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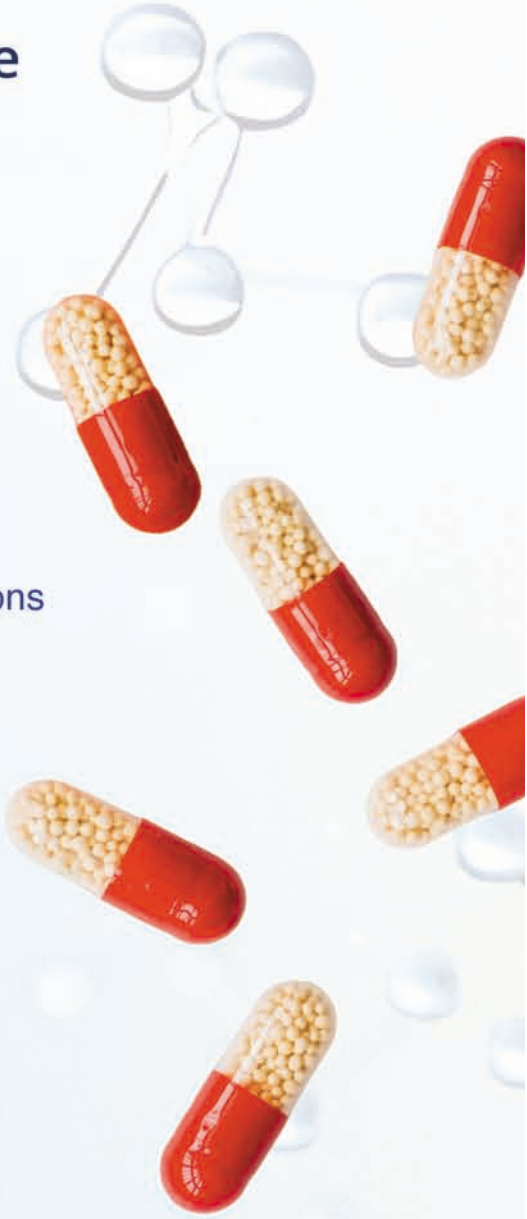

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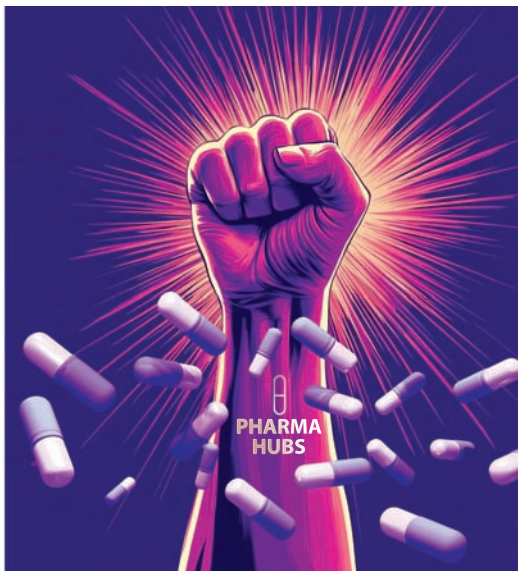

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In the March 2026 issue (page 34, Cover Story: When She Leads), the names and images of Neha Thakore, Director, Avik Pharmaceutical and Committee Member, IDMA and Asawari Sathaye, Director – Communication and Patient Advocacy, OPPI were inadvertently interchanged. As a result, the articles were incorrectly attributed. The error has been corrected in the digital version available on the Express Pharma website.

Express Pharma®

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

Sun Pharma bets on Organon for its next wind

Sun Pharma's $12 billion acquisition of Organon will prove to be a milestone as the largest takeover by an Indian pharma company. Though the deal looks like a near term millstone, Sun Pharma has a history of digesting acquisitions and emerging stronger.

There is no doubt that Sun Pharma has used the M&A route to scale up faster than its peers. Of the nine acquisitions in the past 16 years, some of them proved to be challenging (Taro, Ranbaxy come to mind). But past integration challenges, like the 17-year dogged pursuit of Taro and settling Ranbaxy's dysfunctional manufacturing standards are sure to have honed the team's due diligence process to a razor sharp focus on the end goal.

And this big move just adds to Founder Dilip Shanghvi's legacy as a carefully bold dealmaker. That may seem like a contradiction in terms but consider his statement at the post deal press meet, that he is "debt-averse, not risk-averse". For the right asset, he's comfortable going from net cash to net debt, indicating that the company believes that Organon scores on the risk/reward ratio.

But as the bellwether of India Pharma Inc, the company faces higher than normal market perceptions and expectations. Shanghvi tempered his "debt-averse, not risk-averse" stance with the reassurance that the aim would be to repay the debt as fast as possible, as well as maintain the company's history of keeping shareholders satisfied with regular dividends.

The company plans to fund the all-cash buyout through a combination of available cash resources ($2-2.5 billion of cash on hand) and the balance ($9.25-9.75 billion) as committed financing from banks. An HDFC Securities report sees the growth trend for the combined entity falling from 10-12 per cent to mid-single digits, terming this a "major near-term overhang". The analysts also note that debt restructuring with better rates and strong free cash flow generation from both the companies will help reduce debt over the next few years.

Most analysts are betting that Shanghvi and team will once again mould a stressed asset into a vital part of its ongoing transformation into an innovation-led global partner of choice. Stock markets had reacted warily as buzz about the deal picked up over the past few weeks, cautious about the sizable debt burden that Sun Pharma would take on its books, for an entity that seems to have run its race.

But sentiment seems to have recovered a bit since the deal was announced, as more details on the rationale were revealed. Subject to concurrence from Organon shareholders and the usual regulatory approvals, the deal once it closes in early 2027, would give Sun Pharma a sizable boost in multiple global rankings. The Mumbai-headquartered company would claim a spot among the top 25 companies, a top 3 slot in women's health, and become the seventh largest biosimilars company.

More importantly, even as most of Organon's own brands near loss of exclusivity (LoE), its portfolio, global manufacturing footprint and capabilities in complex modalities will complement and scale up Sun Pharma's existing operations. The combined entity could become a more comprehensive and competitive launch pad for future innovative medicines, from Sun Pharma's own pipeline of specialty medicines as well as future in-licensed opportunities.

After acquisition and consolidation, revenue share from innovative medicines is projected to increase to 27 per cent (from 20 per cent in Sun Pharma's FY25 revenue mix), overtaking generics, which drops from 30 per cent to 15 per cent. Revenue from branded generics is projected to increase from 46 per cent to 51 per cent. Another major win for Sun Pharma is that biosimilars will emerge as a new slice in the combined entity's revenue pie, with Organon's biosimilar brands contributing six per cent of revenues.

Sun Pharma's bold bet is not just one company's aspirations to pivot from volume to value at scale. The deal and its execution will hopefully trigger more peers from India Pharma Inc to make this transition

Footprint wise, the Organon acquisition expands Sun Pharma's reach to 150+ countries (most notably improving its presence in China and South Korea, difficult geographies at the best of times). Post deal, the combined entity will have approximately 2x revenues and EBITDA.

At the post-deal press meet, Kirti Ganorkar, MD, Sun Pharma, stressed how the deal would make Sun Pharma "a partner of choice for acquiring and launching new products." While the immediate priorities will be business continuity, disciplined integration and responsible value creation, he added that Sun Pharma sees "strong potential in leveraging Organon's talent pool." He also spoke of the "scope for synergies including significant revenue upside opportunities to be realised over the coming years."

Jayashree Satagopan, CFO, Sun Pharma also elaborated on the opportunities for cross cultural assimilation, harking back to Sun Pharma's past transformative acquisitions, starting with Taro (2010), Dusa (2012), Ilumya (2014), Ranbaxy (2015), Odomzo and Cequa (2018), Winlevi (2021), Concert Pharmaceuticals (2023), and Checkpoint Therapeutics (2025).

Beyond the balance sheet, such mega mergers usually result in layoffs (or what industry terms 'right sizing'). The investor presentation alludes to tapping potential synergies of over $350 million stemming from synergies through procurement, human resource and supply chain over the next 2-4 years, 'leveraging efficient and lean operations, to unlock cost improvement opportunities.' This is yet another perception challenge that will need to be addressed as the integration proceeds.

As per an analyst note from Equirus Securities, the acquisition will be EPS accretive from year one, but integration will happen from FY28E. Commenting on factors which could delay this process, they state that FTC approval is key. Secondly, a few products are required to be divested, which can impact the overall timelines.

A slide from the investor presentation mentions that the company intends to build a shared culture, blending Sunology and the Organon Way, with patient centricity at the core. The world will be watching to see how this unfolds because it could signal an overdue mindset change. Sun Pharma's bold bet is not just one company's aspirations to pivot from volume to value at scale. The deal and its execution will hopefully trigger more peers from India Pharma Inc to make this transition. That is why the Sun Pharma-Organon deal is such a big deal.

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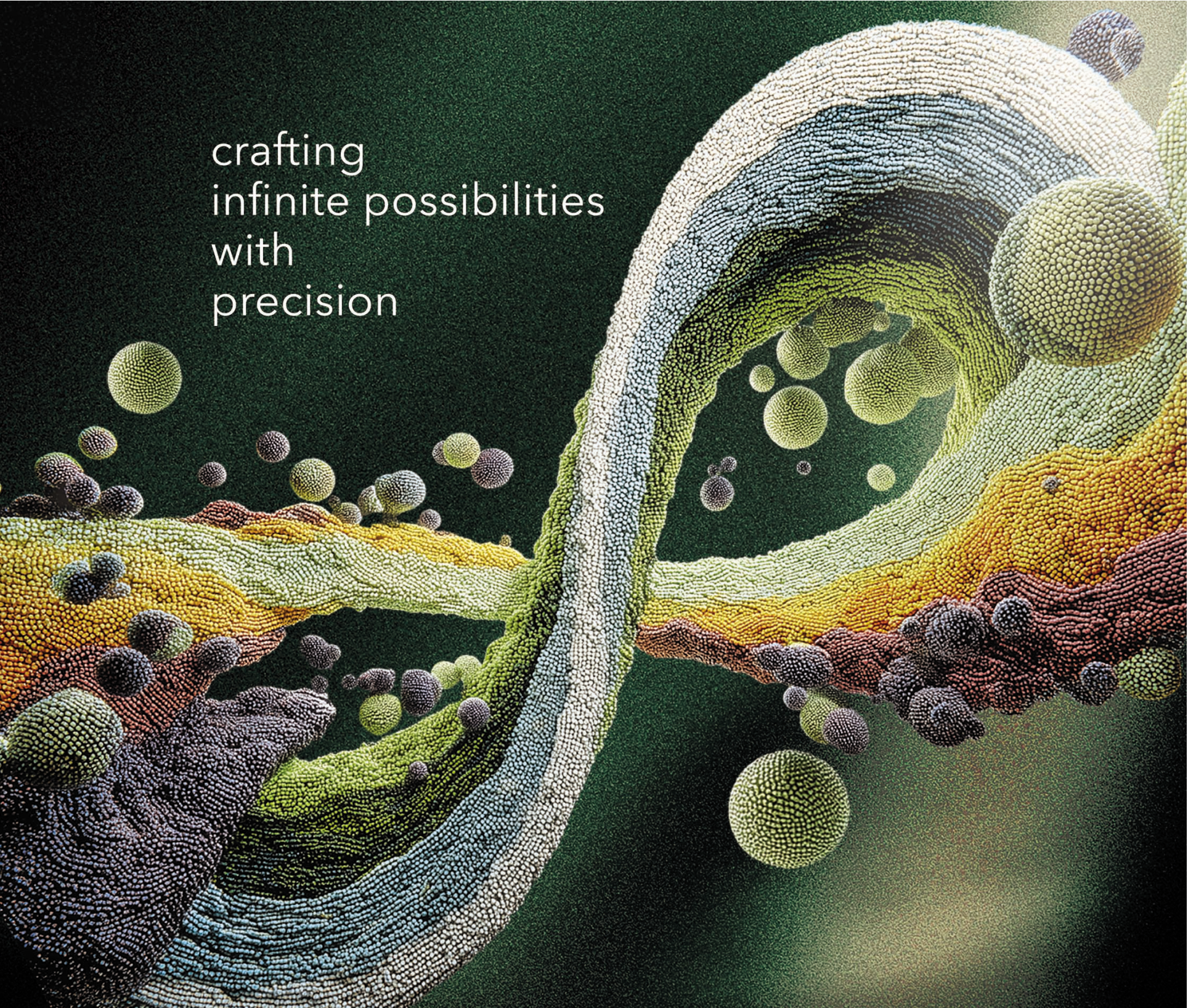

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A differentiated regulatory framework is essential. A uniform pricing regime ignores the heterogeneity within the pharma sector

Dr Amit Kumar, Assistant Professor of Law, Maharashtra National Law University (MNLU) and **Prof. Uma Bhattad,** Professor of Law at Maharashtra National Law University, Mumbai, and Chair Professor of the DPIIT IPR Chair, discuss aligning pharma innovation with public health through better incentives, pricing, and IP policy. They emphasise balancing affordability, access, and innovation to build a more equitable and sustainable healthcare system in India, in an interaction with **Kalyani Sharma**

How can policy frameworks better align commercial interests in the pharma sector with broader public health goals?

Dr Amit Kumar: I believe the starting point is to recognise that pharma companies respond to incentives, not intentions. So instead of expecting them to voluntarily prioritise public health, policy has to reshape the incentive structure itself. One effective way of doing this is through public funding for early-stage research, which already plays a huge role. For instance, a large proportion of foundational biomedical research globally is publicly funded through agencies like the NIH in the US yet the downstream products are often priced as if they were entirely privately developed. That creates a disconnect. Governments can correct this by attaching conditions to public funding, such as affordable pricing, technology transfer, or wider licensing once a drug is commercialised.

At the same time, the current model where profits depend heavily on patent-based exclusivity and high prices is increasingly being questioned. This model works reasonably well for chronic or high-income market diseases, but it has clearly failed in areas like antibiotic development, where the World Health Organisation has repeatedly warned of a drying pipeline.

> Government intervention in drug pricing and access is not merely a policy choice in countries like India, it is a necessity rooted in the realities of income inequality, out-of-pocket health expenditure, and uneven access to healthcare infrastructure
>
> **Dr Amit Kumar**

> Greater transparency in R&D costs and patent filings, helps stakeholders in analysing data and taking informed decisions related to drug pricing and access to medicines
>
> **Prof. Uma Bhattad**

The problem is structural: antibiotics are meant to be used sparingly, which makes them commercially unattractive under a volume-based profit model. That's why there is growing support for "delinkage" models, where companies are rewarded through lump-sum payments or prizes based on the social value of the drug, rather than sales volume.

We've already seen some movement in this direction. For example, the UK's "subscription model" for antibiotics pays companies a fixed annual fee based on the public health value of the drug, regardless of how much is sold. Similarly, advance market commitments used successfully for vaccines guarantee a market for products targeting neglected diseases. These models show that it's possible to de-risk innovation while steering it toward public priorities.

Data also reinforces why this shift is necessary. According to global health estimates, diseases that disproportionately affect low and middle income countries receive a tiny fraction of total pharma R&D investment, despite accounting for a significant share of the global disease burden. This mismatch is not a market failure in the traditional sense it's an incentive failure.

So, the larger point is this if you design the system well, you don't have to choose between profitability and public health. You can align them structurally by ensuring that firms are rewarded for health impact, not just market size or purchasing power. That's ultimately a more sustainable and equitable model of pharma innovation.

What role should government intervention play in areas such as drug pricing and access, without discouraging innovation?

Dr Amit Kumar: Government intervention in drug pricing and access is not merely a policy choice in countries like India, it is a necessity rooted in the realities of income inequality, out-of-pocket health expenditure, and uneven access to healthcare infrastructure. However, the real policy challenge lies not in whether to intervene, but how to calibrate intervention so that it simultaneously ensures affordability, incentivises innovation and sustains long-term pharma investment.

At the core of the case for intervention is the undeniable evidence that markets for medicines do not function like competitive markets. Information asymmetry (patients relying on doctors), inelastic demand (life-saving drugs cannot be substituted) and monopolistic conditions created by patents mean that prices, if left unchecked they tend to rise beyond socially optimal levels. In India, this is particularly acute. According to data from the World Health Organisation and the World Bank, out-of-pocket expenditure still accounts for nearly 50–60 per cent of total health spending, one of the highest proportions globally. Empirical studies have shown that high medicine costs are a leading cause of "medical impoverishment," pushing millions below the poverty line annually.

This is where institutions like the National Pharmaceutical Pricing Authority (NPPA) become indispensable. By regulating prices of drugs listed under the National List of Essential Medicines (NLEM), the NPPA has demonstrably reduced the cost burden on households. For example, price caps on essential cardiovascular and anti-diabetic drugs, conditions that account for a large share of India's disease burden have led to price reductions of up to 50–80 per cent in certain cases. Similarly, the government's intervention in capping prices of coronary stents in 2017 resulted in reductions of over 70 per cent, making life-saving procedures significantly more accessible.

However, the argument cannot stop at defending price controls; it must confront the countervailing concern that excessive regulation may dampen innovation. Pharma R&D is inherently high-risk and capital-intensive: estimates suggest that bringing a new drug to market can cost upwards of $1–2 billion globally. If firms anticipate that successful innovations will be subjected to rigid price caps, their expected returns diminish, potentially leading to under investment in research, particularly in areas already underserved such as rare diseases or antimicrobial resistance.

This is why a differentiated regulatory framework is essential. A uniform pricing regime ignores the heterogeneity within the pharma sector. Essential medicines those addressing widespread, high-burden conditions justify strict price ceilings because they are often based on older molecules with established production processes and lower R&D recovery needs. In contrast, newer therapies, especially biologics or precision medicines, require more flexible pricing models. Countries like the United Kingdom and Germany have experimented with value-based pricing, where the price of a drug is linked to its clinical effectiveness and broader social value, often assessed through health technology assessment (HTA) bodies. India has begun moving cautiously in this direction, with discussions around institutionalising HTA through bodies like HTAIn.

Another critical instrument is public funding and risk-sharing. Early-stage drug discovery is often underfunded by private actors due to uncertainty. Governments can step in through grants, public research institutions, and public-private partnerships. The rapid development of COVID-19 vaccines offers a powerful illustration: substantial public investment de-risked private innovation globally. In India, initiatives involving the Indian Council of Medical Research (ICMR) and domestic firms helped accelerate vaccine development and manufacturing capacity. When public funds contribute to innovation, it strengthens the normative case for imposing affordability conditions on the final product—aligning private incentives with public health goals.

In addition, strategic procurement and market shaping can achieve affordability without blunt price controls. Large-scale government procurement such as through schemes like Jan Aushadhi creates economies of scale that reduce per-unit costs while guaranteeing manufacturers a stable demand. Similarly, promoting generic competition has been one of India's most successful policy tools. India's strong generic pharma industry has made it a global supplier of affordable medicines, particularly for HIV/AIDS treatment in low- and middle-income countries. The use of compulsory licensing provisions under the TRIPS agreement though sparingly applied also serves as a credible threat against excessive pricing, reinforcing negotiating power.

Importantly, the concern that price regulation inherently discourages innovation is often overstated, especially in the Indian context. Much of India's pharma sector is focused on generics rather than frontier innovation. Therefore, moderate price controls on essential drugs are unlikely to significantly distort high-end R&D incentives. Instead, targeted incentives such as tax credits, faster regulatory approvals, and exclusivity periods for genuinely novel drugs can be deployed to stimulate innovation where it is most needed.

