led propositions

India's online pharmacy boom and the perils of unregulated medicine

Dr Amit Kumar, Head, Centre for Applied Research in Public Health, Rights and Policy, Maharashtra National Law University, Mumbai; and **Pranava Shah,** LL.M candidate, Maharashtra National Law University Mumbai, explain that as online medicine sales surge, a robust legal framework is urgently needed to safeguard patient safety, curb antibiotic misuse and protect health data

Online shopping has trained us to value one thing above all others: visibility. Yet what empowers a consumer comparing prices becomes a liability when the same screen displays prescription drugs with ratings and discounts inviting us to treat medicine as a commodity, substitute a prescribed brand for a cheaper alternative or abandon a drug course because the refill seems expensive. The question worth asking is whether this visibility serves us equally well when the product in the cart is medicine or whether it turns a prescription into a shopping list inviting edits that can cost lives.

India's e-pharmacy industry has witnessed a phenomenal growth from around $0.5 billion in 2019 to about $3.71 billion in 2025, with predictions of growing to $14.08 billion by 2034. Over-the-counter medicines currently make up about 56 per cent of sales of online pharmacies in India. E-pharmacy platforms as well as quick commerce applications providing ten minutes delivery have made medicine purchase hassle-free. This growth nevertheless has taken place in the absence of regulation; the draft of e-pharmacy regulations of 2018 is yet to be finalised after seven years and the Drugs and Cosmetics Act, 1940, dates back to pre-internet era and remains inadequate by far to meet the challenges brought forth by e-commerce in medicine.

Dr Amit Kumar

Pranava Shah

An e-pharmacy legislation with compulsory registration, secure electronic prescriptions, data protection, defined liabilities and oversight is not a deterrent to growth but a prerequisite for sustainable growth

The regulatory deficit

The Drugs and Cosmetics Act of 1940, together with the Drugs Rules of 1945 and the Pharmacy Act of 1948, forms the legal basis for regulating the sale of drugs in India. This legislative regime is predicated on the existence of a physical store and a licensed pharmacist. However, a legislation enacted in 1940 evidently does not envisage a sale taking place via a digital application.

The newer statues too fail to bridge the gap. The Information Technology Act of 2000 enables the platform to take shelter under the cover of being an intermediary; the Consumer Protection Act of 2019 addresses the transactions but not the clinical risks it entails; the Telemedicine Practice Guidelines of 2020 binds the doctor prescribing the drug but not the platform dispensing it and the Digital Personal Data Protection Act of 2023 does not designate health data as a category requiring any special protection. The draft rules containing provisions relating to registration, inspection, advertisement prohibition, grievance redressal and monitoring have still not seen the light of the day.

Judicial intervention has tried to address the risk but has not been able to make any real dent. In December 2018, for instance, the Delhi High Court placed an interim ban on the sale of medicines online, stating that it was impermissible under the Drugs and Cosmetics Act, 1940 and the Pharmacy Act, 1948. In November 2023, the court gave the government "one last chance to formulate a policy in eight weeks", stressing that "more than five years have lapsed and the Union of India has had sufficient time to frame a policy". However, as of now none has been formulated yet.

The antibiotic time bomb

Nowhere is the danger of this regulatory paralysis more acute than with antibiotics. The portal through which users can search symptoms and treatments renders the need for prescription a formality. As per the cross-sectional survey conducted in 2024 among 50 Indian e-pharmacies, it has been observed that antibiotics from all three WHO AWaRe categories including "Watch" and "Reserve" antibiotics, which have relatively more resistance potential, are available for online sales. None of the portals fully complied with the safety criteria. Whereas 82 per cent of the portals demand prescription, none of the websites mentions the registration number of the pharmacist on duty and none of them has any mechanism to restrict the excessive ordering of antibiotics. The study concluded that increased access to high-risk antibiotics may translate into antibiotic misuse.

All India Organization of Chemists and Druggists has consistently expressed its concern that illegal online pharmacies are dispensing antibiotics without authorised prescriptions misusing even the telemedicine guidelines and issuing frivolous prescriptions. The Drugs Controller General of India also has flagged unchecked antibiotic sales as a major contributor to rising drug resistance.

According to 2021 figures, antibiotic resistance is thought to have been responsible for about 267,000 deaths in India alone with another 940,000 deaths indirectly related to it. Projected estimates indicate that about 1.2 million people will die annually from AMR by 2030 unless concerted action is taken with alacrity. Worldwide, it is predicted that there will be 39 million AMR-related deaths from 2025 through 2050. This highlights the pervasive extent of the issue.

The data privacy gap

In addition to the aforementioned concerns, there is another major problem with

data privacy that e-pharmacies bring along. Each prescription, health history and diagnostic report uploaded constitutes a wealth of private health information. However, health information is not regarded as "sensitive personal data" in the Digital Personal Data Protection Act of 2023.

A prescription contains information about chronic ailments, mental disorders and other sensitive aspects of a patient's health status. Without being licensed according to the Drugs and Cosmetics Act, online portals do not have any obligation to safeguard patients' confidentiality. While the e-pharmacy rules in 2018 included provisions regarding data privacy, these were never enforced. Patient information provided to e-pharmacies is thus left in a legal limbo, without proper safeguards and protections.

In fact, when something is going wrong, a counterfeit drug, an adverse reaction or a prescription fulfilled without verification, the issue of liability remains unsettled. The e-pharmacies have tried to defend their stance that they do not need any license as they simply deliver drugs like food delivery applications. This argument deliberately misconstrues the nature of pharmaceutical transaction because the platform which controls the price, manages the interface and processes the payments cannot be considered only as a passive intermediary. In fact, in February 2023, more than 20 online pharmacies received show cause notice from the Drug Controller General of India (DGCI) as they were operating without any license. However, no punitive action was taken. As a result, the industry continues in legal uncertainty, with marketplaces disclaiming responsibility for the transactions they design.

Charting a safe path forward

The fix is not very complex but is certainly long overdue. What India needs is an e-pharmacy act that plugs several important regulatory gaps. To start with, there should be mandatory registration at the Central Licensing Authority level using a dedicated website for a specified period of time with proper verification of compliance. The draft rules proposed Form 18AA in this regard and this must be carried out immediately. Moreover, the portal must prominently display registration details, the firm's constitution and the registered pharmacist's name.

In addition, the Act must provide for a reliable electronic prescription system through the Ayushman Bharat Digital Mission as opposed to accepting scanned copies of handwritten prescriptions. There should be a centralised prescription database so that the same prescription cannot be used on multiple platforms. Patient and practitioner verification must be done by registered pharmacists before dispensing any medication.

Moreover, the Digital Personal Data Protection Bill has to be modified in so as to classify health-related data including prescriptions, past medical history and diagnostic information under a specially protected category. Data localisation should be ensured in such a manner that all the data is stored only in India, with the platforms being subjected to greater data protection obligations than generic intermediaries. The liability conundrum must also be settled definitively. E-pharmacy platforms cannot escape liability as an intermediary while regulating the transaction. There should be a clear delineation of liability and its sharing between the platform, pharmacist, prescriber and manufacturer. The platforms need to be considered as active players in the pharma value chain.

Additional safeguards must include an absolute bar on online sale of narcotics, psychotropic substances and Schedule X drugs. It is also crucial to clearly prohibit advertising of prescription medicines since this kind of advertising results incentivizes self-medication among patients. Every e-pharmacy must employ a registered pharmacist available round-the-clock for verifying prescriptions and answering customer questions. There should also be regular inspections of the premises in addition to risk-based transaction audits. Finally, the framework must provide for a robust grievance redressal system, a dedicated monitoring body and complete supply-chain traceability from manufacturer to patient, guarding against counterfeit medicines.

The way forward

It needs to be acknowledged that the advent of E-pharmacies in India is no passing trend. It is a radical change whose time has come. These e-commerce platforms have the potential to bring much-needed relief to many Indians, from the bed-ridden elderly, the chronically ill to those in the rural parts of the country who have trouble finding well-stocked physical pharmacies. They can also democratise access, make prices transparent and provide convenience that is simply unachievable through brick-and-mortar outlets. Moreover, the pandemic has accelerated this process and has expanded the market and there is no turning back now.

Yet paradoxically, the features that make e-pharmacies convenient also make them dangerous if the regulatory architecture fails to keep up. The interface that makes it possible for a rural patient to order his life-saving medicines can also make it possible for a teenager to order antibiotics without a doctor's prescription. The same platform that makes it easy to compare prices can also allow a substitute product to be ordered in lieu of the one prescribed by a doctor.

The solution should not thus be to turn away from digital healthcare but to create safeguards proportionate to the size of the challenge. E-pharmacies need to be brought under the ambit of law, not to curb innovation but to ensure that innovation doesn't come at the expense of the safety of patients. An e-pharmacy legislation with compulsory registration, secure electronic prescriptions, data protection, defined liabilities and oversight is not a deterrent to growth but a prerequisite for sustainable growth.

E-pharmacies are here to stay. But the question is whether India will legislate to ensure that the benefits are delivered without risks. The role of the legislature and the regulator is not to impede progress but to guide it. The need is to have an online pharmacy ecosystem that delivers both convenience and safety, because a prescription should never turn into a shopping list.

Redefining pharma warehousing: The shift from storage facilities to compliance-driven supply chain hubs

Suresh Narayanan, Head of Operations – Consultative Logistics, Allcargo Logistics opines that warehousing has become a strategic function in pharma that directly influences operational resilience, market access and ultimately, patient safety

Pharmaceutical warehousing has evolved significantly from a back-end storage function to a critical component of regulated supply chain operations. As pharma supply chains become more complex and compliance expectations intensify across global markets, warehousing is now expected to support not only inventory management, but also product integrity, traceability, audit readiness, and risk mitigation throughout the distribution lifecycle.

This shift is being driven by increasingly stringent regulatory frameworks, greater scrutiny from global procurement markets, and rising expectations around visibility and quality assurance. In this environment, the warehouse is no longer evaluated solely on storage capacity or operational throughput. It is assessed on its ability to maintain compliant conditions, ensure process consistency, and provide end-to-end traceability across every product movement within the supply chain.

The pharma warehouse of the next decade will be a node in an interconnected network-a facility that receives, validates, stores, tracks, processes, and dispatches with the same rigour applied at the manufacturing stage

The compliance burden has shifted downstream

India's pharma sector supplies nearly 20 per cent of the world's generic medicines by volume. That scale comes with regulatory obligations that extend well beyond the manufacturing floor. Good Distribution Practice (GDP) guidelines from the WHO, procurement requirements from regulated markets in the US, EU and Australia, and CDSCO's evolving domestic framework have collectively raised expectations for how pharma products must be stored, handled and moved.

What this means in practice is that the warehouse is no longer simply assessed on throughput or space utilisation. It is assessed on its ability to demonstrate documented adherence, audit readiness, and unbroken traceability across every product movement. The burden of compliance, once concentrated upstream, has migrated decisively into distribution and storage.

Process standardisation is not optional

The most consistent failure mode in pharma warehousing is not infrastructure-it is process variability. Facilities that invest in controlled temperature zones, zoned storage for product segregation, and rigorous pest management often fall short when standard operating procedures are inconsistently applied or when staff rotation leads to knowledge gaps.

GDP-aligned warehousing requires that every touchpoint i.e. goods receipt, quality inspection, storage allocation, pick and pack, cold chain handover follows a documented, auditable procedure. These are not aspirational standards. They are enforceable requirements against which logistics providers are evaluated both by regulatory bodies and by pharma clients conducting their own supply chain assessments.

What distinguishes a genuinely compliance-ready facility is institutional discipline-teams that understand the rationale behind the protocols, not merely the sequence. A process executed because it is understood is far more reliable than one executed because it is mandated.

Traceability: The infrastructure behind accountability

End-to-end traceability has moved from a best practice to a regulatory baseline. Export markets now require batch-level tracking, serialisation compliance, and full chain-of-custody documentation as conditions of market access. Domestically, the expectation is accelerating. A consignment that cannot be traced-precisely, across every leg of its journey is a consignment that creates liability.

This means every inbound receipt, every storage movement, every dispatch must generate a verifiable digital record: batch numbers, expiry dates, temperature logs, vehicle and driver credentials, consignment handover confirmations. When a quality concern arises and in a sector of this scale, it will — the ability to execute a precise, time-bound recall depends entirely on whether this infrastructure existed before the issue occurred.

Building traceability requires more than technology investment. It requires process architecture ensuring that digital documentation is embedded in daily operations rather than layered on top of them. Audit readiness is not a project. It is a standing operating posture.

Visibility across a fragmented network

India's pharma distribution challenge is, in part, a geography problem. Managing compliant movement from manufacturing hubs to distribution centres, and from distribution centres to hospital pharmacies, rural stockists, and export consolidation points requires coordination across a network that is structurally fragmented-multiple carriers, multiple han-

dover points, uneven infrastructure.

Technology infrastructure in the form of Transportation Management Systems and supply chain control towers has become the governance layer that makes compliant distribution at scale achievable. These platforms do more than optimise routes or reduce freight costs. In a regulated context, they monitor shipment parameters in real time, flag deviations before they become violations, and give logistics managers the visibility to intervene with confidence rather than react after the fact.

For pharma companies managing multimodal movements-air for time-sensitive biologics, rail and road for bulk generics, sea for export volumes, this integrated visibility is not a convenience. It is the mechanism through which compliance is maintained across modes and across stakeholders who do not share systems.

The coordination gap that compounds risk

One underappreciated dimension of pharma supply chain compliance is stakeholder alignment. A pharma supply chain involves manufacturers, contract logistics providers, third-party carriers, customs agents, regulatory bodies, and end-distribution channels, each with their own systems, timelines, and information asymmetries.

Gaps in coordination between these parties compound compliance risk. A carrier that does not receive temperature excursion alerts in time. A customs clearance delay that leaves a cold chain shipment in a sub-standard environment. A handover that is not documented because two parties assumed the other was responsible. These are not edge cases, they are recurring failure modes in a fragmented logistics ecosystem.

Integrated logistics models that bring planning, execution, and visibility under a coordinated framework reduce these gaps. When a single logistics partner manages multimodal movement with end-to-end accountability rather than multiple vendors each accountable for their own segment-the structural causes of coordination failure are significantly reduced.

From storage to supply chain hub

The pharma warehouse of the next decade will not resemble its predecessor in function or expectation. It will be a node in an interconnected network-a facility that receives, validates, stores, tracks, processes, and dispatches with the same rigour applied at the manufacturing stage.

Purpose-built infrastructure, designed from inception around GDP requirements rather than retrofitted to meet them, will become the benchmark. Facilities that integrate ambient and cold chain zones, digital monitoring, controlled ancillary processes such as kitting and repacking, and seamless connectivity with transportation partners will be positioned to serve pharma clients who can no longer afford compliance ambiguity in their distribution networks.

The shift is already underway. Pharma manufacturers are deepening their scrutiny of logistics partners not just on cost and capacity, but on demonstrated compliance capability. The providers who have invested in process integrity, traceability architecture, and technology-enabled visibility will earn that scrutiny. The rest will find themselves increasingly difficult to justify in an environment where the cost of a compliance failure is measured not in penalties, but in patient safety.

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Romaco launches KTS 840 triple-layer tablet press

The new tablet press and KTP 1X compaction simulator support pharmaceutical and nutraceutical tablet development and manufacturing

Karlsruhe/Germany, 2026-06-18

Romaco Kilian launched the KTS 840 – its new tablet press for triple-layer applications. This robust rotary tablet press offers specific advantages for the nutraceutical production. Another advancement in tablet manufacturing can be accessed at Romaco India's Experience Centre in Hyderabad, Telangana State. Here, a processing laboratory houses the KTP 1X compaction simulator, which supports pharmaceutical, nutraceutical and food companies in their research and development efforts.

KTP 1X compaction simulator


KTS 840 triple-layer tablet press

KTS 840 tablet press

The versatile and robust KTS 840 tablet press by Romaco Kilian was engineered specifically for compressing triple-layer tablets for the nutraceutical industries. It is, however, suitable for all kinds of dosage forms and sizes. Equipped with up to 91 press stations and featuring a pitch circle of 840 mm, this flexible all-rounder achieves a maximum output of 300,000 tablets per hour. This machine operates with impressively low vibrations, even at pre- and main compression forces of up to 100 kN. The cGMP compliant hygienic design, which hermetically separates the compaction area from the machine compartment, enables the KTS 840 to satisfy all the quality requirements of the production process.

For the production of triple-layer tablets, the rotary tablet press has three specially designed fill shoe systems, which can also feed sticky, abrasive, corrosive and poorly flowing powders reliably and with absolute control. Its segmented rotor not only increases the machine's productivity but also speeds up format changes. Last but not least, the powerful, maintenance-free and, above all, highly efficient torque drive ensures a long service life for the KTS 840 triple-layer tablet press.

KTP 1X compaction simulator

The KTP 1X is Romaco Kilian's smart compacting simulator for tablet development using digital tools. This all-in-one instrument was designed for research and development activities but also allows targeted troubleshooting and process optimisation in addition to upscaling. The single-stroke press is capable of simulating any standard rotary press, making it much easier to conduct technology transfer and scale-up trials, among other things. The versatile measurement system is perfect for designing and analysing mono-layer, bi-layer and triple-layer tablets as well as tab-in-tab formats. The KTP 1X determines the ideal compression force/hardness profile for any tablet design, taking account of the various ingredients and parameters. Its compression studies are highly automated, and so only a few test series are needed to obtain meaningful results when characterising a formulation. A special data module gives users worldwide access to raw measurement data at any time, even when the press is not in operation. Decentralised data analysis and processing have numerous advantages, enabling research projects to be implemented more efficiently. Thanks to its very small compaction area, this space-saving instrument fits conveniently into any laboratory as well as being quick and easy to clean. The use of just one pair of punches is both economical and sustainable, and ensures very low product consumption. Depending on the model, the KTP 1X achieves compression forces of up to 80 kN and a maximum output of 1,800 tablets per hour.