Ultimately, the government's role is to act as a market shaper rather than merely a market corrector. This involves designing a layered policy architecture: strict regulation where market failures are most severe (essential medicines), flexible and evidence-based pricing where innovation is critical (new therapies), and proactive investment in public health infrastructure and research. The goal is not to suppress profit, but to align it with public health outcomes.

In a country like India, where access disparities are stark, the ethical imperative of ensuring affordable medicines cannot be subordinated to market logic. Yet, sustainability demands that innovation ecosystems remain viable. A carefully calibrated mix of price regulation, public investment, and institutional innovation offers a pathway to reconcile these objectives—ensuring that the pharma market serves not just those who can pay, but all those who need care.

How can India evolve towards a more balanced healthcare model that integrates preventive, promotive, and curative approaches alongside pharma growth?

Dr Amit Kumar: I think India's healthcare architecture has, for a long time, been fundamentally skewed toward curative, hospital-based care. While that has undoubtedly expanded access to life-saving interventions, it has also produced a system that feels reactive, expensive, and uneven in reach. To me, the real challenge and opportunity is to move toward a more balanced model where preventive, promotive, and curative care are not treated as separate silos but as parts of a single, integrated continuum. This shift is not just desirable from a public health perspective; I see it as fiscally necessary in a country where resources are limited and the disease burden is rapidly evolving.

When I look at current policy efforts, I see Ayushman Bharat as an important starting point. Its attempt to combine financial protection for hospital care with the strengthening of primary healthcare through Health and Wellness Centres is a step in the right direction. But I also feel that the deeper structural

shift still lies ahead. For me, the real transformation will come from genuinely re-centering primary healthcare so that it becomes the first point of contact for most health needs. Evidence from the World Health Organisation reinforces this intuition, countries that invest heavily in primary care tend to achieve better outcomes at lower cost, particularly when dealing with non-communicable diseases, which now account for the majority of deaths in India.

What stands out to me most is how underutilised preventive care still is. Interventions like vaccination, early screening, and lifestyle modification offer disproportionately high returns compared to the cost of treating advanced disease. India's Universal Immunisation Programme, for example, has saved millions of lives at relatively low cost, which makes it one of the most effective public health interventions we have. Similarly, I think the expansion of screening for hypertension and diabetes through primary care networks can fundamentally change health trajectories by preventing complications like stroke or kidney failure. The World Bank has repeatedly pointed out that investments in prevention generate long-term economic benefits by reducing both healthcare expenditure and productivity losses, and I find that argument particularly compelling in the Indian context.

At the same time, I believe promotive health needs to be taken far more seriously as a core component of healthcare policy. Factors like nutrition, sanitation, and behavioral awareness often determine health outcomes more than clinical care itself. Initiatives such as Swachh Bharat Mission and POSHAN Abhiyaan clearly show that improvements in these areas can significantly reduce disease burden, especially for infectious diseases and child malnutrition. What I think is missing, however, is deeper integration, these programs often operate in parallel rather than being embedded within a unified health strategy.

From the perspective of the pharma sector, I do not see this shift toward prevention as a constraint; I see it as an evolution. A system that prioritises prevention actually creates new and more sustainable forms of demand, vaccines, preventive therapies, and early diagnostics become central rather than peripheral. India's leadership in vaccine manufacturing, particularly during the pandemic, is a strong example of how pharma growth can align with public health priorities. I also think that the expansion of affordable diagnostics and point-of-care testing represents an important frontier, both in terms of improving early detection and creating new market opportunities.

For me, the institutional challenge lies in building the connective tissue that links all these elements together. Digital health infrastructure, such as the Ayushman Bharat Digital Mission, has the potential to integrate patient data across different levels of care, making the system more coherent and responsive. At the same time, expanding the role of community health workers and enabling task-shifting can bring preventive and promotive services closer to people's everyday lives. I also think financing models need to evolve, if incentives continue to reward only treatment volumes rather than health outcomes, the system will remain biased toward curative care. Moving toward outcome-based approaches could help realign priorities.

Ultimately, the way I see it, the goal is to move from a system that primarily treats disease to one that actively manages health. Prevention should reduce the need for cure, and curative care should, in turn, generate insights that strengthen preventive strategies. Unless these elements are connected in a continuous loop, we will keep addressing symptoms rather than causes.

What steps can be taken to ensure that patient access and affordability remain central to decision-making in the pharma sector?

Dr Amit Kumar: For me, the question of access and affordability is where the entire healthcare system is ultimately tested. No matter how advanced the technology or how sophisticated the policy design, if patients cannot actually obtain the medicines they need, the system has failed at its most basic level. In India, this is not an abstract concern, it is a structural reality. Out-of-pocket expenditure still makes up a large share of total health spending, and medicines account for a significant portion of that burden. What this means in practice is that affordability often determines whether people seek treatment at all, which is why I see it not just as a welfare issue, but as central to the functioning of the system itself.

One of the most immediate ways to address this, in my view, is by strengthening the generic medicines ecosystem. India is often described as the "pharmacy of the developing world," yet domestically we continue to rely heavily on branded generics that are far more expensive than necessary. Initiatives like Pradhan Mantri Bhartiya Janaushadhi Pariyojana show what is possible when policy is aligned with affordability, quality-assured medicines made available at prices that are often 50 to 90 percent lower than branded alternatives. And yet, I think the gap lies in implementation, limited awareness, uneven distribution, and entrenched prescribing habits continue to restrict the impact of these efforts.

I also believe that regulatory intervention has a legitimate and necessary role in ensuring affordability. The work of the National Pharmaceutical Pricing Authority demonstrates that targeted price controls can have immediate, tangible effects. The sharp reductions in the cost of coronary stents and knee implants following price caps are a clear example of how policy can directly expand access to critical treatments. At the same time, I do not think affordability should depend solely on price caps. Procurement strategies that leverage scale, such as centralised purchasing models, have shown that it is possible to bring prices down through competition and negotiation, without undermining the broader market.

Another issue is the gap between insurance coverage and actual access. While schemes under Ayushman Bharat have expanded financial protection for hospitalisation, a large share of healthcare spending in India still happens in outpatient settings, particularly on medicines. If these costs remain outside the scope of coverage, the financial burden on households will persist. To me, this highlights the need to rethink insurance design so that it reflects how people actually incur healthcare expenses, rather than focusing primarily on hospital-based care.

At the same time, I think it is important to recognise that affordability alone is not enough, availability matters just as much. In many rural and underserved areas, even low-cost medicines are not consistently accessible due to weak supply chains and distribution gaps. Strengthening last-mile delivery, improving logistics, and integrating medicine distribution with primary healthcare systems are essential if policy interventions are to translate into real-world impact. Without this, even the best pricing policies risk remaining ineffective on the ground.

I also feel strongly that transparency and accountability need to be at the core of the pharma ecosystem. Pricing decisions, regulatory approvals, and procurement processes should not be opaque. Greater transparency not only reduces information asymmetry but also builds public trust in the system. Tools like health technology assessment can help ensure that decisions are grounded in evidence and aligned with both clinical effectiveness and cost considerations.

We should frame innovation and access as being in tension with each other. I think that is a false dichotomy. A well-designed system should ensure that innovation actually expands access rather than restricting it. Mechanisms like tiered pricing, public-private partnerships with affordability conditions, and even safeguards like compulsory licensing can help strike this balance. India's experience with HIV/AIDS medicines is a powerful reminder of what is possible, when generic competition was enabled, prices fell dramatically, transforming access not just within the country but globally.

In the end, I see the pharma sector as part of a broader social contract. Profitability is important and necessary for sustainability, but it cannot be detached from the core purpose of healthcare, which is to serve patients. For me, the real measure of success is whether innovation leads to wider access, not narrower. That is the direction in which policy needs to consistently push.

How can India's IP framework better support pharma innovation while ensuring timely access to affordable medicines?

Prof Uma Bhattad: Indias IP framework strives to strike a balance between encouraging pharma innovation and ensuring access to affordable medicines. The various provisions of the Indian Patents Act, such as:

- **Evergreening:** The provision u/s 3(d) of the Act which prevents evergreening of patents ensures early access to medicines. At the same time this provision also allows for protection of incremental inventions.
- **Compulsory licensing:** The provision for compulsory licenses checks on the abuse of monopoly by the Patentee. In case if the medicines are not available at a reasonably

affordable price, then compulsory licenses can be granted so that medicines are available at an affordable cost. This provision is not invoked often as there is a fear that granting compulsory licenses will act as deterrent to companies from launching products in India.

● **Bolar provision:** Generic companies are allowed to conduct R&D and develop drugs similar to the patented drugs during the subsistence of the patent. This enables the generic medicines to be launched as soon as the Patent expires, so that drugs are made easily available without waste of time. As can be seen with the recent case of Semaglutide.

● **Parallel imports:** India follows the International exhaustion of Patent rights. Thus allowing for parallel imports. This enables importation of drugs which are available at a cheaper price outside India, thus enabling access to cheaper medicines.

All of the above provisions are in conformity to the Trips agreement which adapts the Trips flexibilities as affirmed by the Doha Declaration by prioritising public health over patent rights, thus ensuring access to affordable medicines, at the same time supporting pharma innovation.

What changes or clarifications in patent regulations could help create a more balanced environment for both innovators and public health stakeholders.

Prof Uma Bhattad: I believe that section 3 (d) should be removed from section 3 under the head of what are not inventions. A special section be inserted and the section should be reworded in positive language and the term "enhanced therapeutic efficacy" be defined clearly.

Voluntary Licensing should be encouraged. At the same time Compulsory Licensing must be streamlined such that it is considered more as an enabler to easy access to essential and affordable medicines, rather be treated as a sanction to the owner of the Patent rights.

Use of Artificial Intelligence (AI) in drug development may reduce the cost and time of R& D significantly. However, India lacks a regulatory framework when it comes to the use of AI. Therefore, we must have a framework to regulate proper and ethical use of AI particularly in the pharma and healthcare industry to address the issue of affordable access to medicines.

As India strengthens its position in the global pharma landscape, how can it navigate international IP pressures while safeguarding domestic priorities.

Prof Uma Bhattad: India can maintain its "pharmacy of the world" status by strategically partnering and collaborating with the multinational pharma companies. At the same time mandate domestic or local manufacturing. More R&D funding can be provided by way of public and private partnerships. By strengthening Indian pharma companies for R&D and adapting data exclusivity for a period of about five years. as required by the Trips plus, India can navigate International IP pressures, at the same time safeguard its domestic priorities.

How can greater transparency in areas such as R&D costs and patent filings contribute to more informed discussions around drug pricing and access.

Prof Uma Bhattad: Greater transparency in R&D costs and patent filings, helps stakeholders in analysing data and taking informed decisions related to drug pricing and access to medicines.

Pharma companies typically are secretive about their R&D costs and also there is no transparency about the investment in R&D by companies. Also, the drug pricing is determined by the investment in R&D. Transparency in drug pricing helps in fair pricing assessment of medicines. Also, it is advisable to have drug pricing to be based on the quality of the drugs rather than linking the price with the cost of R&D.

Further, transparency in information about patent filings (such as the one available on the Pat-INFORMED (Patent Information Initiative for Medicines), a World Intellectual Property Organisation (WIPO) database) where many companies share information about the status of their patents, across the globe can aid generics in taking informed decision about their entry into the jurisdictions where there is no patent or a drug is off patent, so that generics may enter such markets and access to drugs is made easy and also reduces chances of litigation.

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Even drug-resistant cancer targets can be tackled with the right design strategy

Dr Bajarang Kumbhar, Assistant Professor, Sunandan Divatia School of Science, NMIMS Mumbai, explains how AI-driven computational biology is reshaping CAR-T therapy and highlights how these approaches help cut drug discovery timelines and improve targeted, personalised cancer treatment, in an interaction with **Kalyani Sharma**

Your work leverages AI and machine learning to optimise CAR-T cell therapy. How does this approach fundamentally differ from traditional drug discovery and development pathways?

CAR-T therapy is a powerful treatment used to fight cancer, especially blood cancers like leukemia and lymphoma. It is a type of immunotherapy, which means it uses the patient's own immune system to attack cancer cells. In this treatment, doctors take the patient's T-cells (a type of immune cell) and modify them in the lab so they can better recognise and kill cancer cells. These modified cells are called CAR-T cells. They are designed with two main parts: one part helps them recognise and attach to cancer cells, and the other part activates the T-cells to destroy those cancer cells.

Once these modified cells are given back to the patient, they can find and kill cancer cells more effectively. However, one major challenge is that cancer cells can change over time. These changes (mutations) can alter the markers (antigens) on their surface, making it harder for CAR-T cells to recognise and attack them.

In our Computational Structural Biology laboratory, we are working on designing better CAR-T cells that can overcome this challenge. We use advanced tools like computational modeling, artificial intelligence, machine learning, and molecular dynamics simulations to design these receptors. Our goal is to create more stable and effective CAR-T cells based on energy and structural analysis. These designs can then be further tested and developed for future clinical studies. Our approach using machine learning and molecular modeling is quite different from traditional CAR-T therapy. Normally, developing a new therapy is a long and expensive process that involves a lot of trial-and-error experiments in the lab. Scientists test many different options step by step, which can take years.

> We use advanced computer tools, such as machine learning, molecular modeling and molecular dynamics simulations, to carefully design the part of CAR-T cells that recognises cancer markers on B cells, such as CD20, BCMA, and CD19. Our goal is to improve how precisely these engineered immune cells can identify and bind to attack cancer cell markers

In contrast, machine learning and molecular modeling allow us to speed up this process by using computers to predict which designs are most likely to work. Instead of physically testing thousands of possibilities, we can first screen and optimise them virtually. This helps us quickly identify the best CAR-T cell designs with higher accuracy. Another key difference is that traditional methods are often more general, while machine learning and molecular modeling based approaches can be more precise and personalised. We can design CAR-T cells that are better suited to specific cancer targets or even individual patient variations.

Overall, our approach reduces time, cost, and effort, while improving the chances of developing more effective and targeted CAR-T therapies.

With R&D costs rising and clinical failure rates remaining high, how can computational structural biology help de-risk early-stage drug development and improve success rates?

With drug development becoming more expensive and many drugs failing in later stages, computational structural biology offers a smarter and faster way to reduce risk early in the process.

In simple terms, instead of relying only on trial-and-error in the lab, we use advanced computer tools to understand how drugs interact with their targets (like tubulin) at a very detailed level. This allows us to predict which drug candidates are most likely to work-even before testing them in the lab.

For example, in our work on cancer targets like tubulin

and CAR-T cell design, we use methods like molecular modeling, simulations, and machine learning to:

- Identify the best drug candidates early
- Understand why some drugs fail (such as due to mutations or weak binding)
- Design better molecules that can bind more strongly and effectively

This helps in "de-risking" drug development because:

Fewer weak or ineffective candidates move forward to expensive lab and clinical testing

Potential problems (like drug resistance or poor binding) are identified early

Time, cost, and effort are significantly reduced

While laboratory and clinical testing are still essential, computational approaches act as a powerful filter at the beginning. They improve the chances that only the most promising and safer drug candidates move ahead.

Overall, computational structural biology makes drug discovery more efficient, more targeted, and more likely to succeed-helping bring better treatments to patients faster.

Computational structural biology makes drug discovery more efficient, more targeted, and more likely to succeed-helping bring better treatments to patients faster

You've used Molecular Dynamics simulations to study drug resistance in cancer cells, particularly with drugs like Taxol. What key insights have emerged from this research, and how can they influence future oncology treatments?

In our earlier research, using computer based molecular modeling and molecular dynamics (MD) simulations helped us understand drug resistance in cancer at a very detailed, molecular level - something that is difficult to observe through experiments alone. One key insight from our study is that mutations in the tubulin protein (the target of drugs like Taxol, Vinblastine and Colchicine) can change how the drug binds. Even small changes in the protein structure can reduce the binding strength of the drug, making it less effective. MD simulations showed that these mutations can alter the flexibility and stability of important regions in the protein, especially near the drug-binding site. Another important finding is that drug binding is not static-it is dynamic. The interaction between traditional drugs such as taxol, vinblastine and combretastatin, and tubulin changes over time, and resistant mutations can disturb this interaction, leading to weaker or unstable binding. This explains why some cancer cells initially respond to treatment but later become resistant.

We also observed that changes in microtubule behavior and dynamics contribute to resistance. Cancer cells can adapt by altering these dynamics, reducing the effectiveness of drugs designed to stabilise them. These insights are very important for future cancer treatment because:

- They help us understand why drug resistance occurs at the molecular level.
- They enable the design of new drugs that can bind more strongly, even in mutated proteins.
- They support the development of personalised

therapies based on specific mutations in patients.

Overall, our work shows that machine learning, molecular modeling and MD simulations can guide the design of next-generation anti-cancer drugs that are more effective and less prone to resistance, improving long-term treatment outcomes.

Your research claims to significantly reduce drug discovery timelines from years to months. What are the practical challenges in translating these computational findings into clinical and commercial applications?

As mentioned earlier, cancer can become resistant to treatment because the proteins in cancer cells change over time. These changes make existing drugs less effective, so there is a need to find new drugs that can still work against these mutated proteins. To tackle this, we use natural compound libraries and advanced computer methods to find molecules that can bind well to these mutated proteins and correct their behavior. We combine computer-based drug design with machine learning to quickly identify and improve the most promising drug candidates. Once we identify these compounds, we test them in the laboratory using cell-based experiments and by studying how strongly and effectively the drug interacts with the target protein.

Although this approach can reduce drug discovery time from years to months, there are still several real-world challenges:

- All computer predictions must be tested in the lab and in living systems, which takes time and resources.
- The human body is very complex, so results from computer simulations may not always work the same way in real life.
- Even if a compound works well in theory, it must be proven safe and non-toxic for humans.
- Machine learning depends on good quality data, and poor or limited data can affect accuracy.
- Finally, before reaching patients, every drug must go through strict clinical trials and regulatory approvals, which are time-consuming and expensive.

Overall, while computational methods help us move faster and save time, cost, and effort in the early stages, careful testing and approvals are still essential to ensure the treatment is safe and effective for patients.

AI-driven redesign of immune cells is a significant advancement in immunotherapy. Can you elaborate on how your work enhances the precision and efficacy of CAR-T cells, especially in targeting markers like CD20?

We use advanced computer tools, such as machine learning, molecular modeling and molecular dynamics simulations, to carefully design the part of CAR-T cells that recognises cancer markers on B cells, such as CD20, BCMA, and CD19. Our goal is to improve how precisely these engineered immune cells can identify and bind to attack cancer cell markers.

A key focus of our work is improving how strongly and accurately CAR-T cells bind to cancer cell marker. To do this, we design different versions of the binding region (called scFv), based on antibodies using machine learning and molecular dynamics simulations followed by energy calculations. This allows us to predict which designs are likely to work best before moving to laboratory testing.

One important finding from our study is that even small design changes-such as modifying the linker that connects different parts of the binding region-can significantly improve the strength and stability of binding. This is especially important for targets like CD20, which are located very close to the cancer cell surface and are harder to access.

Overall, our approach helps create CAR-T cells that are more precise in targeting cancer cells and more effective in killing them. By improving their stability and performance, this work has the potential to make CAR-T therapy more reliable and beneficial for patients with cancer.