Romaco Group

Romaco is a leading supplier of machinery specialising in processing and packaging. With its technologies, the international group serves the global pharmaceutical, nutraceuticals, food, cosmetics, and chemical industries. The one stop solutions provider's portfolio covers the entire process chain from powder processing to the finished pallet. From granulation, tableting, and coating of solid products through primary packaging in blisters, strips, and rigid tubes as well as sterile and non-sterile filling of liquids and powders to secondary and tertiary packaging, Romaco offers the right solution for every application. Whether standalone or as an integrated line – the supplier configures all technologies flexibly according to each customer's requirements. With its products and solutions, Romaco is committed to sustainable production and to systematically reducing carbon emissions. Through targeted energy, material, and space savings Romaco not only improves the technologies' carbon footprint but also cuts customers' manufacturing costs.

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Precision air flow and IAQ measurements with testo 400 and testo 440

The solutions support cleanroom monitoring, HVAC commissioning and indoor air quality assessment

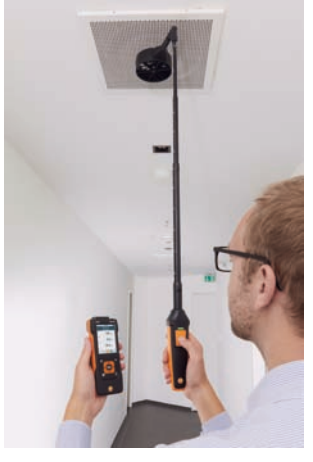
Maintaining accurate environmental conditions is essential in pharmaceutical facilities where air quality, comfort parameters, and process reliability play a critical role. Testo's advanced measurement solutions - testo 400 and testo 440 provide reliable, efficient, and standard-compliant measurement of air flow and indoor air quality parameters.

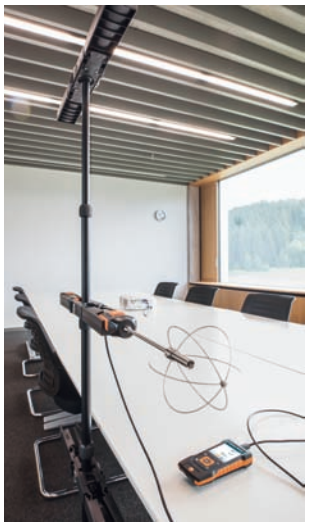
The testo 400 universal IAQ measuring instrument is designed for a wide range of air flow and comfort measurements. With smart technology, intuitive measurement assistants, and an extensive range of digital probes, it enables precise measurement of parameters such as air velocity, temperature, humidity, CO2, and other IAQ values.

Its guided measurement menus simplify complex applications, while the integrated evaluation system helps users achieve accurate and consistent results. The instrument also supports seamless documentation, allowing measurement reports to be prepared and shared directly on-site, improving efficiency and traceability.

The testo 440 climate measuring instrument combines versatility with user-friendly operation and wireless probe technology. It enables convenient measurement of air velocity, temperature, humidity, CO2, turbulence, and other environmental parameters. With pre-configured measurement functions and flexible probe options, testo 440 supports accurate assessments across various controlled environments.

Together, testo 400 and testo 440 deliver precision, flexibility, and digital convenience, helping pharmaceutical professionals ensure reliable environmental monitoring and maintain the highest standards of quality and compliance.





Supporting Pharmaceutical Excellence Through Smarter Measurement Technology

Maintaining controlled environmental conditions is fundamental to pharmaceutical manufacturing. Accurate HVAC measurements support cleanroom performance, energy efficiency, employee comfort, and compliance with industry standards.

With the testo 400 and testo 440 measurement solutions, Testo provides pharmaceutical professionals with reliable tools for ventilation assessment, indoor air quality monitoring, HVAC commissioning, and qualification processes.

By combining intelligent technology, extensive probe compatibility, guided measurement workflows, and digital documentation capabilities, Testo continues to help industries achieve greater measurement confidence and operational efficiency in critical environments.

Service & Calibration made easy

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

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

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

Prime Clean Reset delivers air leakage control for clean room environments

The high-speed door system combines rapid operation with low air permeability to support controlled manufacturing processes

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

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

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

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

Given the critical role these doors play in maintaining the purity and safety of highly specialised environments, selecting the appropriate door system is a decision of strategic importance.

Prime Clean Reset, our high-speed door is designed specifically for clean rooms. This innovative solution is engineered to meet the stringent requirements of controlled environments, ensuring exceptional performance and reliability.

Designed with precision to meet the stringent requirements of controlled environments, Prime Clean Reset is the epitome of performance and reliability, ensuring that your clean room operations consistently meet the highest standards of regulatory compliance and product integrity.

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

Engineered with cutting-edge European technology and innovative design principles, Prime Clean Reset offers rapid cycle times for both opening and closing, making it the optimal solution for medium to large entrances in clean room applications.

The door's construction is specifically tailored to minimise air leakage and particulate infiltration, ensuring that it supports the rigorous cleanliness standards necessary for applications such as pharmaceutical manufacturing, semiconductor fabrication, food processing, and other highly specialised sectors.

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

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

● **Low air permeability:** Designed to maintain low air permeability in pressurised rooms with both positive and negative air pressure.

● **Compact design:** The doors are designed to fit inside the columns, with a self-supporting construction that minimises air leakage.

● **Customisable transparency:** They can be equipped with transparent PVC horizontal sections or vision windows for visibility.

● **Specialised side guides:** The special side guides ensure a tight integration of the curtain, providing high leak tightness.

● **Efficient operation:** The doors offer high efficiency and low permeability values, compliant with EN 12426 and EN 12427 standards, ensuring < 12 m^3/m^2 h Δ 50 PA.

● **Durable control device enclosure:** The control device enclosure is made of Stainless-Steel SS 316, ensuring durability and resistance to corrosion.

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

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

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Controlled porosity osmotic pump technology enables controlled-release tablets without laser-drilled orifices

The approach uses cellulose acetate polymers to simplify osmotic drug delivery system manufacturing while supporting controlled drug release

Cellulose acetates are cellulose esters that play a pivotal role in advanced drug delivery systems, particularly in osmotic-controlled release formulations. This white paper explores the physicochemical properties of cellulose esters, their application in osmotic pump systems, and the innovative controlled porosity osmotic pump (CPOP) technology that enables zero-order drug release independent of pH.

The evolution of drug delivery systems has significantly improved therapeutic outcomes by enabling controlled and sustained release of active pharmaceutical ingredients (APIs). Among these innovations, osmotic drug delivery systems (ODDS) stand out for their ability to provide zero-order release kinetics, largely independent of gastrointestinal pH, motility, and other physiological variables (Swanson D., et al., 1987; Grundy et al., 1996). A major advancement in this field is CPOP, which was developed as an extension of elementary osmotic pumps. Unlike traditional osmotic systems that require a predrilled orifice, CPOP employs a semi-permeable membrane embedded with leachable, pore-forming agents.

Cellulose, a natural polysaccharide composed of ß-D-glucose subunits, can be chemically modified to form esters or ethers. Cellulose acetate and acetate butyrate chemistry belongs to the cellulose esters class of polymers that form semipermeable films and are used in coating pharmaceutical tablets to obtain controlled release profiles. Cellulose acetate phthalate is an enteric polymer that dissolves above pH 6.0.

Eastman provides three different grades of cellulose esters that possess suitable semipermeable film forming properties, making them ideal for osmotic drug delivery systems:

- **Cellulose acetate CA 320S NF:** relatively high permeability
- **Cellulose acetate CA 398-10 NF:** low permeability
- **Cellulose acetate butyrate (CAB 171-15 NF/EP):** relatively least permeability

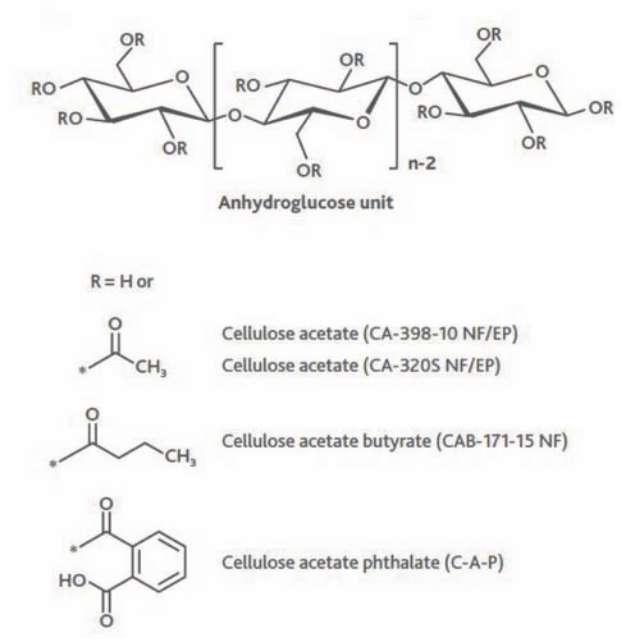

Figure 1. Cellulose esters in drug delivery

Cellulose esters have been used in multiple commercially available osmotic drug delivery systems, including Procardia XL, Adalat, Topamax, Concerta, Invega, etc., due to the precise controlled release possible while formulating with these polymers.