You are also exploring targets like tubulin for drug-resistant cancers. How promising is this approach in addressing so-called 'undruggable' or treatment-resistant malignancies?

Targeting tubulin is still a very promising way to treat cancers, even those that have become difficult to treat due to drug resistance. From our research, we found that tubulin proteins in cancer cells are not all the same. There are different types (called isotypes like ßI, ßII, ßIII, etc.), and these differences can make common cancer drugs like Taxol and vinblastine less effective. This is one of the main reasons why some cancers stop responding to treatment.

Using advanced computer methods, we studied how these drugs interact with different tubulin types. We found that drug resistance happens because of small changes in the structure and movement of the tubulin protein. These changes make it harder for drugs to attach properly and do their job.

The good news is that this understanding helps us find solutions. By knowing exactly how these proteins change, we can design or identify new drug molecules-especially from natural sources-that can bind better to these resistant forms.

This machine learning, and molecular modeling approach is promising because:

- It helps us understand why drugs stop working,
- It allows us to design more targeted and effective treatments,
- It opens the door for personalised therapies based on the patient's cancer type

Our work shows that even drug-resistant cancer targets can be tackled with the right design strategy. Overall, this approach can lead to better and more reliable treatments for drug-resistant cancers, making therapies more effective and less likely to fail.

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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.


PHARMA
HUBS

INDIA'S NEXT PHARMA POWERHOUSES

India’s pharma growth is increasingly being shaped not just by companies, but by clusters. From Hyderabad Pharma City and Genome Valley to Jawaharlal Nehru Pharma City and Gujarat’s bulk drug park in Jambusar, a new generation of integrated manufacturing ecosystems is taking form across the country.

These clusters reflect a structural shift towards scale, shared infrastructure and multi-segment capabilities spanning APIs, biologics, injectables and CDMO-led models. A look at that transition through a cluster-first lens: examining what is being built, how far execution has progressed, and what it signals for India’s next phase of pharma growth

Genome Valley: Aligning with what comes next

By Neha Aathavale

For years now, the Indian pharma industry has been talking about moving beyond scale. The shift towards innovation and complex therapies, has been a familiar narrative in policy discussions and boardrooms alike. The more useful question now is what that looks like on the ground.

A closer look at Genome Valley in Hyderabad offers some answers.

Spread across more than 2,000 acres, it houses over 200 companies from upwards of 18 countries, with an estimated 15,000 to 20,000 professionals working across biotechnology, pharma, and research services. Over time, it has been central to India's position as a global vaccine supplier, with companies here contributing significantly to international supply chains.

What becomes more relevant then is not just how the cluster is expanding, but the role it is beginning to play within the broader pharma landscape.

Over the next decade, clusters that succeed will be those that consistently demonstrate execution reliability, delivering predictable, regulator-accepted outcomes across therapies

Dr Priya Kapoor G Hingorani
MD, Miltenyi Biotec India and VP APAC

We are currently in the stage of Advanced Integration. The physical infrastructure at Genome Valley is robust, but the next 18–24 months will be defined by digital and precision maturity

Dr Krishna Ella
Executive Chairman, Bharat Biotech

Why it matters

Often described as India's first organised life sciences cluster, Genome Valley has long been tied to the country's vaccine story, contributing nearly one-third of global vaccine production and serving as a key node for biopharma innovation. What stands out now, though, is not just that association, but how the cluster is being read in the current moment.

The growing focus on vaccines, biologics and other complex therapies has brought a different set of demands to the forefront. These are segments where scale alone does not determine outcomes. They require far tighter coordination across research, process development, manufacturing, and regulatory functions. In that context, the cluster is increasingly being seen as a space where different parts of the pharma lifecycle can come together more cohesively.

That broader shift is also being reinforced at a policy level. As Dr Priya Kapoor G Hingorani, MD, Miltenyi Biotec India and VP APAC points out, the Rs 10,000 crore Biopharma SHAKTI initiative announced in the Union Budget 2026 signals a clear move away from volume-driven generics towards higher-value biologics and biosimilars. In effect, it formalises a direction the industry has already been moving towards.

"In that context, well-developed life sciences clusters will play a critical role. Their relevance lies in their ability to reduce fragmentation and enable tighter integration across research, development, manufacturing, and regulatory functions, an essential requirement for improving execution consistency," she explains.

She adds that this becomes particularly important in precision biotherapeutics, where even small variations can impact patient outcomes, and where success is increasingly tied not to investment alone, but to the ability to deliver globally trusted, audit-ready products..

Seen in this light, the role of the cluster becomes clearer.

"We are transitioning from the 'Pharmacy of the World' (manufacturing) to the 'Laboratory of the World' (innovation). Over the next decade, Genome Valley will be the bedrock of India's self-reliance, and dominance in complex therapeutics," says Dr Krishna Ella, Executive Chairman, Bharat Biotech.

This positioning also fits into a larger global shift. As companies look to diversify supply chains and reduce risk, the emphasis is moving towards ecosystems that can deliver consistent, regulator-ready output. Genome Valley, in that sense, is increasingly being positioned as an execution platform within the global pharma value chain.

For now, what makes this cluster relevant is that it is already aligning with where the industry is headed.

And that is where the ground reality starts to add more context.

Where things stand

On ground, momentum is visible across biologics, biosimilars, cell and gene therapies, and CRDMO-led models, segments that are steadily reshaping the nature of activity within Genome Valley.

And this activity is no longer confined to the original cluster footprint.

The Genome Valley ecosystem is steadily extending outward, with the Telangana government and private players building additional nodes to support different segments of the value chain. Greenfield "pharma villages" in Vikarabad, Medak, and Nalgonda are expected to house up to 30 companies at each site, with a focus on bulk drugs and high-end manufacturing.

Alongside this is Green Pharma City, a 19,000-acre integrated pharma cluster in Ranga Reddy district. With over 11,100 crore in investment commitments, it is being positioned as a large-scale manufacturing base, built around zero liquid discharge, centralised waste management, and energy-efficient systems.

Within Genome Valley itself, expansion continues. The Phase-II addition of 300 acres, backed by a Rs 2,000 crore investment, is expected to bring in three million sq. ft. of lab and clean manufacturing space, aimed at accommodating more R&D and advanced therapy work, along with an additional $100 million life sciences campus being developed by Rx Propellant.

According to the official website, the cluster already offers over 2.5 million sq. ft. of laboratory space and operates

GENOME VALLEY & REGIONAL ECOSYSTEM: KEY HUBS

Hub / Initiative	Location	Primary Focus	Key Details
Genome Valley (Core Cluster)	Shamirpet, Hyderabad	R&D, Vaccines, Biologics	2,000+ acres; 200+ companies; 18+ countries; 15,000–20,000 workforce
Pharma Villages (Mega Master Plan-2050)	Vikarabad, Medak, Nalgonda	Bulk Drugs (APIs), High-end Manufacturing	Up to 30 companies per site; focus on reducing import dependence; Infra partner: RX Propellant
Green Pharma City	Ranga Reddy district (25 km from airport)	Bulk Drugs, Formulations, Large-scale Manufacturing	19,000 acres; ₹11,100 crore investment commitments; Zero Liquid Discharge; NIMZ status
Genome Valley Phase-II Expansion	Hyderabad	R&D, ATMPs, Lab Infrastructure	300 acres; ₹2,000 crore investment; 3 million sq. ft. lab space; Partners: Terminus Group, Rx Propellant
B-Hub (Biopharma Hub)	Genome Valley	Biopharma incubation, scale-up	10,000 sq. ft.; 10L–200L bioreactors; GLP labs; PPP models

Source: Telangana State Portal

under IALA status, enabling single-point clearance for government approvals, which directly impacts how quickly projects can move from setup to operation.

This is supported by a broader infrastructure base that includes ready-built lab facilities, dedicated effluent treatment and waste management systems, analytical testing services, and access to continuous power and natural gas supply. The presence of the ICMR-led National Animal Resource Facility, the country's largest of its kind, adds another layer of specialised R&D capability within the cluster.

At the same time, there is a growing layer of shared infrastructure around the cluster. Facilities such as the Biopharma Hub (B-Hub) and the "1 Bio" scale-up centre are being set up to support companies moving from research into early-stage manufacturing, with access to bioreactors, analytical labs, and plug-and-play lab spaces.

Looking ahead, the focus on building a more integrated, capability-driven ecosystem is also outlined in the Genome Valley 2.0 Master Plan, which aims to evolve the cluster into a knowledge-led corridor with stronger emphasis on connectivity, liveability, and long-term sustainability.

Taken together, the cluster today reads less like a single site and more like a network of connected capabilities, each addressing a different part of the pharma lifecycle.

That said, building the structure is only one part of the equation. How efficiently it functions is where the real test lies.

"Speed is the only currency that matters in this industry. Our biggest challenge is not lack of ambition, but the velocity of administrative and regulatory decision-making. As we scale, our infrastructure must grow ahead of the industry's demand, not behind it. We must also aggressively continue to foster 'industry-ready' talent, ensuring our academic pipelines are producing the specialised skill sets required for next-gen technologies like genomics and precision medicine," says Dr Ella.

From an ecosystem standpoint, the challenges are becoming more specialised. Dr Hingorani points out that as the focus shifts towards more complex therapies, the need for deeper scientific expertise and tighter coordination between process development and manufacturing becomes more critical. She highlights that even small disconnects can affect timelines and outcomes, particularly in biologics, where regulatory readiness and GMP compliance demand consistent, disciplined execution across facilities.

Overall, the ecosystem is already in place, barring a few challenges. The immediate question now is how effectively the cluster will leverage it.

The ecosystem advantage

What starts to matter more at this stage is not just the infrastructure itself, but everything that has built up around it — the ecosystem.

In a place like Genome Valley , "The greatest strength is 'Regulatory Fluency.' Because the ecosystem is so concentrated, there is a deep understanding of compliance and safety standards among the local workforce and administration," says Dr Ella.

That familiarity tends to show up in execution, in how processes are designed and how reliably facilities operate within global regulatory frameworks.

Dr Hingorani adds further that this is reinforced by a growing base of scientific talent and specialised CRDMOs, along with professionals experienced in global regulatory systems, all of which support more consistent execution. At the same time, she notes that early-stage innovation and venture-backed ecosystems are still evolving, and remain critical to strengthening long-term execution reliability.

What Genome Valley offers is not just capacity, but a certain level of predictability, something that becomes more valuable as therapies grow more complex and the margin for error narrows.

What's next?

Keeping an eye on tomorrow, the focus shifts to how these capabilities translate into actual output.

At present, Genome Valley is moving into a more execution-heavy phase. Dr Hingorani notes that the emphasis going forward is on strengthening
capabilities in biologics, injectables, and integrated R&D environments, with the real shift lying in moving from infrastructure creation to operationalising it in line with global benchmarks.

"We are currently in the stage of 'Advanced Integration.' The physical infrastructure at Genome Valley is robust, but the next 18–24 months will be defined by digital and precision maturity," adds Dr Ella.

"Industry interest is becoming more focused and aligned with areas that require strong execution capabilities. Companies are no longer expanding broadly—they are investing selectively," says Dr Hingorani.

Ultimately, the next phase for Genome Valley comes down to one thing: not how much more it can build, but how reliably it can deliver.

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JNPC: Carrying forward a 20-year old legacy

By Viveka Roychowdhury

Billed as India's first bulk drug, chemicals and allied manufacturing parks and one of the most successful public-private partnerships (PPP) in the pharma sector, the Jawaharlal Nehru Pharma City (JNPC), also known as Visakha Pharma City, was set up in February 2005 as a PPP initiative by the Govt of Andhra Pradesh (GoAP) through its nodal agency Andhra Pradesh Industrial Infrastructure Corporation (APIIC) with the Ramky Group on a Build-Own-Operate (BOO) basis for 20 years.

A dream run

Reflecting back on the early days of JNPC, Dr Divakar Marri, VP & SBU Head - SPV, Ramky Infrastructure indicated that the gestation period from signing on to commercial operations was fairly minimal, thanks to the modular nature of the park design. As per Dr Marri, construction was initiated from 2005, commercial operations started in 2008, when companies began to sign on.

The 2400-acre JNPC became operational in 2010, with a second phase in 2019. By July 2023, JNPC was rated as leader (SEZ) with the highest level of aggregate performance category in the Industrial Park Rating System (IPRS) Report brought out by the Department for Promotion of Industry and Internal Trade (DPIIT).

As per the website, JNPC houses 104 operating companies, including MNC and domestic pharma companies and accommodates around 30,000 employees. The pharma city spans companies manufacturing bulk drugs, chemical and allied industrial units, with facilities to comply with all relevant national and global environmental and social standards and regulations.

JNPC reportedly includes leading global pharma companies like Pfizer Mylan Laboratories, Eisai Pharma, PharmaZell, and SNF. Most of India's big pharma companies too have chosen JNPC, including Biocon, GVK Bio, Granules, Lauras Labs, Hetero Pharma, Aurobindo Pharma, and Orchid Chemicals and Pharmaceuticals.

As per the JNPC brochure, the project was reportedly designed to offer 'a hassle-free production environment and allow pharmaceutical industries to save up to 40 per cent of the project cost by providing all the common infrastructure and clearances required. Apart from several infrastructure facilities and services offered, the park-level environmental and other clearances save two years in development for industries.'

Growth pains

Ironically, JNPC's success also resulted in challenges. JNPC was a pioneer in a sense, as one of the first functional pharma cities in the country. Like most pharma manufacturing zones, the park faced growth pains as operations outgrew the facilities provided.

Around 2014, media reports indicated a tussle for power with the state electricity board, a key challenge for a continuous manufacturing sector like pharma. A Care Ratings Report on the Ramky Group dated October 23, 2020, flagged concerns about a Central Bureau of Investigation (CBI) litigation, initiated in FY13, related to reduction of green belt area in JNPC to create more saleable plots than the original masterplan.

Challenges of 'red category' manufacturing

Pharma manufacturing results in hazardous waste effluents which need rigorous treatment before release. This puts the industry in the 'red category' and most pharma manufacturing locations default on this count to various degrees.

Even though JNPC's environmental infrastructure included a green belt of 353 acres, a 12 MLD capacity effluent treatment plant with multiple effect evaporator, a solid waste management facility, and a 20 MLD water treatment facility, there are indications that the park's effluent treatment plant was stretched.

Newspaper reports highlight environmental and safety issues, like agitations of the local fishing community of dwindling catch due to insufficiently treated effluents. There have also been explosions at units within the plant, like the massive fire and explosion at Visakha Solvents in July 2020. Such reports caused the pollution control board to launch detailed inquiries. Local administration also paused further permissions to onboard new pharma companies in JNPC.

These challenges took some time to be resolved. JNPC's experiences over two decades will no doubt help new upcoming pharma cities to develop more comprehensive measures and check and balances to avoid environmental and legal issues.

Signalling the next phase of JNPC, on March 30, 2026, RIL divested its 51 per cent stake in its subsidiary, Visakha Pharmacity, to Brij Gopal Construction for 165.24 crores.

RIL's divestiture in Visakha Pharmacity was preceded by RIL being awarded Maharashtra Industrial Development Corporation (MIDC) has appointed Maha Integrated Life Sciences City (MILeS City), a wholly owned subsidiary of RIL

While RIL simultaneously starts executing its next project, a lifesciences city in Maharashtra, this sale hopefully marks the start of the next phase of growth for the Ramky Pharma City, but will existing pharma companies prefer to migrate to newer pharma cities, which will have more updated infrastructure?

Given that most pharma companies have sizable revenues from contract manufacturing for overseas clients, they might prefer to migrate to newer bulk drug parks with more updated, automated facilities.

However, newly announced bulk drug parks have a long gestation and stabilisation period and will take a few more years to get fully operational. JNPC remains a template for today's pharma cities, but needs to get back its mojo with a future-proof strategic roadmap. Will the new partners Brij Gopal Construction set this uptick in motion? Only time will tell.

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Gujarat's bet on Jambusar

By Lakshmipriya Nair

Between the Gulf of Khambhat and the Narmada, India is staking 3,920 crores on the Jambusar Bulk Drug Park in Bharuch, Gujarat.

This is more than an industrial project. It is a strategic statement that India can produce the building blocks of its medicines at scale, at home and at competitive cost.

Over the next five to ten years, how well this park delivers on that promise will determine how effectively India can reduce its import dependence.

Backed by Gujarat's strong industrial base, Jambusar Pharma Park brings together infrastructure, policy support, reduced stamp duties, faster approvals and improved facilities into a single, execution-ready ecosystem that accelerates investments and operations.

It is set to strengthen India's API backbone, driving both scale and quality in domestic manufacturing, reducing import dependence and improving global cost competitiveness through lower production costs.

Opportunities

Jambusar offers a compelling opportunity for companies to scale, diversify, and build globally competitive API manufacturing within a compliant, well-supported, and integrated ecosystem.

Challenges

While PLI-listed APIs will see momentum, expanding focus to a broader API basket and staying competitive amid inter-state competition will be critical to building long-term resilience at Jambusar.

- Dr Hemant Koshia,
Ex-FDCA Commissioner, Gujarat

The gap India needs to close

India is the world's largest supplier of generics but depends heavily on imported APIs and KSMs, largely from China. Bulk drugs made up more than 60 per cent of pharma imports in 2021–22. COVID-19 clearly exposed the fragility of this dependence. The Jambusar pharma park is designed as a structural fix to this problem by lowering API production costs through shared infrastructure like effluent treatment, solvent

recovery and utilities.

Over the next decade, as global pharma supply chains continue to diversify away from single-source dependencies (a trend driven by geopolitics and events like the pandemic), a fully operational Jambusar park can help India compete with China on price and emerge as a credible alternative in global supply chains.

Why Jambusar

The park's most compelling differentiator is geography. Bharuch is home to more than 1,300 industries across major clusters including Ankleshwar, Panoli, Jhagadia, Dahej, Saykha and Vilayat, providing direct and indirect employment to nearly two lakh people and contributes approximately 19 per cent to the country's total chemical exports. Jambusar sits in the middle of this ecosystem, embedded within it.

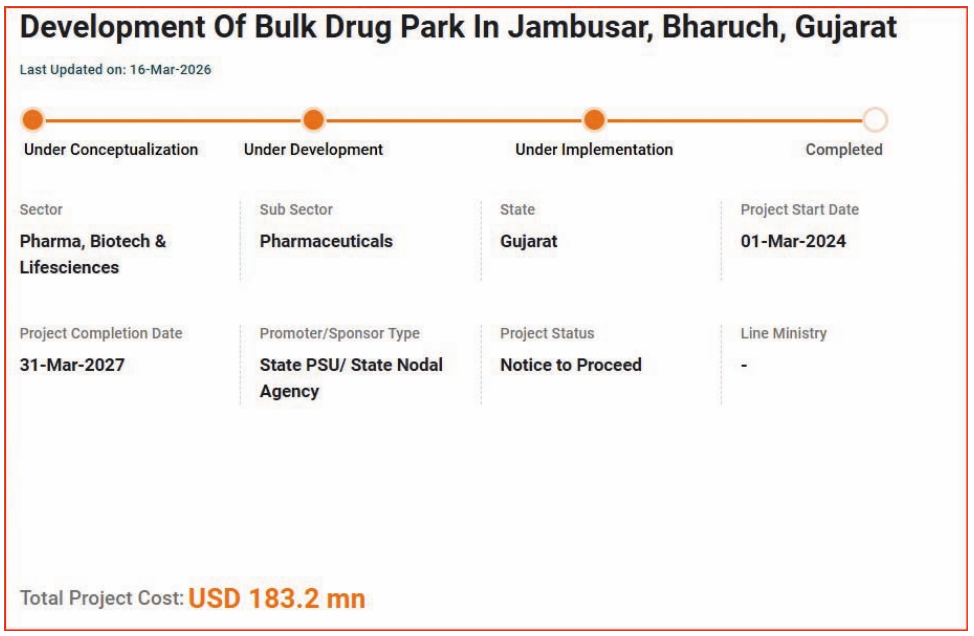
Ankleshwar alone has over 1,500 chemical plants producing pharma, APIs, intermediates, and specialty chemicals, with a dense network of logistics, regulatory expertise, and technical manpower already in place. No greenfield park in Andhra Pradesh or Himachal Pradesh can replicate this instantly. The solvent suppliers, chemical traders, freight forwarders and regulatory consultants who facilitate API manufacturing are already present in Bharuch district.