Controlled porosity osmotic pump (CPOP) technology

CPOP systems represent a significant advancement in oral drug delivery. They eliminate the need for mechanical drilling by incorporating water-soluble additives into the semipermeable membrane. Upon contact with gastrointestinal fluids, these additives dissolve to form micropores that facilitate drug release.

Advantages of CPOP vs. conventional osmotic systems with drilled orifice:

- **Eliminates laser-drilled orifice:** Drug release occurs through a semipermeable membrane with controlled porosity, removing the need for mechanical drilling and complexities.
- **Simplifies manufacturing and reduces costs:** No specialised equipment is required, making production more economical.
- **Consistent and controlled drug release:** Maintains zero-order release kinetics unaffected by gastrointestinal pH or motility
- **Improved bioavailability and therapeutic efficacy:** Ensures steady plasma drug concentrations over extended periods
- **Suitable for all biopharmaceutical classification system (BCS) classes of APIs:** Solubilising agents within the core may be added to facilitate drug release from a CPOP system incorporating BCS Class II and IV (water-insoluble) APIs. For highly water-soluble APIs, there is no need to incorporate additional solubilisers.
- **Enhanced patient compliance:** Reduces dosing frequency, making treatment more convenient

Mechanism of action

The CPOP works through a series of well-orchestrated steps to ensure controlled drug release. Upon oral administration, the tablet encounters gastrointestinal fluids, allowing water to permeate through the cellulose ester-based semipermeable membrane. As water enters, it dissolves the embedded pore-forming agents within the membrane, leading to the formation of micropores and transforming the membrane into a porous structure (See Figure 2). This process continues as water further infiltrates the tablet core, dissolving both the osmogen and the drug, thereby generating internal osmotic pressure. The resulting pressure drives the dissolved drug solution out through the newly formed micropores. The rate of drug release is precisely controlled by several factors, including the thickness of the membrane, the concentration of pore-forming agents, the solubility of the drug, and the osmotic pressure gradient. Ultimately, this system achieves zero-order kinetics independent of pH and/or gastrointestinal motility, enhancing therapeutic efficacy and patient compliance.

Metoprolol Succinate Extended Release (ER) case study

The study was conducted using metoprolol succinate as the model API. The me metoprolol succinate ER tablet requires a precisely tuned controlled-release profile because it is prescribed for patients with cardiovascular (CVS) issues such as angina, heart failure, and hypertension. The high-water solubility of metoprolol succinate poses a formidable challenge for controlled-release formulation, making it an ideal choice to demonstrate the power of CPOP coatings.

Metoprolol succinate was blended with diluents by geometric mixing, followed by blending with an osmogene, and finally blended with glidant and lubricant to yield free-flowing powder. The powder was then compressed using 10-mm SC punches to a tablet weight of approximately 330 mg with thickness of approximately 4.4 mm.

The resultant tablets were then coated with cellulose acetate CA 398-10 NF polymer coating solution, the composition of which is detailed in Table 1.

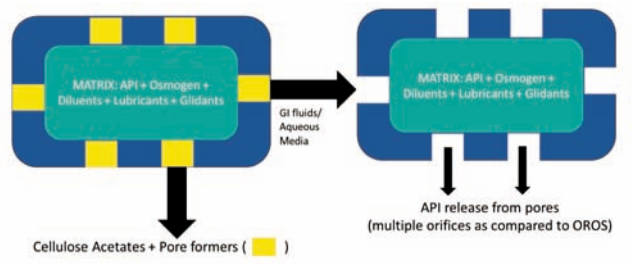

Figure 2. Mechanism of CPOP

Table 1. Coating solution composition

Ingredient	Concentration
Acetone	83.5%
Isopropyl alcohol (IPA)	9.3%
CA 398-10 NF/EP	6.0%
Polyethylene glycol (PEG) 400	20% relative to CA398-10 NF/EP content
Porogen	As detailed in Table 2

Table 2. List of porogens (pore-forming agents) used and their concentrations tested

Porogen	Concentration (% CA 398-10 NF conc)
Polyvinyl pyrrolidine (PVP)	10, 20, 40
Cellulose acetate phthalate (C-A-P)	10, 20, 30, 40
Tween 80	10, 20, 40
Triethyl citrate (TEC)	10, 20, 40
Hydroxypropyl cellulose (HPC)	10, 20, 40

Solutions were prepared by first dissolving CA 398-10 NF/EP in the acetone/IPA mixture. This was followed by the addition of PEG 400 and the appropriate porogen, with additional mixing as needed to dissolve or suspend the porogen (depending on porogen solubility in the solvent system). Tablets were coated with no orifice being drilled and tested for dissolution and adherence to a true zero-order release profile. See Table 3 for the profile that was targeted.

Table 3. Zero-order profile targeted for developed tablets

Parameter	Condition
Media	Phosphate buffer pH 6.8, 500 ml
Apparatus	USP apparatus 2
RPM	50
Test points (hr)	1, 2, 3, 4, 6, 10, 12, 18,20, 24
Measurement wavelength	222 nm
Target profile	
6 hr	25%
12 hr	50%
18 hr	75%
24 hr	100%

The dissolution profiles obtained for different poragens and at different percentage inclusion are illustrated in the Figure 3 graphs, along with a purple line in each graph representing an ideal zero-order release desired with cellulose acetate coatings and useful for APIs like metoprolol for maintaining constant plasma levels of the API.

As seen in Figure 3, only PVP and C-A-P polymers helped to show good correlation to ideal zero-order release desired to ensure more than 85 per cent drug release at last time point.

Tablets with a standard 6 per cent coat of CA 398-10NF and 1.2 per cent plasticizer without poragens did not demonstrate a strong sustained release profile. Including poragens increased the release rate for PVP and C-A-P polymers significantly, thereby achieving desired zero-order dissolution profile. Some of these profiles were also compliant to metoprolol ER tablet dissolution profile as desired to meet USP compliance (1 hour, not more than 20 per cent release; 4 hours, 20 per cent –40 per cent release; 8 hours, 40–60 per cent release; and 20 hours, not less than 80 per cent release).

For other poragens, namely TEC and HPC, release profile did not improve significantly compared to one without poragens. However, for polysorbate 80, there was a little, modest rise in release profile as the percentage of poragens increased from 10 per cent to 40 per cent.

See Figure 4 for cross-sectional images of 10 per cent PVP in CA 398-10 NF-based coated tablets before and after dissolution. It is visible that pores have opened to facilitate complete drug release in a sustained manner over 24 hours.