The site is within the influence zone of the Delhi Mumbai Industrial Corridor (DMIC), approximately 47 km away, and is around 65 km from the Ahmedabad-Vadodara Expressway, giving it multimodal logistics access to major ports and consumption centres.

Adding to this mix is GIDC's track record as a state implementing agency. It is one of India's most experienced industrial estate developers.

The progress so far

Spread across 2,015 acres (approximately 815 hectares), the park is being developed at an estimated cost of 3,920 crore, with key construction works including approach roads, compound walls, internal road networks, precast drainage systems, internal water supply, and effluent disposal systems underway.



Source: India Investment Grid

According to the PIB release from February 2026, all civil infrastructure tenders for roads, drainage, water infrastructure, effluent collection, and rack systems have been awarded and work is at an advanced stage of completion. Utility tenders for the common effluent treatment plant (CETP), solvent recovery, and treatment storage and disposal facilities (TSDF) have also been awarded and execution is underway.

A 40-km pipeline to supply water from the Narmada canal is now being laid, the tender for parking facilities was completed in November 2025, and proposals for steam generation are currently under evaluation. Over the next 18–24 months, the park will witness a transition from civil construction to utility commissioning such as CETP, solvent recovery and steam distribution systems. If industrial allotment and unit construction can proceed in parallel, it put the park on track for its stated completion target of March 2027.

The ecosystem edge

Beyond the infrastructure, Jambusar benefits from proximity. Gujarat's well-established pharma parks such as Ankleshwar provide an ideal ecosystem for API manufacturers. It offers efficient connectivity through ports like Mundra and Kandla for export, and an extensive road and rail network for transportation of raw materials and finished products.

As an established industrial belt, Bharuch has decades of knowledge in chemical process engineering, environmental compliance and hazardous material handling. It also has GIDC-managed estates which offers regulatory familiarity and a workforce trained in chemical manufacturing. So, the Jambusar park does not need to build an industrial culture from scratch. It only needs to amplify one that already exists.

Clear demand signals

The park is designed to house approximately 400 companies. The government has not released a detailed breakdown of allotment applications, but the PLI Scheme for Bulk Drugs, running parallel to this initiative, is a plus. The PLI scheme targets 41 KSMs, intermediates, and APIs, with 48 projects approved across 33 bulk drugs. It focuses on segments like antibiotics, cardiovascular drugs, anti-retrovirals, and oncology, areas where reducing reliance on China is both viable and critical.

Early occupants are likely to be domestic generics companies integrating backwards, CDMOs seeking reliable API supply and mid-sized exporters targeting US and European markets. Interest from global firms looking to reduce China dependence could follow.

Risks are real

However, while the rewards could be high, the risks are real as well. Environmental compliance is the foremost. The park falls partially within Coastal Regulation Zone (CRZ) areas and the deep-sea disposal line for treated effluent requires ongoing regulatory clearance.

Utility commissioning is another challenge. CETP and zero liquid discharge systems take time to stabilise, and delays will slow unit operations and investment inflow. The Gujarat government expects the park to attract large-scale investments from domestic and international pharma companies, but actual private investment inflow depends entirely on how quickly common utilities become reliable and operational.

Finally, China's pricing remains unpredictable. Any price cuts in response to India's capacity build-up could erode the viability of domestic API manufacturing.

Outlook for 2027–28

Success by 2027–28 will not be full occupancy, but clear momentum. That means common infrastructure facilities fully commissioned and operational; 150-200 plots under development, and the first units producing and exporting with lower API costs.

By 2028, the real test is simple. Jambusar should be able to point to at least one critical API, previously imported, manufactured competitively at scale within the park.

That would be proof of concept. Not just for one park, but for India's push for Atmanirbharata in pharma.

The groundwork is in place. What matters now is execution.

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Haroli: Himachal's next pharma play

By Kalyani Sharma

In Haroli, a quiet industrial location is being positioned at the centre of India's next pharmaceutical shift. The Bulk Drug Park coming up here is not just another infrastructure project—it is a strategic attempt to correct one of the most persistent gaps in India's pharma story: dependence on imported APIs and intermediates.

Spread across 1,405.01 acres, the project carries a total investment of Rs 1,923 crore, including a Common Infrastructure Facility (CIF) cost of Rs 1,118.46 crore, and is being implemented by Himachal Pradesh Bulk Drug Park Infrastructure Ltd. (HPBDPIL).

For a country that leads in formulations but still imports critical inputs, Haroli represents a structural reset.

Closing the API gap

India's pharmaceutical exports are anchored in finished formulations, but upstream dependencies continue to expose the supply chain to external shocks. The Bulk Drug Park scheme is designed to address this imbalance by building shared infrastructure that reduces manufacturing costs and improves scale efficiencies.

The logic is straightforward. If infrastructure costs can be pooled and optimised, domestic API production becomes more viable. Haroli is one of the first real tests of that model.

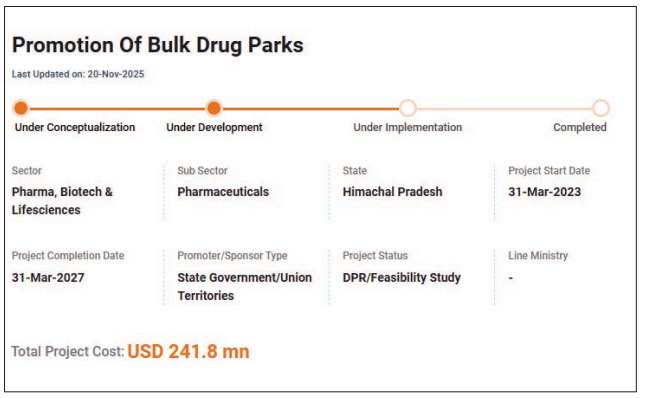
Why Haroli matters

The choice of Haroli is not incidental. The Himachal Pradesh government has positioned the park as a key lever to strengthen the pharma sector and reduce dependence on Chinese imports.

Located in Una district, the project sits within reach of an established pharmaceutical ecosystem, giving it access to industry networks while allowing for planned, large-scale infrastructure development. The intent is not just expansion—but integration of upstream capabilities into the broader pharma value chain.

Location of Project site on District Map

Location of project site on Google Earth Map



Source: India Investment Grid

The project blueprint

At its core, the Haroli Bulk Drug Park is defined by three numbers:1,405.01 acres of land, 1,923 crore total project cost and 1,118.46 crore allocated to common infrastructure (CIF)

These figures, approved under the central scheme, outline a project built on scale and shared efficiency.

The park is being executed by HPBDPIL, the designated state implementing agency, ensuring institutional oversight of infrastructure development and industrial rollout.

Infrastructure as the differentiator

Unlike traditional industrial estates, Haroli is being designed around a common infrastructure backbone.

The model focuses on creating shared facilities such as effluent treatment systems, utilities, and logistics suppor that individual manufacturers would otherwise have to build independently. By centralising these, the scheme aims to lower entry barriers and improve operational efficiency.

For bulk drug manufacturing, where compliance and infrastructure costs are high, this model is expected to be a decisive advantage.

Execution gathers pace

The project has moved beyond approvals into execution. Infrastructure tenders covering roads, drainage, bridges, and water systems have been awarded, and work is in progress. Parallel development of utilities such as zero liquid discharge systems and steam infrastructure is also underway.

Site-level activities, including land preparation and grading, indicate that the project is transitioning from planning to physical development.

A strategic play, not just a park

Haroli is one of three bulk drug parks approved under the national scheme, alongside projects in Gujarat and Andhra Pradesh. Together, they represent a coordinated effort to reduce production costs, strengthen domestic manufacturing, and build resilience into pharmaceutical supply chains.

For Himachal Pradesh, this is also an opportunity to move up the value chain—from formulation manufacturing to integrated pharma production.

What will define success

The success of Haroli will not be measured by land allocation alone. It will depend on whether the shared infrastructure model translates into actual cost advantages and sustained industrial activity.

If the park can enable competitive domestic production of APIs that are currently imported, it will validate the broader strategy behind the Bulk Drug Park scheme.

The bottom line

Haroli is not a quick win. It is a long-term industrial bet. With Rs 1,923 crore in project investment, Rs 1,118.46 crore committed to shared infrastructure, and a clearly defined policy objective, the foundations are in place. What follows now is execution.

If delivered as intended, Haroli could mark a turning point shifting India from being a formulation powerhouse to a more integrated pharmaceutical manufacturing hub.

Opportunities and challenges

Haroli creates an opportunity for manufacturers to build API capacity within a cost-optimised, infrastructure-ready environment supported by government policy.

Timely infrastructure delivery and the ability to translate cost efficiencies into globally competitive production will determine the park's long-term impact

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The next wave

India's next pharma leap is being built from the ground up, through a new generation of bulk drug parks. While some are near completion, many are still in early stages but carry strategic importance. These hubs are key to cut API import dependence, secure supply chains, and position India as a globally competitive manufacturing powerhouse

Maha Integrated Life Sciences City Limited (MiLeS City), Maharashtra

One of the key announcements during the Pulse Maharashtra Summit held over March 27-28, 2026 was the unveiling of the state's bulk drug park, to be built by Ramky Infrastructure, under a PPP model with Maharashtra Industrial Development Corporation (MIDC). With substantial initial anchor investments from Pharmax (committed INR 470 crore) and Savvycare (INR 50 crore), the bulk drug park seems off to a good start.

As per a BSE filing of March 13, 2026, MIDC has appointed Maha Integrated Life Sciences City Limited (MILeS City), a wholly owned subsidiary of Ramky Infrastructure as a 'developer for the development, operation, maintenance and management of the upcoming high-tech pharmaceutical park in Dighi Port Industrial Area Mangaon and Roha Taluk, Raighad District in the state of Maharashtra on PPP Basis'.

This project has been awarded for a period of 95 years concession including construction period of five years. The project includes development of an industrial park over an area of 1000 hectares in Raigad District of Maharashtra primarily consisting of an Industrial Zone, Commercial Zone, Common Amenities, Utilities, Open spaces and Roads.

As per the filing, the Life Sciences City 'aims to act as a one stop holistic solution to the Life Sciences and Pharma Sector in providing them with all the requisite sustainable Infrastructure for establishing their units.' The total project cost is estimated at around INR 3,000 crores and the company would be able to earn revenue by way of Land Lease Premium, Development Charges, Maintenance income for the Services and Operation income from the Utilities.

Speaking on the sidelines of Pulse Maharashtra, Dr Divakar Marri, Vice President & SBU Head - SPV, Ramky Infrastructure drew attention to the name of the project, highlighting that the plan is to go much beyond being a bulk drug park. "We are going to develop the entire value chain of the life sciences sector. That is the reason we have not named this park as a bulk drug park or a pharma park. We are calling it a life sciences city."

Dr Marri revealed that MiLeS City would offer end-to-end facilities, right from basic chemicals, key starting materials, APIs, bulk drugs, formulations, covering the entire value chain. To address the talent issue, there are plans to start a skill development academy.

RIL has already proved its mettle in setting up and operating pharma cities in India, given that it successfully operated the Jawaharlal Nehru Pharma City (JNPC) in Visakhapatnam (Vizac) since 2005. Two decades later, will the Ramky Group recreate the same success in Maharashtra?

Ramky Infrastructure obviously hopes to leverage the experience of running a pharma park for two decades and as Dr Marri indicated, "fill in the gaps".

All industries have to prepare for elevated standards of Environment, Social and Governance (ESG) to comply with national and global standards. This is more challenging for pharma manufacturing, as hazardous effluents require appropriate treatment before discharge. It is hoped that Ramky Infrastructure and MiLeS City will set new benchmarks on this front, given the current global focus on climate change and preventing environment degradation.

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Nakkapalli Bulk Drug Park, Andhra Pradesh

Andhra Pradesh was one of three states selected by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India in 2020 under the "Promotion of Bulk Drug Parks" Scheme to establish Bulk Drug Parks, along with Gujarat and Himachal Pradesh. First mooted in 2022 as a bulk drug park in Kakinada, the project faced a delay due to land acquisition issues. The Department of Pharmaceuticals, GoI, released Rs.225 crore towards the first instalment in March 2023. As per a report on the Andhra Pradesh Industrial Infrastructure Corporation (APIIC) site, in September 2023, the Andhra Pradesh government approved the relocation of the bulk drug park project from Kakinada to Nakkapalli in Anakapalli District, as over 3000 acres of land was already available with APIIC.

On January 8, 2025, Prime Minister Modi laid the foundation for the new bulk drug park at Nakkapalli. The Bulk Drug Park is tipped to be an integrated pharma zone, due to its proximity to the Visakhapatnam-Chennai Industrial Corridor (VCIC) and Visakhapatnam-Kakinada Petroleum, Chemical and Petrochemical Investment Region.

Replying to a Lok Sabha query on February 6, 2026, Union Minister for Chemicals and Fertilizers, Jagat Prakash Nadda gave details of the progress on the three new bulk drug parks. The total project cost of the Nakkapalli bulk drug park is Rs 1876.66 crore, with the project cost of Common Infrastructure Facilities (CIF) as Rs 1457.01 crore.

> Andhra Pradesh's bulk drug park, shifted to Nakkapalli after delays, is progressing with key infrastructure work underway and environmental clearance secured in January 2026

The Minister's written reply indicated that infrastructure tenders for internal roads, power, water, drainage, and utility buildings have been awarded and work is progressing at the Nakkapalli site. Fencing along the project boundary has been completed, the external water pipeline is under installation, and approval of the power infrastructure design is under process. Land acquisition for additional land is underway, and environmental clearance for the land was granted in January 2026.

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Lalitpur Pharma Park, UP

The Lalitpur Pharma Park, also referred to as the Lalitpur Bulk Drug Park, is a state-led industrial project being developed by Uttar Pradesh State Industrial Development Authority in the Bundelkhand region of Uttar Pradesh. The project is conceived as a dedicated ecosystem for bulk drugs, KSMs, APIs and formulation units, with the objective of reducing import dependence and strengthening domestic manufacturing. UPSIDA's 2026 Expression of Interest (EOI) positions the park as a plug-and-play pharma zone with common infrastructure facilities designed to lower production costs and support self-reliance. In January 2024, the Uttar Pradesh government announced plans to develop a bulk drug park in Lalitpur with an estimated investment of Rs 8,000 crore, with initial development proposed on around 300 acres and MoUs worth Rs 11,000 crore already signed. By July 2024, preparations for common infrastructure had begun, and a Global Expression of Interest was issued to identify development partners.

The park is entirely state-sponsored, spread over approximately 1,472 acres, with Phase I covering around 350 acres and already under development, supported by environmental clearances. The state also projected around Rs 250 crore investment in core infrastructure, with expected private investment of about Rs 12,000 crore and employment potential of approximately 14,000 jobs.

As of February 2026, the project has entered a more defined implementation stage. Phase I, covering roughly 352–353 acres, is focused on bulk drugs, formulations, and common facilities, while subsequent phases are under development. The Detailed Project Report (DPR) has been approved, and environmental clearances are in place. In April 2026, UPSIDA signed an agreement with Jawaharlal Nehru Port Authority to strengthen maritime connectivity, positioning the park for export-oriented growth.

At its current stage, the Lalitpur Bulk Drug Park is under active development, with foundational infrastructure, approvals, and investor outreach progressing in parallel.

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Gopalpur Pharma Park, Odisha

For a long time, India's pharma growth story has been concentrated in a few established regions. What is beginning to shift now is where the next set of opportunities might emerge. In that context, Odisha's recent policy push offers an early indication of how new geographies are positioning themselves within the life sciences value chain.

With the launch of the Pharmaceutical and Medical Devices Policy 2025, the state is making a more structured entry into a sector where it has historically had limited presence. Odisha is positioning itself as part of the next wave of pharma and MedTech expansion.

The state aims to attract ?25,000 crore in investments and generate over one lakh jobs by 2030, while building an integrated ecosystem spanning pharmaceuticals, bulk drugs, and medical devices. As outlined in the IPICOL policy brochure, the intent is to position Odisha as the "Eastern Gateway" of India's health economy, addressing a regional gap in life sciences manufacturing.

This comes at a time when supply chains are realigning and expansion costs are rising in established hubs, creating space for newer regions to emerge as alternatives.

On the ground, this is translating into a cluster-led development model centred around a set of emerging pharma and MedTech parks. Odisha is establishing a 500-acre Pharma Park at Khordha–Nayagarh and a 200-acre MedTech Park at Khordha under the new policy. Designed as plug-and-play ecosystems for API, formulation, and device manufacturing, these parks are expected to enable 12–18 month faster project initiation due to their proximity to Bhubaneswar.

Location and connectivity remain central to this strategy, with access to highways, the airport, and, in the case of Gopalpur, port-linked infrastructure.

The policy also leans on incentives to attract early investments, including a 30 per cent capital subsidy on plant and machinery, land subsidies linked to employment, and support for power infrastructure, alongside faster approvals through pre-identified land banks.

Early signals suggest growing interest. At a state-led summit held in December last year, 69 MoUs were signed across pharmaceuticals, MedTech, and industrial infrastructure, amounting to over ?7,000 crore in investment commitments.

At the same time, the state is positioning its relatively late entry as an advantage. As Hemant Sharma, Additional Chief Secretary, Industry Department, Government of Odisha, noted in an earlier story featured at Express Pharma, the aim is not to compete directly with established hubs, but to offer a viable alternative for companies looking to expand beyond saturated locations. Whether this translates into sustained industry presence will depend on how effectively these plans move from policy to execution.

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AI: Revolutionising Pharma R&D

Artificial intelligence is transforming pharma laboratories,across drug discovery, formulation development, and manufacturing processes. Industry leaders believe it will accelerate innovation, while human expertise and regulatory validation remain indispensable.

From one-size-fits-all to precision medicine: AI's impact on pharma

Drug development has traditionally followed a "one-size-fits-all" approach, with medications designed for broad populations rather than individual patient needs. However, this model is undergoing a significant transformation. AI is driving this shift by leveraging large datasets, predictive modelling, and advanced analytics to design therapies tailored to specific patient factors such as genetics, lifestyle, age, and disease progression.

What once seemed like a daunting task is now increasingly manageable through AI. These systems can process vast amounts of clinical, genomic and real-world patient data, identifying patterns that would be difficult for humans to detect. This enables a deeper understanding of how different patient subgroups respond to specific active ingredients and excipients. As a result, drug formulations can be optimised for greater efficacy, reduced side effects and improved patient adherence. AI is also playing a critical role in accelerating formulation development. Machine learning models can simulate how drugs interact with various excipients under different conditions, significantly reducing reliance on trial-and-error experimentation. This not only shortens development timelines but also lowers early-stage development costs.

In the case of complex generics, such as topical formulations, inhalers, transdermal patches and long-acting injectable, success depends on precisely replicating the reference product's performance characteristics, and not just its chemical composition. AI can help identify subtle differences in formulation and device design, enabling developers to achieve bioequivalence more efficiently. For biologics and other large complex molecules, AI-driven tools can predict protein structure, stability and interactions. This supports the design of formulations that enhance shelf life and minimise immunogenicity. AI can also assist in identifying optimal buffers, stabilisers, and storage conditions, all of which are critical for maintaining the integrity of biologic drugs. In advanced drug delivery systems such as nanoparticles, liposomes, and implantable devices, AI can model how drugs are released and distributed within the body. This capability helps improve therapeutic outcomes while minimising systemic exposure.

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Furthermore, the integration of digital health technologies, including smart inhalers and wearable injectors, creates continuous feedback loops in which patient data is used to refine and personalise treatment strategies.

The adoption of AI in pharmaceuticals is accelerating due to several converging factors. The COVID-19 pandemic underscored the need for faster and more adaptable drug development pipelines. At the same time, regulatory agencies are increasingly supportive of digital innovation and pharmaceutical companies are investing heavily in AI-driven research and development. The rise of precision medicine, coupled with growing patient expectations for individualized care, is further pushing the industry toward personalized solutions.

Despite these advancements, challenges remain. Integrating AI into existing pharmaceutical workflows requires significant infrastructure and expertise. Concerns around data privacy, regulatory uncertainty, and the availability of high-quality, standardised datasets must be addressed. From a patient perspective, AI-enabled personalisation promises more effective and safer treatments. Therapies tailored to an individual's genetic profile, disease state and lifestyle can lead to better outcomes, fewer adverse effects, and smarter drug delivery systems. However, issues such as data privacy, trust and transparency are critical, particularly when sensitive health and genomic data are involved. Additionally, highly personalized therapies may raise concerns about affordability and the potential widening of healthcare disparities if not managed carefully.

Ultimately, real-world data originates from patients, regulators provide oversight and guidance, and the industry drives innovation. When implemented responsibly, AI can serve as an unbiased integrator, aligning these stakeholders and providing the direction needed to advance the future of pharmaceutical development.

Next-gen pharma labs powered by AI

In the coming 3–5 years, the role of AI in pharmaceutical laboratories is set to expand dramatically, reshaping the landscape of drug discovery and development. AI-powered tools will increasingly be integrated into every step of the research pipeline, from screening vast chemical libraries to predicting molecular interactions and potential side effects. This acceleration in computational capabilities will help researchers identify promising drug candidates far more efficiently, reducing both the time and costs traditionally associated with bringing new therapies to market.

Additionally, advanced machine learning will enhance the design and execution of clinical trials by analysing complex datasets for patient selection, risk assessment, and outcome prediction. The rise of personalised medicine—treatments tailored to an individual's genetic profile—will be accelerated by AI's ability to interpret genomic and biomedical data. Laboratory automation, powered by AI, will optimise workflows, reducing manual errors and enabling real-time monitoring of experiments. Such advancements are also expected to foster greater collaboration between interdisciplinary teams, breaking down traditional silos in pharma research. Ultimately, AI's evolution in pharma labs is poised to drive unprecedented innovation, leading to safer, more effective therapies and improved patient outcomes in the near future.

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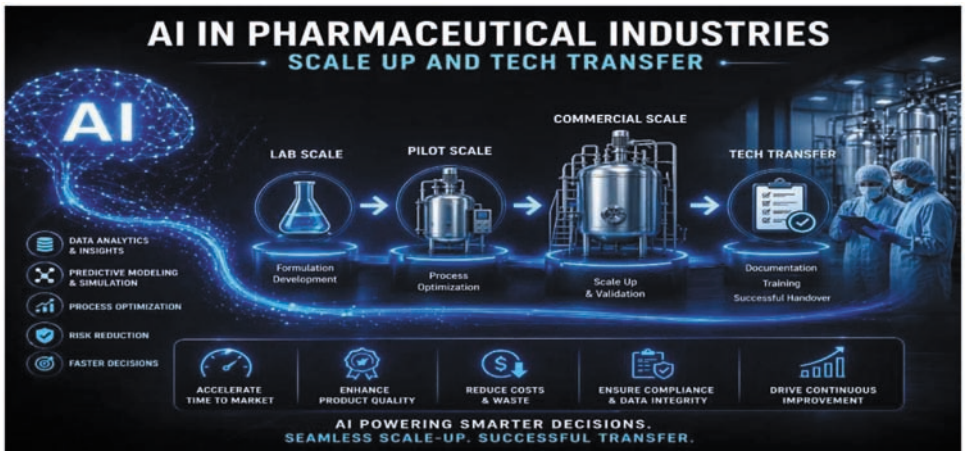
R & D Head, India Sub Continent, Haleon

AI & advanced technologies: Powering India's next pharma leap

From tech transfer to regulatory filing — AI is reshaping every stage of pharma development, globally and in India.

DR KHALID AKHTER ANSARI
Senior Director R&D, Technical Operations, Rising Pharmaceuticals



India's pharma 4.0 moment

India, the world's largest generic medicine supplier, is at a defining crossroads. Advanced laboratory technologies — PAT (Process Analytical Technology), digital twin modeling, and AI-assisted formulation platforms — are transforming how Indian companies design and commercialize drugs. Rising Pharmaceuticals, Dr. Reddy's, Cipla, and Biocon are already integrating machine learning into R&D workflows, compressing development timelines and building stronger regulatory dossiers. With over 3,000 FDA-approved facilities and a $50 billion export market, India has both the scale and urgency to lead this transformation.

Global AI tools reshaping pharma

Globally, AI is operational infrastructure, not aspiration. Key platforms driving change include: Schrödinger and Dotmatics for AI-guided molecular design and formulation optimisation; DataRobot and IBM Watson for predictive analytics across clinical and manufacturing datasets; Veeva Vault for intelligent eCTD regulatory submissions and lifecycle management; and Synthesia AI for automated training and tech-transfer documentation. NLP engines now surface pharmacovigilance signals months earlier than traditional methods, while AI-driven DOE platforms compress multi-variable optimisation from months to days.

AI in tech transfer & scale-up efficiency

Tech transfer — pharma's most expensive failure point — is being transformed by AI. Predictive process models simulate scale-up behavior from lab to commercial equipment, sharply reducing failed batches and deviations. Digital twins identify Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs) before the first commercial run. For injectables and biologics, AI-guided comparability protocols and real-time release testing frameworks replace time-consuming QC paradigms — directly improving batch success rates, reducing investigation cycles, and compressing submission timelines for USFDA and EMA filings.

FDA's perspective on AI

The FDA has moved decisively from observation to active engagement. Its AI/ML Action Plan encourages AI-assisted CMC submissions, predictive stability modeling, and real-time batch release. The Emerging Technology Program (ETP) has approved continuous manufacturing lines governed by AI control systems. FDA's Process Validation Guidance and PAT framework now explicitly reference AI tools. For regulatory teams, AI-powered eCTD assembly, intelligent gap analysis, and automated literature review are reducing deficiency letters — turning compliance from a bottleneck into a lasting competitive advantage.

AI in drug discovery: Accelerating innovation while wet labs remain essential

AI can significantly reduce trial-and-error, but cannot replace lab validation. However, the work pattern is shifting from blind experimentation hypothesis-driven, AI-guided experimentation. AI usage is causing paradigm shift in drug discovery, but the biological complexity of the human body ensures that "wet lab" validation remains good standard.

Instead of screening existing libraries, generative AI "builds" molecules from scratch to fit a specific target. This has reduced physical screening costs by 80–90 per cent as it helps researchers synthesise the most promising candidates and instead of synthesising 1,000 molecules and test and discard, only the top 40-50 high-probability candidates are chosen. AI also helps explore genomics, proteomics, transcriptomics and corroborate with real-world data and hasten the process. AI also Identify disease pathways and novel targets better and earlier than traditional biology-first approaches

Preclinical studies

AI models rationalise preclinical studies by enabling effective simulation of Toxicity (hepatotoxicity, cardiotoxicity), PK/PD behavior and potentially reduce animal studies.

However, lab validation in preclinical toxicity studies is necessary as the effects in a complex animal and system & predictability in human systems are still too unpredictable for pure simulation. These include but are not limited to iImmune responses, idiosyncratic toxicity and microenvironment interactions (tumor, CNS, microbiome). These require wet lab and clinical confirmation. Also, FDA and EMA currently mandate physical evidence (In Vitro and In Vivo) for every "AI-designed" drug.

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Clinical trials

AI usage has been instrumental in reducing redundancy, improving accuracy and hastening the conduct and process. Usage of AI helps in better patient stratification (biomarkers, digital twins), predictive enrolment and endpoint modelling, adaptive trial simulation. The major benefits include fewer protocol amendments, reduced trial failures due to poor design/

However, as per regulatory requirements such as ICH GCP E6(R3), NDCT 2019 (India), empirical evidence is mandatory as AI outputs are considered supportive evidence and not acceptable as standalone evidence.

For areas like Biosimilars, Peptides / ADCs, complex injectables, AI is most effective in formulation optimisation, process parameter prediction, immunogenicity risk modeling

However, AI cannot replace essential testing/ studies such as analytical comparability studies, PK/PD bridging, clinical equivalence trials.

Conclusion

AI including generative AI is a great enabler in drug discovery, R&D and preclinical, clinical studies, however, additional wet labs experimentation, analytical testing, clinical and preclinical invivo and invitro testing cannot be matched in terms of real life evidence generation and also unwaivable in purview of regulatory guidelines.

This is the current scenario but as we evolve in research and as AI becomes more intelligent, there is scope for changes and alteration in approaches towards research and development.

Role of AI in transforming pharmalaboratories

Artificial Intelligence (AI) is emerging as a key force transforming all the sectors in the industry. How can a knowledge industry like the Pharma sector be away from it? Especially when it relies on smart research, quality and smart operations. AI, which was largely limited to simple automation, is now reshaping how pharmaceutical laboratory activities are carried out. Modern pharmaceutical labs are evolving into intelligent, data-driven environments to support faster translation, be it generic or innovation of higher quality, with enhanced decision-making.

Impactful transformation

AI is moving laboratories from routine execution to predictive and decision-centric systems. For example: In Drug discovery and R&D, machine learning models analyze large chemical and biological datasets. It helps identify new drug targets, predict molecular interactions, and optimize lead compounds. This significantly reduces timelines and experimental costs. In analytical development, AI-powered image recognition and spectroscopy interpretation improve accuracy in impurity profiling and stability testing. Advanced pattern recognition detects subtle trends that human analysis may miss. Millions of Toxicology slides are screened rapidly to reduce it to few slides that require human intervention. In Formulation or API development, AI systems can design experiments, analyze real-time results, and refine hypotheses. Human scientists guide direction to AI which then accelerates execution and learning. These labs are shifting from reactive problem-solving spaces to continuous learning and optimization systems.

AI is playing an important role in quality assurance and regulatory compliance, especially in GMP-regulated environments. For example, AI analytics applied to LIMS and ELNs can detect anomalies and predict deviations. Early alerts can help move manufacturing from reactive investigations to proactive quality management. NLP tools can support documentation review and data integrity checks. In Manufacturing it can help Predictive maintenance to minimize instrument downtime. Integration with Process Analytical Technology (PAT) tools could improve process control and efficiency. The most important role and a low hanging transformation/implementation is knowledge management. AI structures unorganized scientific data into usable insights. It preserves institutional knowledge and helps to speed up scientific and business decisions.

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Careful adoption

Besides these advantages, there are several key barriers to AI adoption in Pharma Laboratories. Several challenges limit its widespread implementation, some of the problems Industry is facing is- Data quality and standardization. Lab data is fragmented across legacy systems and in inconsistent formats. Such poor data management reduces AI effectiveness. Besides, there are infrastructure limitations. AI requires scalable computing, secure cloud environments, and system integration. This remains a challenge, especially for mid-sized organizations. Finally, the cost and skills. The AI implementation expenses include technology, validation, cybersecurity, and skilled talent. Continuous training of talent, and change management are essential which is a part of bringing major cultural shifts. There are also genuine regulatory concerns. It is difficult to trust AI systems that may look like "black-box" to scientists. Meaning, they are still not sure if it makes them absolutely free of checking data when it comes to final submissions. Regulatory validation of AI models is quite complex.

Way forward

India has already established itself as a global hub for affordable medicines of high-quality. But when it comes to lab technology, smart operations and quality processes, the industry must adapt to changing needs towards the use of this advanced artificially intelligent technology. For that, it needs to invest in data standardization and digital infrastructure, focus on human–AI collaboration, not replacement, upskill scientists and quality professionals, embed AI thoughtfully within validated, compliant workflows, engage regulators early in digital transformation initiatives.

Conclusion

AI has the potential to redefine pharmaceutical laboratories—enhancing quality, reducing costs, and accelerating innovation. Companies that successfully integrate AI with people, processes, and compliance will lead the next phase of India's pharmaceutical growth.

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India's pharma future: Smarter labs, faster development, better innovation

Over the next five years, Indian's pharma R&D and manufacturing lab technology landscape will undergo tremendous transformation. This transformation would revolve around digitalisation, automation and predictive analytics which would help in faster drug development.

Already many excipient manufacturers have initiated AI driven compatibility and formulation development guidance online platforms. For drug excipient compatibility there is software available which provides predictive analytics such as PharmaDem & Formulation AI. This software provides an intelligent, category-driven approach to formulation design by leveraging an extensive excipient database. Unlike manual trial-and-error, this module applies AI-powered compatibility screening to systematically shortlist the most stable excipients for each functional category (e.g. binder, disintegrant etc). Usage of these AI developed tools would help in shorter formulation development timeline and cost optimisation.

With 'go green' evolution and sustainable growth transitioning in digital workflows with usage of electronic lab notebooks, real time data sharing has already been initiated in many pharma R&D & manufacturing plants.

Cloud based platforms will enable real-time monitoring, remote operations, and seamless data integration across R&D, manufacturing, and quality functions. This will support regulatory compliance and faster audits. During Covid time period, the world has experienced implementation of online audits for seamless regulatory compliance.

Another major shift which has initiated is continuous manufacturing, with adoption of PAT tools for high volume products which has reduced dependence on end-product testing and enabling real-time release.

Many companies have initiated investment in biologics, biosimilars and oncology products. In future India will see growth in these areas including personalized medicine. Formulation development of such products

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requires more sophisticated lab infrastructure and analytical capabilities.

Pharma formulation development is a highly complex, interdisciplinary process balancing API physicochemical properties, stability, bioavailability, and manufacturability. Each chemical or biological molecule's properties change even though the basic structure remains the same. This change in physicochemical properties limits the direct AI adoption. AI can be used for initial screening of excipients to reduce the number of experiments; however understanding each molecule complexity is the biggest challenge.

A variety of formulations are developed in R&D which are not limited to tablets, capsules, semisolid, sterile, inhalation formulations. With so many formulations, the manufacturing process also changes based on product criticality such as solubility, stability, bioavailability, active content etc.

AI provides predictions based on historical data, while human expertise is required to validate, scale, and interpret those predictions practically. Formulation development work involves physical material, manufacturing actual lab trials. Based on molecule properties & excipient properties, granulating solvent quantity may change. Hence physically reality lab trial batches may not behave based on predictive digital models.

Usually in R&D batches are manufactured at smaller scale & scientists performing the trials have complete knowledge of product development and molecule behavior. With AI predicted models many times it is observed that often AI miss this knowledge and experience scientists are necessary to bridge this scale up gaps such as tablet lamination, capping or content uniformity issues.

During the initial stage of validation batches manufacturing when sufficient historical data is not available adopting AI also becomes risky. Human experience is required to troubleshoot unexpected issues, such as batch-to-batch variability in excipients or unexpected chemical degradation in specific packaging.

Regulatory bodies (FDA, EMA) require clear justifications for Quality by Design (QbD) which necessitates human interpretation of the AI-suggested path.

To conclude AI can help for initial screening and compatibility experiments and optimisation, however adoption for formulation development completely may not be possible which needs human experience and expertise.

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India's counterfeit drug crisis and the role of AI

Dr Sumedha Nadkar, Pharma Strategy and Technology Consultant highlights that counterfeit high-value drugs in India are endangering patient safety and exposing supply chain gaps. AI can help, but enforcement and awareness are critical to stopping the threat

India is facing a perilous rise in counterfeit high-value medicines, from cancer immunotherapies like Keytruda (pembrolizumab) to fast-growing weight-loss injections such as tirzepatide and semaglutide. These are not routine quality lapses—they are organised criminal operations that put patients at immediate risk.

In today's healthcare ecosystem, supply chain is no longer a support function—it is the engine of survival in the VUCA world. These demands have increased the need for organisational and government agility, resilience, and strategic flexibility. Even with AI tools embedded in our supply chain, despite latest technological tools such as IoT-enabled visibility, real-time data, predictive analytics, and connected ecosystems, we as a nation are still struggling to root out the foundational disruptors that threaten patient outcomes.

The counterfeit saga

Recent investigations have shown how counterfeiters exploit gaps in hospital waste disposal and supply chains. In the case of Merck's Keytruda, a therapy which has shown promising results across several cancers, particularly in advanced or metastatic stages, used authentic vials were allegedly collected, refilled with ineffective or unrelated substances such as saline or antifungal medication, resealed, and resold as genuine therapy. For cancer patients, the consequence is devastating: no therapeutic benefit, delayed treatment, avoidable toxicity, and in some cases, fatality.

The same pattern is now appearing in the obesity and diabetes segment. In Gurugram, authorities recently uncovered a counterfeit injectable racket valued at over 70 lakh, involving fake versions of popular GLP-1 and GIP-based therapies. Raw materials, including peptides, were allegedly sourced from vendors on the Chinese e-commerce platform Alibaba, while finished pens were sold online via IndiaMART at a 27 per cent discount to the genuine product's price. Packaging labels mimicking the original were also recovered. The seized items were not stored under proper refrigeration, raising serious safety concerns. Pharma company Eli Lilly, which manufactures Mounjaro, welcomed the enforcement action by Haryana State FDA and stated that it is actively supporting investigations to safeguard patients from counterfeit medicines.

With the surging demand for these medicines, illegal sellers are targeting desperate buyers through discounted offers, informal channels, and unverified online listings.

For the pharma sector, this crisis highlights three urgent vulnerabilities.

- Packaging and vial recovery controls remain weak, allowing criminals to reuse genuine containers.
- Serialisation and QR-based authentication, while important, are only effective if they are implemented through the entire cycle upto the end-user.
- Public awareness is still low, especially when steep discounts make counterfeit products appear attractive.

Actions beyond AI

AI is emerging as a useful line of defense in all walks of life today. Computer vision tools can detect subtle packaging anomalies, handheld spectroscopy devices can help verify chemical identity in the field, and AI-based monitoring systems can flag suspicious supply-chain movements or illicit online sales.

However, technology alone will not solve the problem. Stronger destruction protocols for used primary packaging materials, tighter risk-based manufacturer distributor audits and enforcement, active market surveillance, and rapid batch-level reporting are absolutely essential.