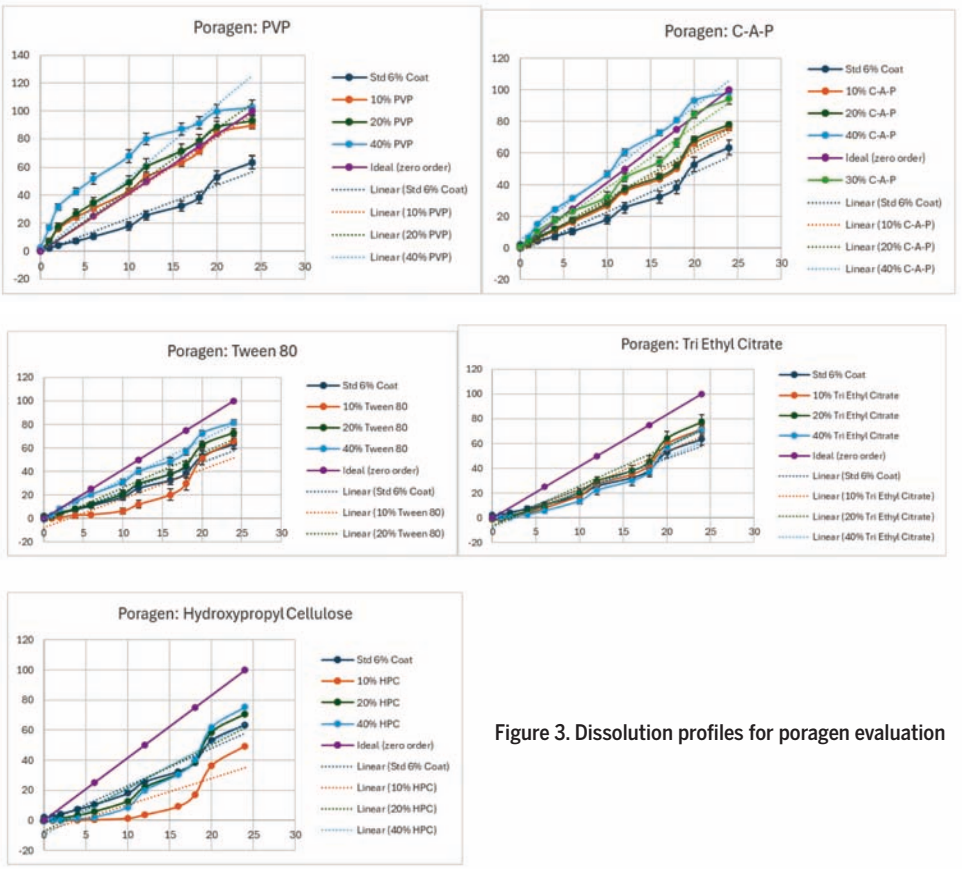

Figure 3. Dissolution profiles for poragen evaluation

Conclusions and recommendations

With the exception of triethyl citrate, all selected poragens exhibited increasing release rate with increasing poragen concentration. This suggests incorporation of a water-soluble moiety in a CA 398-10 coating solution can be used to modulate drug release driven by osmotic pressure in lieu of drilling a hole to facilitate drug release. The 10 per cent PVP concentration provided the best metoprolol release profile without exceeding the target release rate, while 30 per cent C-A-P is a strong secondary option. Both the 20 per cent PVP and 40 per cent C-A-P are close to but modestly exceed the target release rate. These formulations could be viable, depending on the therapeutic index of the selected API. The coating process was evaluated further, and it was observed that reproducible release rates can be achieved, suggesting the process can be validated.

Visit our website at https://www.signetexcipients.com/ to discover the entire range of excipients and order a sample.

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Kajal Sharma, Divya Prabhudesai, Dr. Heeshma Shah: Signet Excipients (An IMCD company) Dr Ankitkumar Jain, Dr Walter Thompson and Dr Matt Stephens: Eastman Chemical Company

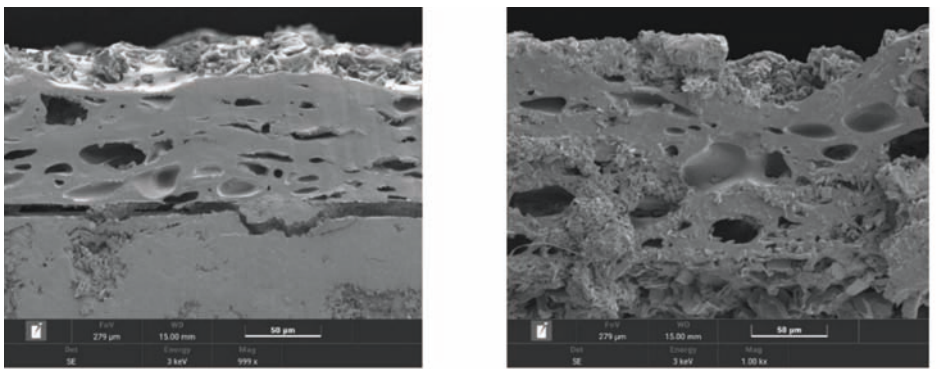

Figure 4. SEM images of tablet coating before(A) and after (B) dissolution for coating having 10 per cent PVP as poragens

The Future of Single-Use Bags: Engineering Reliability for Large-Scale Bioprocessing

Single-use bioprocessing has evolved from a tactical choice for speed and flexibility into a strategic pillar of modern biologics manufacturing. Yet one anxiety endures across process engineers, QA leaders, and supply chain executives alike: bag failures. Whether they occur at receiving, during gamma-aged storage, in a cold-chain handover, or mid-campaign at 2 a.m., the practical and financial consequences can be severe—lost batches, deviation cascades, contamination risk, and reputational damage. As titers rise, scales increase, and modality diversity explodes (mAbs, vaccines, CGT, RNA, and next-gen recombinant proteins), the reliability expectations placed on single-use bags are reaching parity with stainless systems—without compromising agility.

This article examines how the industry can engineer reliability into the next generation of single-use bags, focusing on seven critical levers: film selection, failure modes, seal integrity, mechanical stress, transportation studies, gamma aging, and bag qualification strategies. It closes with the strategic implications for both manufacturers and end users, and points to a set of core references for deeper study.

Why bag failures remain a major concern

Economic impact: A single drug-substance (DS) bag failure at 1,000 to 2,000 L—especially for high-value biologics—can translate to seven-figure losses and weeks of schedule slippage. Beyond direct material costs, the deviation investigation, CAPA, potential requalification, and regulatory exposure magnify the impact.

Complexity and variability: Bags are composite systems - polymer films, tie layers, EVOH or PVDC barriers, UV stabilizers, antioxidants, gamma stabilizers, fluid-contacting layers, ports, gaskets, and heat seals, assembled with process-specific hardware. Any weak link can become the initiating site for failure.

Scale and cumulative risk: Large DS fills (500 to 5,000 L) increase hydrostatic load, weld length, and handling complexity. The probability of an excursion somewhere across storage, shipping, staging, and processing grows with the number of touchpoints.

Regulatory and quality expectations: Agencies expect robust supplier oversight, material traceability, extractable/leachable control, contamination risk management, and change control. Bag integrity failures can trigger broader questions about supply chain robustness and patient safety.

Operating envelope expansion: Bags now see more extremes, i.e., -80 to -196 oC cold chains (frozen bulk, cryogenic hold), aggressive CIP-like detergents for pre-flush, long-term gamma-aged storage, elevated hold times, intensified mixing, and shipping under vacuum or pressure differentials.

Reliability, then, is not a single attribute—it is the emergent property of disciplined material science, manufacturing process control, mechanical design, logistics engineering, and lifecycle qualification.

Film selection: the foundation of reliability

Film architecture is the single most consequential determinant of bag performance. A modern film is a multilayer stack balancing five priorities: chemical compatibility, barrier performance, mechanical toughness, thermal behaviour, and radiation resistance.

The following are the important considerations while selecting single use.

Contact layer chemistry: Common choices for SU material is ULDPE/LLDPE for biocompatibility and weldability, sometimes metallocene-catalyzed grades for toughness. For solvents or surfactants (e.g., PS-80), the contact layer must resist swelling, environmental stress cracking, and additive extraction. Medical master batches and gamma stabilizers must be compatible; antioxidants (e.g., hindered phenols) mitigate oxidative embrittlement but can increase extractable if not controlled.

Barrier layer strategy: EVOH provides excellent oxygen barrier but is moisture-sensitive; humidity cycles during shipping can impact barrier properties and stiffness. PVDC has strong barrier properties but regulatory and sustainability headwinds; careful change control is essential if migrating away. Some "barrier-less" architectures lean on thicker polyolefins plus process controls; trade-offs include O2 ingress and CO2 retention in cell culture.

Mechanical reinforcement: Tie layers and outer layers define puncture and tear propagation resistance. Toughness must be maintained down to lowest-use temperatures (e.g., -80 C), where ductile-to-brittle transitions can occur. Notch sensitivity is crucial: slight cuts from hose barbs or handling fixtures can propagate under cyclic loading.

Thermal behaviour: Films must tolerate gamma-induced heat during sterilization and temperature excursions in transit. Glass transition and crystallinity profiles dictate low-temperature brittleness. For cryogenic applications, specialty elastomer-modified polyolefins or EVA blends can improve impact resistance.

Radiation stability: Gamma (25–50 kGy typical) drives chain scission and crosslinking. Formulation must target minimized embrittlement and controlled yellowing without raising leachable. Alternative sterilization (X-ray, e-beam) is emerging; however, cross-vendor comparability requires new validation as dose distribution and radical chemistry differ.

Supply continuity and change control: Dual-source resin strategies and pre-qualified alternates protect against upstream disruptions. Detailed resin lot traceability, certificate harmonization, and lock-step change notifications are essential to prevent "silent" film shifts.

For end users, the practical approach is a film selection rubric aligning the film to the application's chemical, thermal, mechanical, and lifespan stressors; matched with supplier transparency on resin formulation, additive packages, sterilization dose mapping, and historical change logs.

Failure modes: know them to prevent them

Understanding failure mechanisms enables targeted design and qualification. High-frequency modes include:

1. Incomplete fusion, cold seals, over-welded brittle zones, particulate occlusion in the weld, and misaligned multilayer stacks cause seal failure. These may pass low-pressure leak tests yet fail under thermal cycling or dynamic agitation.
2. Rigid port inserts create stiffness discontinuities, stress concentrates at the weld toe under bending, torsion, and impact during handling or mixing, hence special attention is required for port and weld interface.
3. Film stress cracking and brittle fracture is well known in SU. Low-temperature handling, gamma-aged embrittlement, or solvent exposure can initiate micro-cracks that accelerate under pressure cycles.
4. Abrasion from tubing clamps, transport vibration against pallet edges, trapped sharp particulates, or ice crystals in frozen storage can cause pinhole leaks.
5. Adhesion failures in multilayer structures due to poor tie-layer compatibility, humidity cycles (EVOH), or excessive thermal gradients during sealing cause delamination.
6. Silicone or TPE gasket set under compression creep; reconnect cycles erode sealing force. Mismatched connectors exacerbate. All these cause connector and gasket leakage.
7. Particulate ingress/foreign matter also a concern. Not a "leak" per se, but functionally a batch risk; sourced from film slitting, cutting, or outgassing residues adhering electrostatically.
8. Bioburden breach or sterile barrier compromise the bag integrity. Micro-channel defects that pass gross leak testing but fail sterile hold over time, especially under thermal/humidity cycling.

Failure is often multifactorial. A marginal seal plus gamma aging plus an unvalidated shipment profile is a disaster in combination. Robustness means stacking safety margins across multiple stressors simultaneously.

Seal integrity: where quality meets physics

Seals are typically the weakest structural feature because they alter polymer morphology, introduce geometric stress risers, and depend on process capability. It is important to engineering priorities, specifically process windows and controls. Seal need full characterization w.r.t. time-temperature-pressure windows using designed experiments. It is also essential to include film thickness tolerance extremes and study impact of humidity conditions.

It is essential to control and monitor real-time energy delivery in impulse sealing. Platen temperature uniformity and jaw pressure mapping is also essential. SPC on surrogate metrics (e.g., peel strength) guards against drift need precision control.

Seal geometry is critical. Wider seals distribute stress and stepped or multi-lane seals can localize and arrest tear propagation. It is known that smooth radii at corners reduce stress concentration. It is critical to avoid "knife edges" near port transitions.

Inline vision to detect inclusions/voids; HEPA-filtered sealing stations; anti-static controls to prevent particulate attraction require control and monitoring to assure cleanliness and occlusions.

To assure peel and burst, it is essential to use standardized peel tests (180°/T-peel) with acceptance criteria correlated to end-use loads. Burst tests

should mimic realistic constraints (clamp points, temperature), and validation need to happen at initial and end-of-shelf-life after worst-case gamma and environmental aging. Moreover, port-to-film material compatibility (e.g., PP port with PE-based film) must ensure co-weldability without weak boundary layers.

For end users, supplier seal qualification data should be part of technical files, including histograms of seal strength, not just point estimates. On-receipt AQL sampling with statistically defensible plans (e.g., c=0, tightened inspection when supplier CPk drifts) adds assurance.

Mechanical stress: design for the real, messy world

Bags do not live in ideal test rigs. They are dragged across floors, overfilled, under-supported, and palletized next to heavier components.

Operational controls matter as much as design: SOPs for max stack height, corner protection, minimum support radius, and clamp placement reduce real-world excursions that formal testing may not fully capture.

Transportation studies: closing the gap between lab and logistics

Transit is a crucible for bag reliability. Temperature excursions, vibration spectra, shocks, altitude pressure changes, and handling practices vary widely across lanes and forwarders. When logistics are designed and qualified as deliberately as process steps, bag failure in transit becomes rare rather than routine for biopharma manufacturers.

Gamma aging: the slow, invisible stressor

Irradiation is essential for sterility assurance, yet it initiates long-tail chemical changes in polymers that continue during storage. Gamma aging is manageable when treated as a design variable, not an afterthought.

During gamma exposure, chain scission reduces molecular weight and elongation-at-break, crosslinking become embrittle and radicals drive oxidative reactions if oxygen is present post-sterilization, additives (antioxidants, HALS, UV absorbers) quench radicals but can be consumed or transform into extractable species over time.

Industrial gamma cells produce dose gradients across pallets. Hence it is essential to validate performance at minimum and maximum mapped doses—both can be worst-case depending on mechanism. X-ray and e-beam can also present different dose-rate effects, hence do not assume interchangeability without data.

It is well know that elevated temperature and oxygen accelerate post-irradiation oxidation. Barrier packaging (e.g., aluminium over-pouch with oxygen scavenger) and cool, dark storage can extend mechanical life. It is essential to establish aging curves (e.g., Arrhenius-based accelerated aging) correlating to end-of-life properties: tensile, puncture, seal strength, and leak rate.

Gamma can increase low-MW species. Comprehensive extractable profiles at T0 and end-of-shelf-life, under relevant solvents (WFI, acids/bases, ethanol, PS-80), are table stakes. For high-risk modalities (cell/gene therapy), adopt science-based safety evaluations and clinically relevant leachable studies.

Manufacturers need to define sterilization dose range in

TABLE 1: MECHANICAL RELIABILITY CHECKS

Criteria	Focus Area
Load path engineering	● For large DS bags, enforce uniform support. Sling designs, cradle carts, and contour-matched totes reduce hydrostatic peak stresses at corners and ports. ● Consider "dead leg" elimination in port locations; long, unsupported port necks become levers during transport.
Agitation and mixing	● Modern SU mixers can impart significant shear and slosh. Validate bag-film fatigue life at target RPM and fluid density/viscosity, with worst-case fill heights.
Thermal cycling	● Repeated transitions from cold room to ambient, or frozen to thawed, create differential contraction and expansion at seals and port welds. ● Design and qualify for cycles, not static endpoints.
Handling ergonomics	● Ergonomic handles, reinforced lift points, and visual load guides reduce misuse. ● Color-coded "do not bend" zones near ports help operators.
Stiffness transitions	● Introduce compliant layers or fillets at hard-soft interfaces (port to film) to diffuse stress. ● Consider over-moulding or flexible collars.
FEA and digital twins	● Finite element analyses predicting strain fields under fill, drop, and vibration should inform geometry and film thickness distribution. ● Validate with strain gauge or DIC (digital image correlation) on prototypes

TABLE 2: WHERE TO PAY ATTENTION FOR SINGLE-USE SHIPPING LOGISTICS

Focus	Measure
Following Standards as baselines	● ISTA 3A/3E and ASTM D4169 provide structured vibration, drop, and compression profiles. Use these as minimums, then layer route-specific data. ● For bulk DS, include ISTA 7D/7E thermal profiles to capture realistic seasonal extremes
Use Data-logger informed profiles	● Equip pilot shipments with tri-axial accelerometers, temperature/humidity loggers, and pressure sensors. ● Build route "fingerprints" by lane, season, and packaging configuration.
Map altitude and pressure	● Air cargo can experience reduced ambient pressure; sealed bags can balloon. ● Validate relief strategies (e.g., vented secondary containment) or headspace controls.
Dwell and handover risks	● Most damage occurs in terminals and at handovers. Define packaging that tolerates repeated short drops and forklift impacts at pallet edges. ● Corner posts, edge guards, and rigid over-packs cut pinhole risk from adjacent freight.
Frozen and cryogenic logistics	● Ice crystal formation can act like glass shards against the film under vibration. Pre-freeze protocols (controlled rate), consistent bag orientation, and cushioning layers mitigate. ● For -80 C shipments, ensure the film's ductility at temperature; for LN2 vapour storage (-150 to -196 C), only dedicated cryo-rated films and port materials are appropriate.
Qualification and requalification	● Perform OQ/PQ with worst-case mass, fill heights, and stacking. Requalify upon lane changes, season flips, or packaging redesigns. ● Document packaging bill of materials, torque specs for closures, and tamper-evident seals to enforce configuration control.

the material specification, include acceptance criteria for mechanical properties at both dose extremes, initial and aged, and implement change control triggers for sterilization modality or supplier site moves; require requalification of both mechanicals and E/L.

Bag qualification strategies: from component to system

A robust qualification framework integrates material science with application-specific stressors. This lifecycle approach shifts reliability from reactive firefighting to proactive assurance.

Strategic value: why this matters to manufacturers and end users

For manufacturers (SU suppliers), publishing detailed film architectures, sterilization dose maps, and end-of-life mechanical curves builds trust and shortens customer qualification cycles, and offers differentiation through science and transparency. Investing in SPC on seal processes, advanced NDT leak screening, and route-specific packaging engineering reduces warranty claims and brand risk, which offers advantages related to cost of quality vs. cost of failure. Dual-resin strategies, second-source sterilization, and mirrored production cells in different regions de-risk geopolitical and logistics shocks, offering supply chain resilience. The future is about co-innovation with end users, where joint FEA, lane fingerprinting, and shared E/L toxicology models become sticky partnerships that outlast price cycles.

For end users (biopharma and CDMOs), reliable bags de-risk campaign schedules, increase OEE, and support intensified or continuous operations without buffer overstocking "just in case" offers significant advantage in terms of operational continuity. Traceable, well-qualified single-use systems strengthen filings, reduce pre-approval inspection findings, and simplify post-approval changes offers regulatory confidence. Avoiding one DS batch loss can pay for multi-year reliability programs. Fewer excursions mean leaner deviation management and faster tech transfers, ultimately translating to financial resilience. Standardized, qualified bag families enable global site harmonization, multi-modality flexibility, and faster on boarding of new processes offering platform scalability.

Reliability is not only a technical goal—it is a strategic enabler of speed, quality, and cost competitiveness.