Counterfeit medicines are no longer a peripheral compliance issue. They are a direct threat to treatment outcomes, brand trust, and patient safety—and they demand an industry-wide action coupled with strict government enforcement

What can pharma companies, healthcare providers and patients do?

For pharma companies, the priority is clear: build anti-counterfeit protection across the full product lifecycle, not just at the point of manufacture.

For healthcare providers and hospitals, vigilance in procurement and disposal is critical. For patients, the safest route remains authorised pharmacies, verified invoices, and consultation with treating specialists especially before purchasing any high-cost, potent, life-saving therapies.

AI- Boon and bane?

How AI helped the regulators

- **Supply chain surveillance:** AI-driven "Track and Trace" proposals and the QR code mandate for India's top 300 brands is a significant step to digitally monitor drug movement.
- **Marketplace crawlers:** Regulators used AI algorithms to scan platforms like IndiaMART and social media to find and shut down listings for unapproved and counterfeit weight-loss drugs.

The 'AI-Generated' threat

- **Fake prescriptions:** Recently, the All India Organisation of Chemists and Druggists (AIOCD) warned the Prime Minister in that AI-generated medical prescriptions were being used to illegally buy restricted drugs like opioids and psychotropics from e-pharmacies. Criminals used AI to fabricate hospital letterheads and doctor details that appeared authentic to automated verification systems.
- **Static vs dynamic codes:** Many current QR codes are "static," meaning they contain fixed information that does not change. Counterfeiters have successfully replicated these codes on fake packaging (e.g., Levipil 500), which then scan as "genuine" because the system does not always detect if the same unique ID is being scanned in multiple locations simultaneously.
- **Digital leakage:** There have been instances where active QR codes were leaked from vendors or manufacturing plants before the genuine drugs even reached the market.
- **Cost for SMEs:** Small and medium-sized manufacturers face high costs for the specialised printing and IT infrastructure required, sometimes leading to compromised standards.
- **Low consumer awareness:** A lack of government-led public awareness campaigns means few patients actually scan the codes to verify their medicine.

Final thoughts

Counterfeit medicines are no longer a peripheral compliance issue. They are a direct threat to treatment outcomes, brand trust, and patient safety—and they demand an industry-wide action coupled with strict government enforcement.

By imparting and promoting shared knowledge at the grassroots level, it is an absolute must to educate and empower healthcare and industry professionals even at the grassroot level to embrace their responsibility, ensuring they take proactive and ethical actions to safeguard patient safety.

For patients, outreach programs to disseminate critical health information cannot be compromised. Tools such as visual aids, utilising , community-led workshops, and local language resources can unquestionably bridge the gap for the underprivileged patient pool. Lat but not the least, the success of our healthcare system is measured by a single standard: the safety and well-being of the patients we serve.

Beyond scale: Rethinking new frontiers in building excellence

At the Injectable Innovations Conclave 2026, hosted by ***Express Pharma***, industry leaders examined the trends, technologies and strategies shaping the next phase of injectable growth, reports **Neha Aathavale**

Hyderabad played host to a room full of hard questions as *Express Pharma* brought back the second edition of the Injectable Innovations Conclave last month. Injectables, once a specialised corner of formulations, are now moving to the centre of India's pharma growth story. The shift is already visible, but like in every other segment of pharma, the conversations returned to a familiar and almost unanimous refrain that the industry has been circling for a while now, that growth alone is no longer enough.

Built around the theme, '*The new frontiers in injectable excellence*', the discussions stayed grounded in current realities. A market projected to reach $7.6 billion by 2033 comes with rising expectations. Regulatory scrutiny is tightening, import dependencies persist, and gaps in areas like biosimilars and oncology injectables remain. The conclave brought these threads together to examine what it will take for Indian players to move from just volume-driven growth to credibility built on quality, capability and consistency.

L - R : Shaunak J Dave, CEO & MD, Antares Vision Group; Raja Bhanu, DG, Pharmexcil; Thomas Bühler Heinrich, Director Sales Africa, Middle East & Asia, Optima Pharma GmbH; Ankur Shah, Founder & Chairman, Invengene; Vishal Wagh, Director, Adam Fabriwerk; Dr Raches Ella, CDO, Bharat Biotech; Atul Shastri, President – Global Operations, Eugia Pharma Specialities; and Viveka Roychowdhury, Editor, Express Pharma

Reframing India's injectable identity

Momentarily stepping back from the immediate pressure points, the keynote address brought the bigger picture into focus, shifting the lens from current challenges to the identity of India's injectable ecosystem.

Dr Raches Ella, CDO, Bharat Biotech, centred the address on a question the industry can no longer avoid. India's healthcare model has been built on affordability through generics and biosimilars, but the next phase cannot rely on cost advantage alone. Affordability, he emphasised, must come from innovation, not replace it.

From there, the focus moved to what this shift requires. Dr Ella called for India to evolve into a platform technology hub, building strength in mRNA, biologics, immunotherapies, rare diseases and personalised medicine. He also pointed to a persistent gap between strong manufacturing and weaker early-stage research and clinical translation.

Drawing from Bharat Biotech's approach, he stressed the need for original, platform-led innovation with the confidence to develop and supply novel vaccines globally. The broader shift was clear. India must move from being the world's pharmacy to an innovation partner, where scale is matched by scientific depth and long-term value.

Building the next decade of injectables

If the keynote zoomed out to define direction, the next conversation brought the focus back to execution, where that ambition is tested.

The first panel discussion, *'The next decade of injectables: Science, scale and new therapies'*, was moderated by Viveka Roychowdhury, Editor, Express Pharma. It also featured industry stakeholders Ankur Shah, Founder & Chairman, Invengene, Atul Shastri, President – Global Operations, Eugia Pharma Specialities, and Raja Bhanu, DG, Pharmexcil, who discussed the key idea that the next phase of growth will depend as much on how products are built as on what is built.

A major theme was the need for early collaboration and globally scalable product design to de-risk investments and secure long-term partnerships. The experts highlighted that success will hinge on how smoothly products move from bench to floor, with manufacturing and supply chain considerations built in from the start.

This also brought up a structural gap. While India has strong manufacturing infrastructure, its R&D ecosystem is still evolving. The disconnect between lab and large-scale production is often where compliance and sterility challenges emerge.

Technology is beginning to shift this. AI, machine learning and IoT are being used to reduce human error, strengthen sterility assurance, and compress timelines, though human expertise remains central to quality. There was also clear curiosity around AI, with several attendees raising questions on its real-world applications, signalling a shift from interest to intent.

The discussion closed on a strategic note. With rising geopolitical uncertainty, building self-reliance through stronger domestic networks is becoming essential, even if gradual. The consensus was clear, the groundwork for this shift needs to begin now.

Rewiring execution

From broader questions of scale and collaboration, the sessions moved into the granular layer of execution.

A key theme was how manufacturing itself is being rethought. Vishal Wagh, Director, Adam Fabriwerk, highlighted modular 'superskids' as fully integrated, pre-tested systems that improve efficiency, compliance, and scalability. He pointed to gains in speed, cost, and risk reduction through off-site construction and parallel execution, alongside better sterility control in automated, controlled environments.

This tied into the growing complexity of manufacturing. Thomas Bühler Heinrich, Director Sales Africa, Middle East & Asia, Optima Pharma GmbH, noted that advanced containment systems like isolators and RABS are becoming regulatory expectations, while diverse packaging formats are adding operational challenges. He also stressed tighter control over aseptic environments, including airflow and visualisation studies, as critical for compliance.

From systems, the focus shifted to delivery. Birendra Kumar David, CTO, Graviti Pharmaceuticals, spoke about the rise of device-based formats, with pre-filled syringes, auto-injectors and pens now making up nearly 55 per cent of the market. Driven by home healthcare and patient convenience, therapies like biologics and GLP-1 are increasingly designed for subcutaneous, device-led delivery, requiring early integration of design, fill-finish, and supply chain planning.

Quality, in parallel, is evolving. Shaunak J Dave, CEO & MD, Antares Vision Group, highlighted rising recalls linked to sterility issues and the push for advanced inspection systems. End-to-end traceability, supported by serialisation and AI-driven inspection, is improving transparency and reducing errors, while technologies like VDLD-PDLD and integrated AVI systems enable precise, non-destructive testing.

Bringing these strands together, Dr Vellaian Karuppaiah, COO, Acme and Immacule Group, stressed that technology alone cannot ensure quality, culture plays an equal role. Ownership, discipline, and accountability remain central, alongside a shift from reactive

Dr Raches Ella, CDO, Bharat Biotech

Vishal Wagh, Director, Adam Fabriwerk

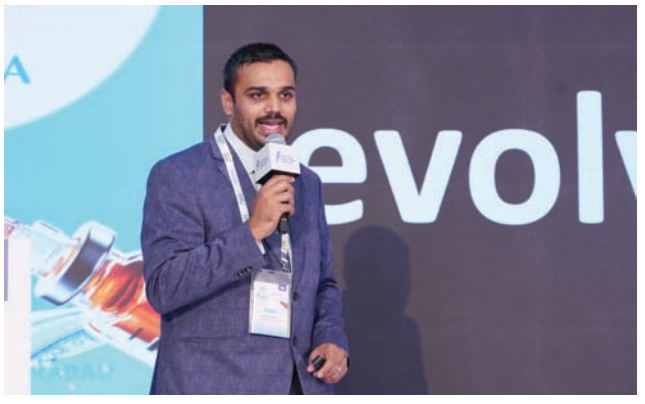
Thomas Bühler Heinrich, Director Sales Africa, Middle East & Asia, Optima Pharma GmbH

Birendra Kumar David, CTO, Graviti Pharmaceuticals

L-R: Ms Viveka Roychowdhury, Editor, Express Pharma (MODERATOR); Ankur Shah, Founder & Chairman, Invengene; Atul Shastri, President - Global Operations, Eugia Pharma Specialities; Raja Bhanu, DG, Pharmexcil

Shaunak J Dave, CEO & MD, Antares Vision Group

Dr Vellaian Karuppaiah, COO, Acme and Immacule Group



Enoch Daniel, Director, Svan Analytical Instruments

to predictive, data-driven systems. His key point was clear, scale without capability does not create advantage, it amplifies risk.

Rethinking sterility beyond checklists

From systems, design, and delivery models, the focus returned to the layer that quietly holds injectables together: how sterility is defined, maintained, and demonstrated as regulatory expectations continue to tighten.

The panel discussion, 'Sterility & compliance 2026: What global regulators expect today', moderated by Rashmi Ranjan Patra, Technical Advisor, brought together Soumya Kumar Panda, Sr VP – Operations, Mankind Pharma, Rakesh Kumar Sinha, Sr VP & Head-Drug Product Manufacturing, Biological E., Pradipta Kumar Swain, COO, Innoxel Lifesciences, Nirvesh C Prajapati, Sr GM, Aspiro Pharma – Specialities (Hetero Group), Pavankumar R Gudi, Manager – Viral Vaccines, Serum Institute of India, and Kinshuk Roy, GM – Quality Assurance, Eugia Pharma Specialities. The core message was clear: compliance is no longer a checklist, it has become an operating system.

From that baseline, the discussion moved to how sterility is managed in practice. A key shift is the move from isolated SOPs to a connected, science-led Contamination Control Strategy, with ownership extending

INJECTABLE INNOVATION CONCLAVE 2026

L-R: Rashmi Ranjan Patra, Technical Advisor (MODERATOR); Soumya Kumar Panda, Sr VP - Operations, Mankind Pharma; Rakesh Kumar Sinha, Sr VP & Head-Drug Product Manufacturing, Biological E.; Pradipta Kumar Swain, COO, Innoxel Lifesciences; Nirvesh C Prajapati, Sr GM, Aspiro Pharma – Specialities (Hetero Group); Pavankumar R Gudi, Manager – Viral Vaccines, Serum Institute of India; Kinshuk Roy, GM - Quality Assurance, Eugia Pharma Specialities

L-R: Ranjan Chakrabarti, Independent Consultant-Biopharma & Drug Discovery (MODERATOR); Dr Shubhadeep D Sinha, Sr VP, Head – CD&MA, Hetero Drugs; Tridip Mazumder, AVP - Strategic Sourcing - Packaging Material, Dr Reddy's Laboratories; Girija Prasad Patro, AVP, Eugia Pharma Specialities; Dr Khalid Akhter Ansari, Senior Director R&D, Technical Operations, Rising Pharmaceuticals; Munindra Roy, AGM- Packaging Development, Gland Pharma

L-R: Venkatanarayan V, Ex-VP & Specialist - Digital & OE, Dr. Reddy's Laboratories (MODERATOR); Sandip Tarate, MD & COO, Tiefenbacher Group; Mahabubi Shadick, President-Quality, Bharat Biotech International; Arvind Kushwaha, VP - Quality, Kemwell Biopharma; Dr Alagumurugan Alagarswamy, Head -Complex Injectable & Ophthalmics, Alembic Pharma; Balasubramanian M, Director- MSAT & Validations, Pfzer; Veeraraju Nalla, Sr GM - Quality, Gland Pharma

Taabish Siddiqui, Product Manager (Sterile Transfer), Getinge

Daneshwar Kumar, Head – MSAT, Dr Reddy's Laboratories

Lenin Babu N, MD, Omega Scienti..c Instruments

Sridhar Balasubramanian, Head Quality – Sterile / Parenteral, Dr Reddy's Laboratories

beyond quality to design, operations, and manufacturing.

This ties directly to data integrity. Weak data leads to weak sterility assurance, making digital, real-time systems essential. The shift is towards continuous monitoring that reduces blind spots and prevents risks from escalating.

At the same time, regulatory behaviour is evolving. With unannounced inspections on the rise, especially in India, the expectation has moved to always-on readiness. Compliance can no longer be reactive, it must be built into daily operations.

Experts highlighted that this is also reshaping quality culture. It is no longer confined to documentation but visible in operator behaviour, deviations, and decisions, all under audit scrutiny. Cultural gaps are now as critical as system gaps.

On the manufacturing side, technologies like isolators, RABS, and automation are becoming baseline expectations. Their role in managing high-risk sterile processes is now central.

Yet a consistent reality remains, pointed out the panelists. Most contamination events stem from human intervention. Reducing these through better design, automation, and training is key to minimising risk at the source.

Even with advancing technology, the panel aligned on one point. Risk can be reduced, not eliminated. Human behaviour still defines outcomes, making the real shift one of designing systems where the right actions happen by default.

Engineering sterility across systems and scale

As the day progressed, the focus shifted deeper into the core building blocks of sterile manufacturing, where control, design, and technology increasingly shape how injectables are developed and safeguarded.

Across the solo sessions, a clear thread emerged: sterility is no longer something proven at the end, but something engineered from the start across systems, equipment, and human touchpoints.

A sharp framing of this came from Enoch Daniel, Director, Svan Analytical Instruments, who noted that contamination control remains one of the biggest regulatory gaps today, with most FDA warning letters tracing back to failures in this area. He mapped risk across four key exposure points, air, indirect contact parts, interventions, and system design, stressing that the challenge is not lack of technology but inconsistent control in how it is applied. His emphasis was on a shift from detection-led approaches to design-led prevention, where the aim is to eliminate the possibility of contamination itself.

That idea of removing risk at the source extended into aseptic transfer systems. Taabish Siddiqui, Product Manager (Sterile Transfer), Getinge, highlighted human intervention as a major contamination risk, with Annex 1 accelerating the shift towards gloveless, automated systems that eliminate manual touchpoints in critical zones. He noted that modern aseptic transfer solutions are now expected to deliver sterility, efficiency, and compliance together, enabling a more integrated approach without trade-offs.

From system design, the conversation moved into formulation complexity. Mr Daneshwar Kumar, Head – MSAT, Dr Reddy's Laboratories, spoke about the rise of nano and liposomal injectables, where improved targeting and bioavailability bring significantly higher manufacturing complexity. He emphasised that critical quality attributes such as particle size, drug loading, and stability directly determine outcomes, while tightly linked unit operations mean even small variations can affect final product quality. This makes scale-up highly dependent on strong alignment between CPPs and CQAs.

Reinforcing the importance of upstream control, Lenin Babu N, MD, Omega Scientific Instruments, underscored a simple principle: sterility is designed, not tested. He pointed out that final testing cannot assure sterility, as outcomes are determined by design choices, process control, and execution discipline. He also highlighted that gaps in capability inevitably surface as variability on the floor, making end-to-end integration across design, fabrication, and automation critical to reducing inconsistency in sterile manufacturing.

The discussion then extended into digital transformation. Sridhar Balasubramanian, Head Quality – Sterile / Parenteral, Dr Reddy's Laboratories, highlighted how digital-first, automated operations are reshaping injectable manufacturing by improving process control, reducing human intervention, and strengthening regulatory compliance. He pointed to isolator-based systems, integrated platforms, digital records, review-by-exception models, and end-to-end traceability as key enablers of a more consistent and future-ready manufacturing ecosystem.

Moving past generics

Until this point, the focus was on getting the systems right. This discussion shifted the lens to what comes next, and whether the industry is ready to move beyond generics into more complex segments.

The panel discussion, 'Beyond generics: Moving into complex injectables, oncology and biosimilars', moderated by Ranjan Chakrabarti, Independent Consultant – Biopharma & Drug Discovery, brought together Dr Shubhadeep D Sinha, Sr VP, Head – CD&MA, Hetero Drugs, Tridip Mazumder, AVP – Strategic Sourcing – Packaging Material, Dr Reddy's Laboratories, Girija Prasad Patro, AVP, Eugia Pharma Specialities, Dr Khalid Akhter Ansari, Sr Director R&D, Technical Operations, Rising Pharmaceuticals, and Munindra Roy, AGM – Packaging Development, Gland Pharma. The discussion made it clear that the global market has already moved past generics, and India needs to accelerate its shift to keep up.

A key concern was capability gaps, especially the shortage of specialised talent to interpret complex analytical data. As products grow more sophisticated, this is emerging as a critical bottleneck, affecting both timelines and regulatory readiness.

This transition is also being shaped by evolving therapies. In oncology, biotherapeutics have moved from adjunct use to frontline treatment, replacing traditional chemotherapy. This shift brings added demands on development and manufacturing precision.

At the same time, biosimilars continue to expand access and affordability, even as price erosion tightens margins and raises questions around long-term sustainability.

Patient behaviour is also shifting. Wider adoption of GLP-1 therapies has increased acceptance of injectables, with visibility and cultural familiarity helping normalise the route.

Looking ahead, the panel noted that while diabetes and obesity have dominated focus, other endocrine areas such as thyroid may regain traction as exclusivity periods end and pricing stabilises.

Overall, the discussion reflected a sector in transition, where moving beyond generics depends not just on entering complex segments, but on building the capability and depth to sustain that shift.

Postioning India as a global CDMO partner

The final discussion of the day brought the focus to where all of this is headed, India's position in the global injectable landscape and what it will take to strengthen its role as a CDMO partner.

The panel discussion, 'India as an injectable hub: Growing CDMO strength and global partnerships', moderated by Venkatanarayan V, Ex-VP & Specialist – Digital & OE, Dr. Reddy's Laboratories, brought together Sandip Tarate, MD & COO, Tiefenbacher Group, Mahabubi Shadick, President – Quality, Bharat Biotech International, Arvind Kushwaha, VP – Quality, Kemwell Biopharma, Dr Alagumurugan Alagarswamy, Head – Complex Injectable & Ophthalmics, Alembic Pharma, Balasubramanian M, Director – MSAT & Validations, Pfizer, and Veeraraju Nalla, Sr GM – Quality, Gland Pharma. The discussion reflected a sector that has made visible progress, but is now being measured against a higher global benchmark.

One clear marker of this progress is compliance, with OAI rates dropping from 19 per cent in 2013 to 8 per cent in 2025. This improvement is now expected to translate into stronger global positioning, especially as companies look to diversify supply chains.

In that context, the China+1 strategy came into sharper focus. The panel highlighted its role in building resilient supply networks, supported by multi-plant and multi-source models, safety stocks, and real-time digital planning for better demand visibility.

Beyond supply chains, the discussion turned to capability building. To compete globally, India needs stronger end-to-end CDMO capabilities, reduced external dependencies, and more standardised policies for advanced therapies.

Technology is central to this shift. Adoption of advanced sterile systems, closed environments, and digitalised fill-finish platforms is increasingly becoming a baseline requirement for global partnerships and consistent quality.

At the same time, regulatory alignment remains a gap. The need for clearer, more progressive frameworks, especially for biologics, was highlighted to better align with global standards and accelerate approvals.

The conversation also widened to the broader ecosystem, including clinical capabilities, advanced technologies, and incentives required to drive innovation and competitiveness. Alongside this, CDMO models themselves are evolving towards data-driven operations, simulations, and risk- and profit-sharing approaches to improve efficiency and cost structures. Taken together, the discussions point to a clear direction. India's ambition to become a global injectable hub will rest not just on manufacturing strength, but on how effectively it brings together capability, policy, technology, and partnerships into a cohesive, future-ready ecosystem.

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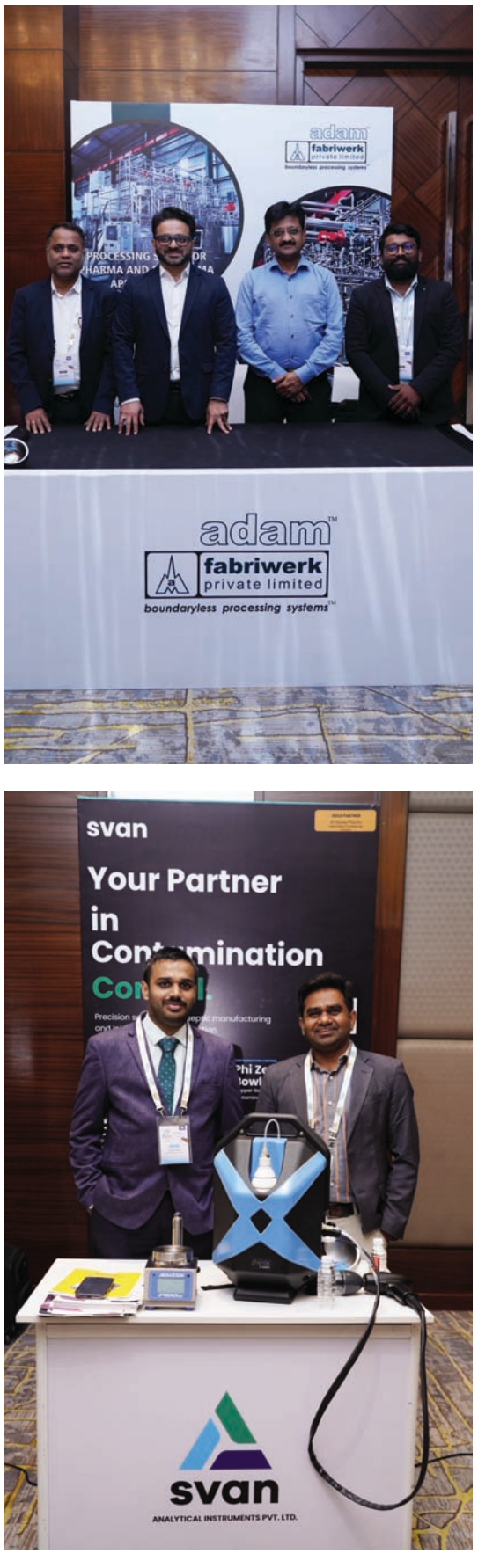

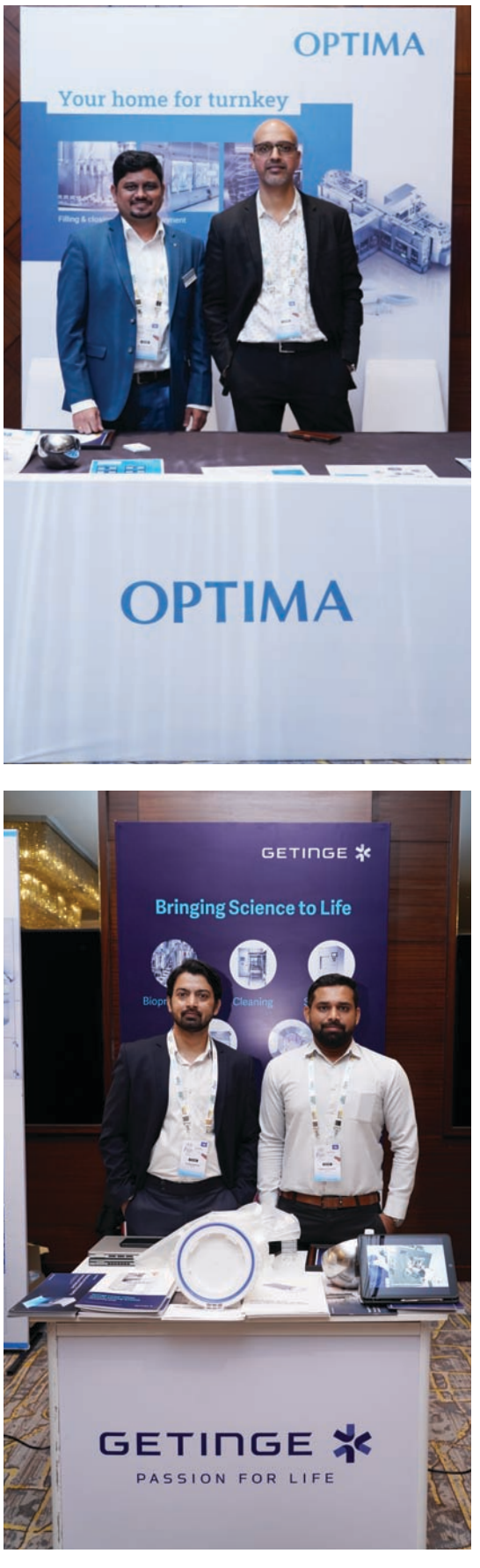

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Navigating legal and regulatory landscape of GLP-1 drugs in India

Parveen Arora, Partner, BTG Advaya and **Ishaan Chopra,** Associate, BTG Advaya outline how GLP-1 drugs are drawing sharp regulatory and legal scrutiny, especially with generics entering post-patent expiry. They emphasise that navigating IP, compliance, and marketing rules is now critical for stakeholders

Parveen Arora

Ishaan Chopra

India is currently facing a growing public health issue, with recent data showing that nearly a quarter of the adult population is now overweight or obese. Amid this increasing metabolic crisis and its associated cardiovascular risks, the emergence of Glucagon-Like Peptide-1 (GLP-1) receptor agonists (molecules that bind to cell receptors and activate them to produce a biological response, mimicking natural substances) has been a groundbreaking medical advancement.

These innovative drugs, which effectively imitate natural gut hormones to control appetite and blood sugar, offer a pharma solution for long-term weight management when traditional lifestyle changes often fall short.

Due to the alarming rise in obesity rates in India and the recent expiry of the patent for 'Semaglutide' (a leading GLP-1 receptor agonist), there has been an immediate surge in generic alternatives in India's domestic market. Most pharma companies, wellness centres, clinics, and other health-sector stakeholders are vying to claim a share of this large market. This has, in a way, significantly lowered prices and made these treatments more accessible to a larger population. However, this rapid democratisation of access has also prompted swift and comprehensive responses from India's regulatory and judicial authorities. Concerns are growing about the risks of self-medication and aggressive commercialisation, fuelled by the unprecedented attention GLP-1 drugs have received as a miracle cure.

This piece provides a structured overview of the current legal framework, recent intellectual property disputes, and the prevailing regulatory environment. The underscored message is addressed to stakeholders across the GLP-1 ecosystem, including pharma manufacturers, digital health platforms, telemedicine providers, and wellness clinics, and outlines the critical operational boundaries.

I. The intellectual property landscape

Beginning with the fact that the expiry of the primary compound patent does not mean the intellectual property landscape is entirely clear. Stakeholders must navigate a complex, ongoing series of patent and trademark disputes that continue to influence market entry and new entrants.

(a) The compound patent: The foundational patent for the Semaglutide molecule (IN 262697) expired on March 20, 2026. Leading up to this significant moment, the patent faced rigorous validity challenges in the Delhi High Court. In a landmark ruling earlier in March, the Division Bench declined to grant an interim injunction against generic manufacturers. Importantly, the Court provided crucial clarity on patent invalidity grounds, clearly distinguishing between 'anticipation by prior claiming' and 'obviousness'. The former requires a strict, identical claim-to-claim correspondence between the suit patent and an earlier patent, while the latter involves a broader analysis of what a hypothetical 'person skilled in the art' might infer from prior disclosures. By identifying a credible prima facie case for obviousness, the Court set an important precedent for future pharmaceutical patent litigation in India, effectively clarifying the evidentiary threshold needed at the interim injunction stage.

(b) The subsisting oral formulation patent: Although the patent for the injectable compound has expired, a secondary patent covering the oral formulation of Semaglutide (IN 325669) remains active and is currently under intense litigation. The commercial importance of an oral formulation cannot be overstated, as it completely bypasses the strict cold-chain storage and logistical distribution requirements associated with injectables. This patent specifically covers a solid oral composition combined with an absorption enhancer within a specific concentration range.

Recent proceedings before the Delhi High Court have seen generic manufacturers submit sworn undertakings not to infringe upon this specific concentration range. Any enterprise planning to develop, manufacture, or distribute an oral semaglutide product must carefully evaluate whether their specific formulation might infringe upon this active, highly valuable patent.

(c) Trademark scrutiny: The rush to market has also significantly crowded the trademark register. With multiple players competing for a share of the GLP-1 sector, brand identity has become a fiercely contested battleground. Recently, trademark infringement proceedings were

initiated concerning the phonetic and visual similarity between the innovator's brand (Ozempic) and a generic entrant's proposed mark (Olymviq). A comprehensive trademark clearance search within the Trade Marks Register is now essential before investing in any new product launch or marketing campaign in this space.

II. The regulatory framework and recent enforcement

The distribution and promotion of GLP-1 drugs in India are governed by a complex set of strict laws. After the patent expires, authorities have shown a zero-tolerance approach towards violations, considering the rise in demand as a major public health risk.

1. Strict restrictions on promotion and marketing: The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (DMR Act) explicitly bans advertising any drug for diagnosing, curing, alleviating or treating 'obesity'. This is a strict legal restriction with criminal penalties, including possible imprisonment for corporate directors and marketing heads.

Furthermore, on March 10, 2026, the Central Drugs Standard Control Organisation (CDSCO) issued an advisory directly targeting the GLP-1 market to restrict aggressive commercial tactics.

> The regulatory framework for GLP-1 drug therapies in India is developing quickly alongside the market it aims to regulate

The advisory clearly classifies indirect promotions - such as 'disease awareness' campaigns, celebrity and influencer engagements, or subtle digital outreach that promotes demand for pharmacological treatment therapy as unlawful surrogate advertising. Marketing communications must present these interventions strictly within the framework of 'comprehensive (weight) management' and must accurately emphasise the vital role of lifestyle changes, like dietary control and physical activity, instead of portraying the drug as a standalone 'magic pill'.

2. Prescription and dispensing mandates

GLP-1 receptor agonists are classified as Schedule H drugs under the Drugs Rules, 1945, meaning they can only be dispensed with a valid prescription from a Registered Medical Practitioner (RMP)1.

Following alarming reports of indiscriminate prescribing, the Ministry of Health confirmed on March 24, 2026, that the Drugs Controller of India had conducted targeted audits across 49 entities. This coordinated enforcement action included online pharmacy warehouses, distributors, retailers, and unlicensed slimming clinics. The authorities have explicitly reminded stakeholders that GLP-1 drugs are approved in India under strict prescribing conditions, such as limiting authorisation exclusively to specialists like Endocrinologists, Internal Medicine Specialists, and Cardiologists for certain indications. A general practitioner's prescription may not be sufficient under the specific conditions of the drug's marketing authorisation.

3. Consumer protection and telemedicine

Under the Consumer Protection Act, 2019, unsubstantiated efficacy claims, exaggerated 'before-and-after' testimonials implying guaranteed results, and the deliberate concealment of potential side effects constitute actionable unfair trade practices. The Central Consumer Protection Authority (CCPA) has broad powers to impose substantial financial penalties and order the immediate withdrawal of misleading campaigns.

Additionally, for digital health platforms prescribing these treatments remotely, the Telemedicine Practice Guidelines, 2020, apply strictly. The legal framework states that an online consultation must match the clinical rigour of an in-person encounter. Conditions of the drug's marketing authorisation are equally important in a virtual setting.

III. Strategic guidance for stakeholders

The regulatory framework for GLP-1 drug therapies in India is developing quickly alongside the market it aims to regulate. To participate sustainably and legally in this heavily scrutinised sector, stakeholders should adopt these basic principles:

Audit marketing assets: Ensure all digital campaigns, website copy, SEO strategies, and influencer briefs strictly adhere to the DMR Act and the latest CDSCO advisory. Avoid any language that promises rapid weight loss, minimises potential side effects, or promotes a prescription drug directly to the public under the cover of an educational campaign.

Enforce clinical governance: Dispensing 'Schedule H' drugs without a valid specialist prescription or through unlicensed premises is a criminal offence under the Drugs and Cosmetics Act. Therefore, entities such as wellness clinics, beauty salons, and digital tech platforms lacking pharmacy licences are prohibited from legally dispensing these products. Furthermore, an informal referral arrangement with a licensed pharmacy doesn't exempt someone from this strict legal requirement.

Ensure proper substantiation: Maintain strong, product-specific clinical data to support any efficacy claims and avoid overpromising. Regulators may consider generic global data on the Semaglutide molecule insufficient, so evidence must demonstrate the brand's performance specifically within the Indian demographic.

Prioritise patient safety: In line with the CDSCO mandate, manufacturers and marketing authorisation holders must prepare and submit detailed Risk Management Plans. Additionally, firms must ensure that Patient Information Leaflets (PIL) clearly and prominently feature a consumer complaint mechanism for the quick reporting of adverse drug reactions.

Thus, stakeholders who base their operations on primary legal instruments, seek independent advice before acting, and clearly distinguish between what is legally and commercially established and what remains uncertain, are best positioned to participate in this market sustainably and on a sound legal foundation.

From back office to brain trust: How life sciences GCCs are redefining leadership hiring in India

Sai Gandhi, Partner, Positive Moves points out that life sciences GCCs in India are moving from support roles to driving core innovation and global strategy. In turn, leadership hiring is shifting toward cross-functional, globally savvy leaders who can deliver enterprise-wide impact

India's rise as a global hub for life sciences GCCs is no longer a story of scale alone—it is a story of strategic reinvention. With 23 of the world's top 50 life sciences companies now operating GCCs in the country (EY, 2025), India has firmly established itself as a critical node in the global healthcare and pharma ecosystem. But what is more significant is the nature of work being anchored here and the resulting shift in leadership expectations.

For years, GCCs in life sciences were largely positioned as execution engines, delivering efficiency across functions such as finance, HR, IT, and supply chain. That paradigm has fundamentally changed. Today, India-based centres are not just supporting global operations, they are shaping them. From drug discovery and clinical data analytics to digital therapeutics and real-world evidence (RWE) generation, GCCs are increasingly at the forefront of innovation. This evolution is also visible in the scale of global mandates being handled out of India. Many organisations now run a majority of their operations through these centres. As GCCs move closer to the core of enterprise decision-making, the leadership model underpinning them is being redefined.

The shift from operational leadership to strategic ownership

The most visible change is in the mandate itself. Earlier, GCC leaders were evaluated on efficiency, cost optimisation, and delivery excellence. Today, they are expected to drive outcomes that are far more complex—innovation, transformation, and global integration. This requires a fundamentally different leadership profile. Organisations are no longer looking for operational heads who can manage large teams and ensure process compliance. They are seeking leaders who can operate at the intersection of science, technology, and business; individuals who can translate global strategy into local execution while also feeding insights back into the global organisation. In many ways, the GCC leader is evolving into a "mini-CEO" role—owning not just delivery, but capability building, stakeholder management, and long-term value creation.

Blurring the lines between science, technology and business

Life sciences, more than most industries, is undergoing a convergence of disciplines. Advances in AI-driven drug discovery, genomics, and digital health are collapsing traditional silos between R&D, IT, and commercial functions. GCCs are at the centre of this convergence. As a result, leadership hiring is increasingly focused on hybrid capabilities. A strong scientific or technical background is no longer sufficient in isolation. Leaders must also demonstrate commercial acumen, digital fluency, and the ability to manage cross-functional teams across geographies. This is a significant departure from traditional career paths in the sector, which have historically rewarded deep specialisation. Today, breadth of exposure is becoming as important as depth of expertise.

Another defining shift is the increasing integration of GCC leaders into global leadership structures. Unlike earlier models where India heads operated in relative isolation, today's leaders are deeply embedded in global decision-making. They are expected to engage with stakeholders across multiple markets, align with global regulatory frameworks, and contribute to enterprise-wide strategy. This requires not just functional expertise, but also cultural agility, communication skills, and the ability to influence without direct authority.

From a hiring perspective, this is expanding the talent pool—but also raising the bar. Organisations are prioritising candidates with international exposure, cross-border experience, and a track record of managing complexity at scale.

Leadership as a lever for innovation

As GCCs transition into innovation hubs, leadership is increasingly being seen as a key enabler of value creation. The ability to build and nurture high-quality talent, foster a culture of experimentation, and drive collaboration across functions is becoming critical. This is particularly relevant in areas such as drug discovery and RWE, where success depends on the seamless integration of data, technology, and scientific expertise. Recent findings by KPMG in India and UnearthIQ highlight the tangible impact of this shift—life sciences GCCs in India are now helping compress drug development timelines from 10–15 years to 9–13 years. Leaders who can break down silos and create aligned, high-performing teams will have a disproportionate impact on such outcomes. At the same time, there is a growing expectation for leaders to drive digital transformation agendas—leveraging AI, automation, and advanced analytics to improve both efficiency and effectiveness.

The challenge of building future-ready leadership pipelines

Despite the progress, one of the key challenges facing life sciences GCCs is the availability of leadership talent that meets these evolving requirements. While India has a deep pool of technical talent, the number of leaders with the right combination of global exposure, cross-functional experience, and strategic mindset remains limited. This is prompting organisations to rethink how they build leadership pipelines. Structured development programmes, global mobility opportunities, and deliberate cross-functional exposure are becoming essential components of leadership strategy. Boards are also becoming more involved in succession planning for GCC leadership roles, recognising their growing importance to the enterprise.