TABLE 3: SU BAG QUALIFICATION STRATEGY

Category	Implementation Plan
Risk-based segmentation	● Classify bag uses by criticality: media and buffer prep (moderate), intermediate holds (higher), DS fill/ship (highest). Tailor qualification depth accordingly. ● Consider contact time, temperature, shear, and value-at-risk to rank scenarios.
Upfront material and design qualification (MQ/DQ):	● Verify material specs, film stack-up, sterilization parameters, and change control. Review extractable packages for process compatibility. ● Conduct design verification: seal maps, port weld tensile, puncture resistance, and burst testing across temperature and aged conditions.
Installation and operational qualification (IQ/OQ)	● IQ: Ensure trays, totes, and hardware interfaces are consistent with supplier recommendations. Calibrate sealing/welding equipment if on-site. ● OQ: Simulate process loads—pressure fill, mixing agitation, thermal cycles, and hold times—at worst-case bounds.
Performance qualification (PQ)	● Full dress rehearsals using surrogate fluids at scale, including representative shipping simulations if off-site transfer is involved. ● Incorporate microbial ingress challenge where sterile barrier performance is critical.
Integrity testing strategy	● Select non-destructive tests (vacuum decay, pressure hold, helium tracer on development lots) with detection limits appropriate to risk level. ● Define go/no-go criteria for pre-use leak tests and post-use inspections. Include visual inspection training and defect libraries.
Statistical control and surveillance	● Set acceptance sampling plans aligned with process capability (e.g., ANSI/ASQ Z1.4, c=0). Escalate to tightened inspection after deviations. ● Track defect taxonomies and apply Pareto/principal cause analysis to drive CAPAs with suppliers.
Change management	● Enforce full-tech file updates for any resin, additive, sterilization, or geometry change. Pre-approve equivalency protocols with QA. ● For high-criticality bags, require parallel lots during transition and side-by-side PQs.

Putting it together: a practical roadmap

It is important to define the operating envelope, to map fluids, temperatures, contact times, shear/mixing, fill heights, and logistics routes. This need to include future-state scenarios (e.g., scale-up, colder chains).

Always select film and design for context. Choose films aligned to chemistry and temperature; confirm gamma aging curves and E/L acceptability. Most importantly, engineer ports, seals, and geometries with FEA-informed stress diffusion that leads to a seal and port integrity control plan. Consider DOE for the sealing process; lock process windows with real-time controls; and validate peel/burst at T0 and end-of-life; include particulate controls.

Consider engineering logistics. It is important to qualify packaging via ISTA/ASTM plus lane-specific profiles, add corner protection, rigid containment, and shock/vibration damping as needed, validating altitude effects. Qualify it as a system - MQ/DQ the design and materials, IQ/OQ the hardware interfaces and process loads, and PQ at scale with worst-case conditions, including integrity testing.

Also monitor and improve. Implement incoming inspection AQL plans, defect taxonomy tracking, and CAPA loops. Requalify upon supplier or lane changes. Share data with your partner to prevent recurrence. It is also important to institutionalize change control where you need to pre-negotiate notice periods, comparability protocols, and parallel-lot strategies with suppliers. Maintain a living risk register tied to bag SKUs and uses.

Last but not least, the culture and training. Engineer-proof designs help, but trained operators prevent the majority of handling-induced defects. Consider using visual aids, do-not-bend zones, and hands-on practice with damaged exemplars.

Thoughtful advances on the horizon

Next-gen radiation sterilization is under consideration where in X-ray and advanced e-beam promise tighter dose control and less collateral polymer damage. It may result in new qualification paradigms and potential shelf-life gains.

Smarter films are under development where in formulations being tailored for cryogenic ductility without raising extractable; or oxygen-scavenging over-pouches; or embedded strain or breach-indicating inks.

Inline non-destructive integrity tests is are in near term horizon. High-sensitivity vacuum decay, acoustic resonance, or laser interferometry are being evaluated by the SU suppliers that could move QC from sampling to 100% screening for critical SKUs.

Digital twins are being considered for logistics. Predictive models fusing bag mechanics with real lane telemetry to recommend packaging configurations and even carrier selections seasonally are being developed.

Standardized data are being packed. Cross-supplier, regulator-endorsed templates for E/L, gamma aging, mechanicals, and seal capability that accelerate cross-qualification and reduce redundant testing packages are under development.

These innovations will raise the reliability floor while en-

abling even more ambitious process intensification and decentralized manufacturing models.

Conclusion

Single-use bags will remain central to bioprocessing's agility and scalability, but the expectations have changed. Reliability must be engineered deliberately across film science, mechanical design, sealing processes, logistics, radiation effects, and comprehensive qualification. When suppliers and end users treat bag integrity as a shared, data-driven discipline—rather than a procurement line item—the risk of catastrophic failures diminishes, regulatory confidence grows, and manufacturing strategies become more resilient.

The future of single-use bags is not just tougher plastics or thicker films; it is a system-level commitment to quality by design, validated in the real world, and continuously improved through transparent partnerships. That future is within reach—and it is a strategic advantage waiting to be seized.

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Arihant Innochem inaugurates state-of-the-art research & innovation centre in Navi Mumbai

Arihant Innochem Pvt. Ltd. (AIPL), India's leading distributor of excipients and speciality ingredients across the pharma, biopharma, nutraceuticals, personal care, and home care segments, proudly announced the inauguration of its cutting-edge Arihant Innochem Research and Innovation Centre in Navi Mumbai.

The grand ceremony was graced by Arihant's esteemed principal partners, including The Lubrizol Corporation, Shin-Etsu Chemical Co. Ltd., Asahi Kasei Corporation, MEGGLE Excipients, Chemische Fabrik Budenheim KG, Jungbunzlauer Suisse AG, Pharmatrans Sanaq AG, SEQENS SAS, Sanyo Chemical Industries, Ltd., YungZip Chemical IND. CO., LTD, Freund Corporation, Pfanstiehl, Inc. and CBC Co., Ltd. Distinguished guests travelled from Japan, Switzerland, France and Taiwan to mark this landmark occasion.

Jinesh Shah, Founder and Managing Director of Arihant Innochem, formally inaugurated the centre, calling it "a milestone achievement in Arihant's scientific journey". He emphasised the company's founding principles of growth, innovation, and meaningful partnerships, adding: "Our values, Trust, Quality, and Commitment, have always guided Arihant Innochem. With excipients taking the centre stage, this is the right time to establish Arihant's own lab where newer ideas can be explored and concepts transformed into solutions."

The event began with an auspicious invocation and lighting of the traditional lamp, followed by a warm welcome from Radhika Thakkar, Head – Business Development. Chitra Shah, Head – Technical, shared her experiences in setting up the lab and highlighted the growing importance of innovation in the excipient space. Dr. Sameer Padhye, Manager – Technical Services, presented the centre's capabilities and roadmap, underscoring its role as a key asset for future advancements.

Guests were then given a guided tour of the facility, which showcased the centre's advanced infrastructure and collaborative environment designed to foster scientific breakthroughs.

The inauguration of AIPL's Research and Innovation Centre marks the beginning of a new horizon for Arihant Innochem, reinforcing its commitment to driving innovation and strengthening partnerships with principals and customers alike.

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EMDEX®-A Multifunctional Binder and Filler

EMDEX® is designed for a variety of tablets and lactose-free applications

EMDEX® (Dextrates, NF) is a directly compressible, water-soluble tablet binder and filler. Its unique composition of 95 per cent glucose monohydrate and different oligosaccharides derived from starch is monographed under Dextrates in the NF, with use levels ranging from one per cent to 99 per cent. EMDEX® is designed for a variety of tablets & lactose free applications[4].

◆ Superior flow, compaction, and tablet robustness in direct compression applications
◆ Does not require a glidant, due to superior flow properties
◆ Exhibits excellent mixing properties
◆ Easy to handle – does not stick to punches
◆ Non-dusting
◆ Results in smooth and shiny tablets
◆ Tablets demonstrate very low friability
◆ Metabolis es fully without osmotic laxative effect
◆ Provides patients with a pleasant, sweet taste and a cool mouth feel
◆ Does not cause dry mouth feel when compared to sugar alcohols
◆ Particle porosity improves EMDEX® solubility and flavour absorption capacity- a key advantage for tablet taste enhancement
◆ Compendial (NF), eliminating regulatory hurdles

◆ EMDEX® has excellent flowability and non-dustiness makes it appropriate to be used as flow improvement aid in sachets and stickpacks.
◆ EMDEX® exhibits narrow particle size distribution with an average particle size of 200 µm. Along with its spherical particle shape and high bulk density, this ensures supreme flow properties.
◆ EMDEX® is a porous material that absorbs fluids, allowing chewable formulation development and manufacture using liquid APIs.
◆ The porous structure of the sparay-dried EMDEX® particles enables excellent content uniformity even for low dose, micronised APIs.
◆ Oily APIs are readily absorbed by the sponge-like structure of EMDEX®.
◆ Highly suited for veterinary products, due to its pleasant taste.

Bulk Density	0.70 g/m3
Tapped Density	0.75 g/m3
Hausner Ratio	1.07
Angle of Repose	300
Loss on Drying	7.8-9.2 (glucose monohydrate, the assay includes crystal water)
Dextrose Equivalent	93 – 99 %
Heat of Solution	-105 J/g
Median Particle size	190 – 220 µm

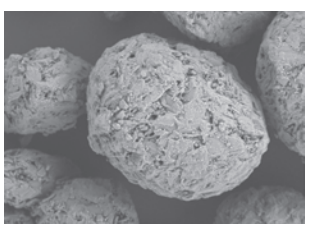
Physical Properties[4]:

◆ Made from corn starch (GMO-free EMDEX® available)
◆ Natural sweet taste of dextrose
◆ Freely and rapidly water-soluble (1000g/L)
◆ Excellent flowability
◆ Spherical, porous particles
◆ Directly compressible filler-binder
◆ High bulk density
◆ Narrow particle size distribution
◆ Calorie content- 4.0-5.0Kcal/gram

SEM of EMDEX®I

EMDEX® Benefits and Applications[5][6]:

Benefits:



Spherical particle shape and porous structure - EMDEX®

Emdex is designed for variety of tablet types and dosage forms:

◆ Chewable tablets
◆ Orodispersible tablets
◆ Effervescents
◆ Sachets
◆ Multi-layer tablets
◆ As a replacement for lactose

Applications:

◆ EMDEX® is 100 per cent water-soluble, it is also perfect for applications in which a good mouth feel or a clear solution is required.

Comparison of powder characteristics of EMDEX® and spray dried lactose [3]:

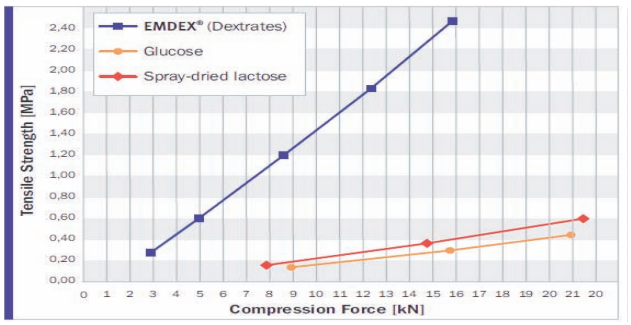
A comparision of EMDEX® and spray dried lactose with regard to their powder characterstics demonstrated the similarility of the two materials. Both are water-soluble, crystallised powders with a porous structure and a spherical particle shape. The particle shape, in combination with the high bulk

Parameter	EMDEX®	Spray-Dried Lactose
Particle Size d50 (µm)	190-220	130-160
Bulk Density (g/L)	600-700	600-700
Tapped Density (g/L)	700-800	700-800
Flodex Index (mm)	4	4
Water Solubility (g/L)	1000	220

Powder Characteristics of EMDEX® and spray dried lactose.

Compactability

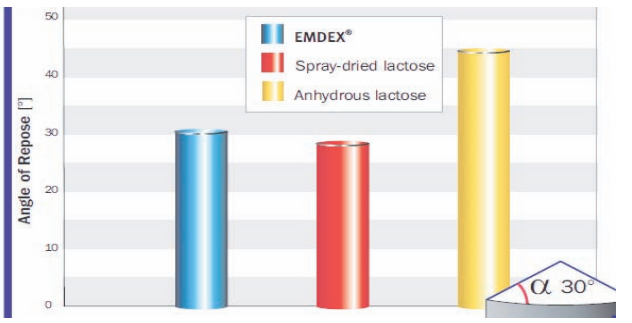
In this study, the effect of different soluble binder on tablet hardness was evaluated.



Observation: The kind of diluent used had a significant influence on the hardness of the tablets. While tablet manufactured with EMDEX® resulted in the highest compactability, those made from glucose and spray-dried lactose exhibited the lowest compactability. Spray drying of EMDEX® as well as the presence of oligosaccharides leads to massive increase in tablet strength.

Flowability

In this study, the flowability of different soluble binders was evaluated.

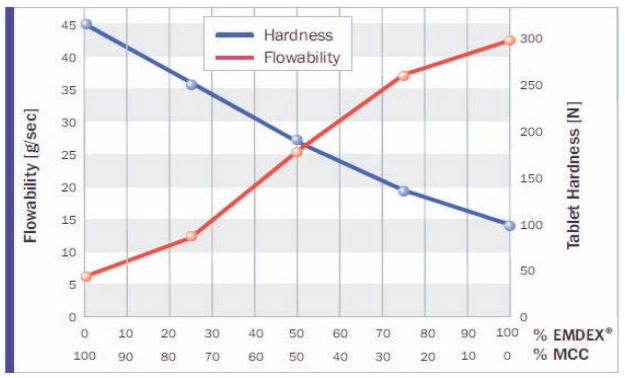


Observation: Due to its high bulk density and spherical particle shape, EMDEX® exhibits excellent flowability. This functional advantage can be utilised in pre-form or for flow enhancement in tableting blends and stickpacks. Angle of repose found to be a 300.

density, leads to excellent powder flow of EMDEX® and spray-dried lactose. Furthermore, both excipients are appropriate for direct compression applications and deform mainly by brittle fracture.

Hardness vs flowability:

In this study, the effect on hardness and flowability was evaluated.



Observation: The flowability of DC-grade micro-crystalline cellulose (VIVAPUR® 102) can be further improved by adding increasing amounts of EMDEX®

EMDEX® is a promising substitute for spray dried lactose as it has similar powder and tableting properties. Spray-dried lactose is widely used as filler and binder in the pharma industry, but many adults are not able to digest lactose. Lactose is absorbed from the gastrointestinal tract once it is hydrolyzed by the enzyme "lactase" into glucose and galactose. Hence, children deficient in "lactase," are unable to absorb lactose (due to congenital defect or lack of the enzyme) and develop flatulence, diarrhoea, gastrointestinal bloating following ingestion of milk due to the build-up of lactic acid, hydrogen and carbon dioxide. Lactose intolerance in infants and children can lead to prolonged episodes of bloating, diarrhoea, dehydration and metabolic acidosis. Therefore, it is indispensable to provide alternatives to lactose-containing drugs in order to make them suitable for lactose-intolerant patients[1][2].

Conclusion:

◆ EMDEX® is a water –soluble filler binder with brittle fracture as the main binding mechansim.

◆ EMDEX® and spray dried lactose show great similarity in terms of particle morphology, bulk density and flowability. EMDEX® was, therefore, ideally suited as a substitute for spray dried lactose in order to make them suitable for lactose-intolerant people.

◆ EMDEX® is well-suited for chewable tablets, effervescent tablets, oro-dispersible tablets, multi-layer tablets and sachet kind of formulation.

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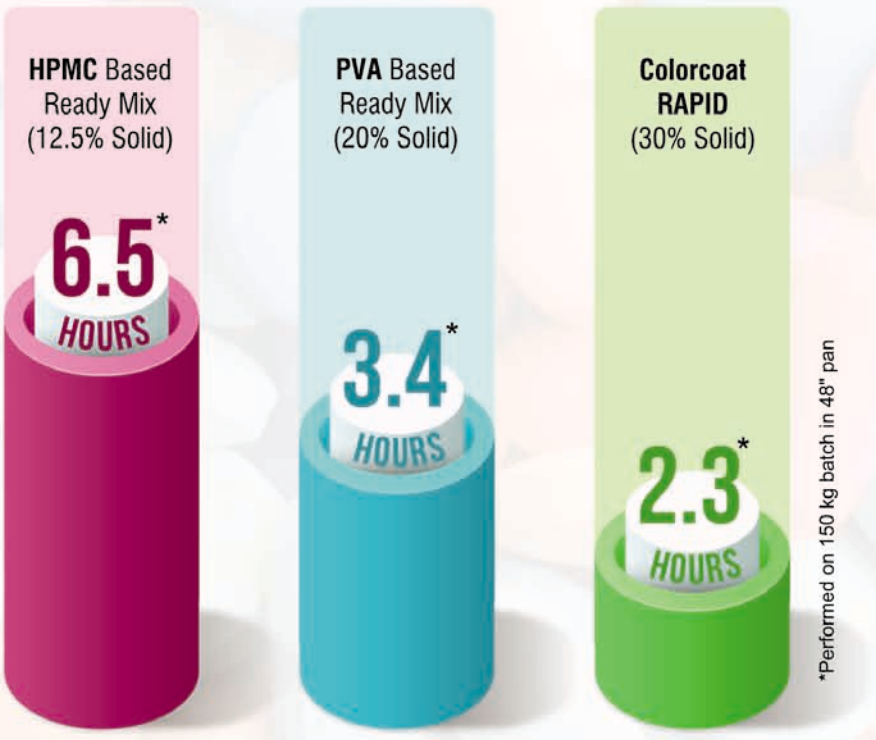

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