AI and digital therapeutics are accelerating the convergence shaping life sciences, redefining innovation and care delivery. AI now spans the entire value chain from drug discovery to clinical trials and real-time patient data analysis, while digital therapeutics are enabling continuous, personalised care. For GCCs, this creates an opportunity to own high-impact global mandates. It also raises leadership expectations, requiring the ability to integrate scientific, regulatory, and technological expertise into scalable, outcome-driven solutions.

The road ahead

The transformation of life sciences GCCs in India is still unfolding, but the direction is clear. These centres are no longer peripheral, they are central to how global organisations innovate, operate, and compete. As this shift accelerates, leadership will be the defining factor that separates successful GCCs from the rest. Organisations that invest early in building globally aligned, digitally fluent, and strategically capable leaders will be better positioned to unlock the full potential of their India operations.

In this new paradigm, the question is no longer whether India can deliver at scale. It is whether organisations can build the kind of leadership that can translate that scale into sustained global impact.

Qurating pharma leadership: India must start within to heal the world

Ajay Trehan, Founder & CEO, AuthBridge emphasises that India's pharma ambitions hinge not just on scale, but on trust built through quality, compliance and continuous transparency

By 2047, India's pharma exports are projected to grow nearly 15 times, reaching an estimated $350 billion. While ambitious, this vision is attainable if the industry aligns with the QuRATE framework—focusing on quality, regulation, access to global markets, talent, and entrepreneurial innovation. However, across each of these pillars, one factor remains critical yet under-addressed: transparency in execution.

Oversight or no sight

In today's pharma landscape, especially within India's organised sector, the margin for error has effectively vanished. Even minor lapses can escalate into national or global crises. Regulatory efforts, including mandates for real-time digital monitoring, have strengthened manufacturing oversight—particularly in response to concerns around high-risk ingredients like industrial solvents.

While supply chains and ingredients are increasingly traceable through digital systems, a significant vulnerability persists: the human element. Existing measures such as background verification and manual approvals provide only a static snapshot of employee integrity. They fall short in delivering continuous, real-time assurance across the workforce.

People: The critical risk layer

Despite robust compliance frameworks and manufacturing protocols, people remain the most unpredictable variable. Historically, discrepancies in credentials and ethical lapses have posed serious risks. More recent incidents, including data theft and internal collusion, highlight how gaps in employee screening and monitoring can lead to severe consequences.

In such a high-stakes industry, even minor inconsistencies in employment history can signal deeper risks—from prior misconduct to potential

data integrity issues. This makes a strong case for continuous, lifecycle-based verification rather than one-time checks at hiring.

For instance, employees in sensitive roles—those handling R&D data, quality control, or regulated substances—may face changing personal circumstances that alter their risk profile. Financial distress or legal troubles can increase vulnerability to coercion or malpractice. Without ongoing monitoring, such risks remain invisible until damage is done.

Reinforcing India's global pharma credibility

India's position as the "pharmacy of the world" is built on trust—but that trust is fragile. Global incidents have demonstrated how quickly confidence can erode when safety or quality is compromised.

Continuous verification should not be viewed as intrusive but as essential governance. For critical roles across quality control, R&D, and supply chain functions, periodic re-verification must become standard practice. Waiting for incidents to trigger action is no longer acceptable.

Organisations should adopt structured approaches, including promotion-linked checks, periodic audits, and randomised assessments. These measures not only strengthen internal integrity but also enhance compliance with evolving data protection and security regulations.

Expanding the definition of compliance

Pharma compliance can no longer be limited to product and process. It must extend to people. Tracking raw materials through the supply chain is essential—but so is ensuring the ongoing integrity of those responsible for certifying and delivering those products.

The next frontier lies in integrating employee risk intelligence into broader governance systems—alongside batch records, audit trails, and quality metrics. By doing so, organisations move from reactive compliance to proactive risk management.

Ultimately, this shift is not just about protecting business interests. It is about safeguarding patients worldwide who rely on the safety and efficacy of Indian pharmaceuticals. Strengthening human oversight is, therefore, not optional—it is foundational to sustaining India's global leadership in healthcare.

China+1 moment for pharma: How India can convert opportunity into long-term contracts

Manish Jain, Director, Naprod Life Sciences explains how India must move beyond cost advantage to lead with reliability, quality, and transparency to reshape global pharma supply chains and position itself as a trusted, long-term partner

The global healthcare industry has long relied on China for the majority of its active ingredients, APIs, and chemicals, making the supply chain vulnerable to disruptions. However, the "China+1" strategy has emerged as a crucial shift, offering a unique opportunity for India to step into a leadership role in global pharma. The 'China+1' strategy is more than just an idea that is discussed in boardrooms; it has now become a critical, evolving force that is changing the entire landscape of the Indian pharma industry to such an extent that long-term planning will no longer be sufficient to prepare for these changes.

For years, the global healthcare industry's reliance on a single source for most of the raw materials including APIs and other chemicals meant that there were very few alternatives if that single source failed to deliver. As of 2020, all of the supply chains of the global healthcare industry began to evolve, with the introduction of various new laws in the early 2020s, such as the US BIOSECURE Act passed in 2025, requiring all businesses worldwide to diversify their supply chains and the associated risk. As a result, India has become a unique opportunity for its economy to no longer serve as a low-cost country for pharma but instead as a reliable partner for key long-term contracts.

The heavy reliance of the entire global healthcare system on a limited number of suppliers has made it susceptible to breakdown. China +1 is likely to be able to eliminate this problem and simplify the manufacturing base (on geographical basis), while also ensuring that patients can have access to their medications. Moreover, India appears to be the best option for this company. The strength of India's pharmaceutical exports already indicates its strength, as it has increased its drug export from approx. $30.47 billion in FY25 with an increase of 9.4 per cent from FY24 and to approx. $28.29 billion by Feb. 26. In this regard, we can see that the world has already made a choice when placing its orders.

We need to move away from a 'just-in-time' manufacturing model and adopt a 'just-in-case' model that allows us to develop our capacity to deal with unanticipated events. Around the globe, companies are now interested in finding partners who can guarantee shorter lead times and demonstrate the competence of their manufacturing process.

To be able to convert these first conversations into long-term agreements — some of which could span up to 10 years — Indian companies must create an understanding of their differentiation in the marketplace: reliability, quick delivery and transparency about everything. India has been winning new contracts largely due to low prices; however, in the future we will determine whether we win contracts based on our ability to guarantee supply with the desired quality. With that said, we need to move away from a "just-in-time" manufacturing model and adopt a "just-in-case" model that allows us to develop our capacity to deal with unanticipated events. Around the globe, companies are now interested in finding partners who can guarantee shorter lead times and demonstrate the competence of their manufacturing process.

Transparency must be a part of the equation for these companies; they expect their partners to provide information, rules and standards with the same level of care as the quality of the drug itself. In addition, this scenario presents a significant opportunity for MSMEs, in India, which have historically received little attention as potential suppliers even though they provide the flexibility upon which the success of the Indian pharma industry really depends. These businesses are very capable of providing customers with small quantities of specialised products that larger companies may not consider viable options.

MSMEs can take advantage of many government supportive initiatives (like the nearly ?15,000 crore Production Linked Incentive scheme) designed to increase local production by upgrading their facilities to meet international standards. The ultimate goal of these businesses is to become trustworthy partners in the development and manufacture of drugs (as CDMOs). With so many countries, looking for suppliers to replace specific restricted suppliers/manufacturers, Indian MSMEs that focus on quality will have an excellent opportunity to leverage this market. Over the next three to five years, many of these pilot projects will evolve into larger, long-term contracts, and bring substantial new revenue to our country. The long-term goal of the Indian pharma industry is to grow from its current value of $60 billion to $130 billion by 2030. In order to achieve these goals, Indian companies need to change their mindset. They do not just sell chemicals; they sell trust and dependability.

India has a unique opportunity with the "China Plus One" Moment, to show that it should permanently have a leadership position in global healthcare. If the healthcare and pharma industries continue to drive innovation through complex generic drugs, biosimilars, and personalised medicine as well as solid supply chains, India can not only support global economic growth but will emerge as the most significant and reliable healthcare provider to the world.

An emerging disruption in drug traceability for India and beyond

Dr Avi Chaudhuri, Founder, The Kulinda Consortium outlines how emerging AI-driven, modular solutions now offer a more flexible and practical path to India's drug traceability efforts

Over the past two decades, I have worked closely on serialisation and traceability deployments in multiple markets, transitioning recently to architectural design of large-scale national programs. As an independent advisor and commentator, I have lately written extensively about why India's domestic drug traceability effort did not (and could not) succeed under the prevailing structural and policy framework. I claimed that the operational characteristics of India's pharma supply chain — its scale, dispersion, multi-tiered distribution and uneven digital maturity — rendered a comprehensive end-to-end traceability regime impractical in its conventional form.

There is however good news on the horizon, not because the complexity has diminished or because policy flaws have been resolved but because the technological landscape itself has materially shifted within a short period. Here, I first revisit the context in which first-generation traceability systems were created so as to understand why the unfolding technological disruption is so pivotal.

The way we were

Many programs took shape in the early 2010s when enterprise software was largely on-premise, integration was bespoke, hardware requirements were capital-intensive and packaging operations were only partially digitised. Serialisation was layered onto existing legacy infrastructure, with aggregation hardware retrofitted into operations that in emerging markets relied heavily on manual processes. In that context, designing traceability around hierarchical aggregation models and tightly coupled data exchanges was not merely logical, it was in practice unavoidable.

Embedded within that architecture were implicit expectations that digital continuity could be maintained across highly heterogeneous supply chains, that downstream scanning discipline would scale uniformly and that regulatory standardisation would evolve in parallel with program maturity. Although these assumptions were appropriate at the time, it is now clear that those expectations no longer apply to the current reality of the Indian traceability landscape.

What followed over the first half of the next decade was rapid acceleration. Pharma manufacturing expanded globally, supply chains became more distributed and outsourcing models introduced new layers of operational interdependence. At the same time, regulatory pronouncements multiplied across geographies, data volumes increased exponentially and yet the constraints that plagued adoption in emerging markets remained in place. The field was ready and eager for innovation.

The future's so bright ...

A quiet disruption is now taking place, not in policy revision but in enterprise technology itself. Modular SaaS architectures have recently become the norm even within regulated industries. API-driven integration has reduced the friction of coordinating across heterogeneous systems. Cloud-scale computing and storage economics have materially lowered the cost of processing and analysing high-volume supply chain data. At the same time, companies have grown more cautious about long-term vendor lock-ins, escalating software costs and losing control over their own data.

Advances in artificial intelligence (AI) and machine learning have further altered the equation. Pattern recognition, anomaly detection and reconciliation that were once dependent on rigid rule sets and manual oversight can now be continuously refined through adaptive models. These developments do not eliminate supply chain complexity. They do however expand architectural flexibility and user autonomy. Traceability no longer needs to be conceived solely as a monolithic network construct. It can function as a modular intelligence layer that is capable of evolving without coercing organisations into inflexible long-term vendor lock-ins.

Technological inflection also introduces advantages in ways that are not immediately obvious. Early adopters absorb the cost and friction of immature technology, whereas those who build later inherit advances in infrastructure, implementation and learnings. In the context of drug traceability, that dynamic is becoming increasingly relevant. Systems designed by a new generation of purveyors today are no longer bound by the constraints that defined first-generation deployments. Advances in modular SaaS architectures, AI-assisted analytics and product identity technologies have revised architectural assumptions that once seemed inflexible. In short, the tumult of the past is paving way for the reality of tomorrow where second-mover advantage will prevail in emerging markets.

Homeward bound

Several countries that attempted comprehensive traceability a decade ago were operating within design limitations and technological boundaries of that era. The hurdles that ensued created some painful failures, such as the Indian drug traceability program that was recently repealed after a decade of effort and investment. But now, India stands at a different moment. Its pharma industry has dramatically expanded, its supply chains are more complex and the prior failure has exposed operational realities that any serious system must now address. That combination of scale, lived experience and advent of a more mature technological landscape creates a distinctly different starting point.

It is within this altered context that the pressing requirements of Indian drug makers warrant renewed consideration by way of both out-of-the-box thinking and execution. What if, for example, an effective drug traceability program could be enabled without involving each and every supply chain participant? That would get around the traceability bottleneck that I have recently written about. And what if the market can capitalise on a markedly different digital environment — one shaped by interoperable platforms, cloud-scale infrastructure and materially lower infrastructure and operational overhead for enterprise software deployment. That is the emerging new reality where machine learning, AI-driven analytics and modular system designs are no longer experimental but are becoming increasingly embedded within mainstream enterprise system architecture.

In that setting, it is becoming increasingly apparent that solutions to India's domestic drug traceability challenges may be closer to home than previously assumed. In my view, traditional solutions providers were suitable for a different technological era — one defined by higher infrastructure costs, limited automation and restricted integration flexibility. By contrast, newer entrants are building solutions under materially different technological conditions. For example, I have been observing AltiusHub, a Hyderabad-based traceability platform develop an AI-native architecture designed to integrate seamlessly with existing enterprise systems while balancing automation with regulatory compliance.

The emerging emphasis is on enabling advanced supply chain traceability intelligence with minimal incremental operational burden. Drug makers may now find that the business and societal benefits long associated with comprehensive traceability are no longer beyond reach, provided they are pursued through platforms aligned with today's technological capabilities. The opportunity lies not merely in scaling operations across India's vast supply chain landscape, but in doing so under economic and deployment models that were previously unattainable.

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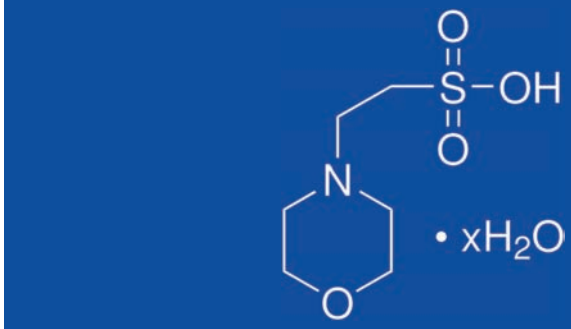

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Pycnogenol® and beauty from within

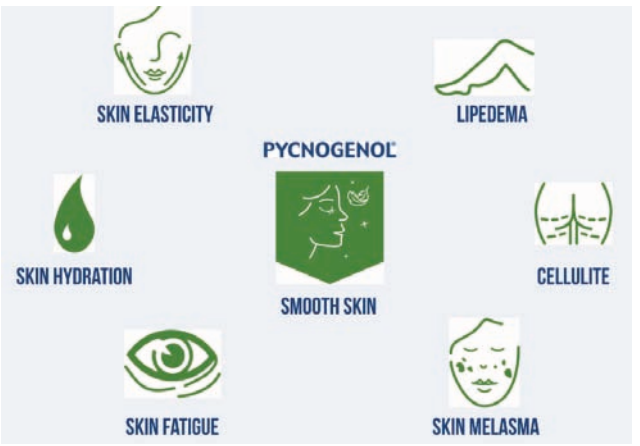
Skin health is increasingly recognized as a reflection of overall physiological balance rather than a purely cosmetic concern. Beyond topical care, oral approaches can support the skin from within by addressing key factors such as hydration, elasticity and structural resilience across the entire body.

Healthy skin is well hydrated and shows a high level of elasticity to be able to better deal with external stress such as sun radiation, air pollution or body changes such as weight fluctuation or aging.

An ever-increasing number of clinical studies demonstrate the efficacy of Pycnogenol® French maritime pine bark extract for skin health and beauty. This includes increased skin elasticity, skin hydration, reinforced skin barrier function and decreased skin fatigue [1-5], as well as improved microcirculation and blood flow [6-11].

In addition, Pycnogenol® was recently shown to have beneficial effects on cellulite severity and skin smoothness [12] as well as symptoms of lipedema such as swollen, heavy and bruised legs [13].

Moreover, Pycnogenol® supplementation contributes to skin health and beauty by helping to reduce melasma development and minimize the effects of photo-ageing [1, 5, 14-18].



Pycnogenol® improves skin hydration and elasticity

Skin firmness and hydration depend largely on the body's ability to produce and preserve collagen, elastin and hyaluronic acid. Supporting these processes helps maintain skin elasticity, moisture and resistance to daily environmental stress.For instance, collagens make up over 30 per cent of the extracellular matrix, acting as supportive tissue material and bringing stability and elasticity [19]. Elastin, which together with fibrillin microfibrils make up elastic fibers, is crucial for elasticity and extensibility of various tissues, including the skin [19]. Another important component of the extracellular matrix is hyaluronic acid, which contributes to water retention in tissues and to their structural integrity [19].

Clinical investigations of Pycnogenol® supplementation for 3 months with healthy female volunteers, aged 55 to 68 years revealed significantly increased expression of hyaluronic acid synthase within the skin by 44 per cent, leading to youthful, hydrated, and resilient skin [2]. Hyaluronic acid synthase is the natural source of water-binding hyaluronic acid in the dermis, which moisturizes the skin and keeps it taut and smooth, and it supports the structural integrity of the extracellular matrix by interacting with collagen and elastin fibers. Additionally, Pycnogenol® was shown to stimulate the synthesis of new collagen - skin´s connective tissue – by increasing its expression in average by 40 per cent [2].

In addition, Pycnogenol® was shown to reduce the release and activity of destructive enzymes (metalloproteinases 1,2 and 9), which break down dermal tissue proteins, like collagen or elastin [3, 4]. The reduced activity of these lytic enzymes saves the connective tissues from degradation, representing the basis for maintaining an elastic and youthful-looking skin.

By increasing hyaluronic acid and collagen production within the body and protecting elastin and collagen from being degraded, Pycnogenol® was shown to increase skin elasticity and skin hydration (1-5).

In the 3-month study with 20 women, mentioned earlier, a significant skin-hydration increase by 21 per cent in the Pycnogenol® group was found, particularly in women presenting with dry skin prior to Pycnogenol® intake (2). Pycnogenol® was also shown to improve skin elasticity by 25 per cent and decrease skin fatigue by 30 per cent. In addition, it was observed that Pycnogenol® supplementation reduced skin wrinkles by 3 per cent and increased skin smoothness by 6 per cent.

In another study with 78 subjects, who work outdoors in an urban area, skin elasticity was shown to be improved with Pycnogenol® by 13 per cent after 3 months, compared to an increase of 1 per cent in the placebo group (1). In this placebo-controlled double-blind study, Pycnogenol® reduced water loss of the skin (trans-epithelial water loss) during the hot summer season by 14 per cent, whereas it only reduced by 5 per cent with placebo. This prevented skin moisture decrease during the hot summer season. Skin moisture was reduced by only 3.3 per cent with Pycnogenol®, while with placebo it was reduced by 14 per cent after 3 months. This shows that the intake of Pycnogenol® reinforced skin barrier function.

Another finding that supports Pycnogenol®'s positive effects on skin barrier function, was an increased expression of genes involved in keratinocyte differentiation and barrier formation including loricrin, indicating that Pycnogenol® supplementation was associated with an improved formation of cornified envelopes and thus preserve skin hydration by reducing trans-epithelial water loss [5].

In addition, healthy blood flow is essential to sufficiently nurture the skin from within. Blood vessels bring oxygen and nutrients through arteries and small microvessels all over the body, providing beneficial effects from head to toe. Pycnogenol® helps to optimize blood flow by regulating microcirculation [6-8] and blood flow [9-11], which is crucial for skin and overall health.

Pycnogenol® reduces melasma development and limits photo-ageing

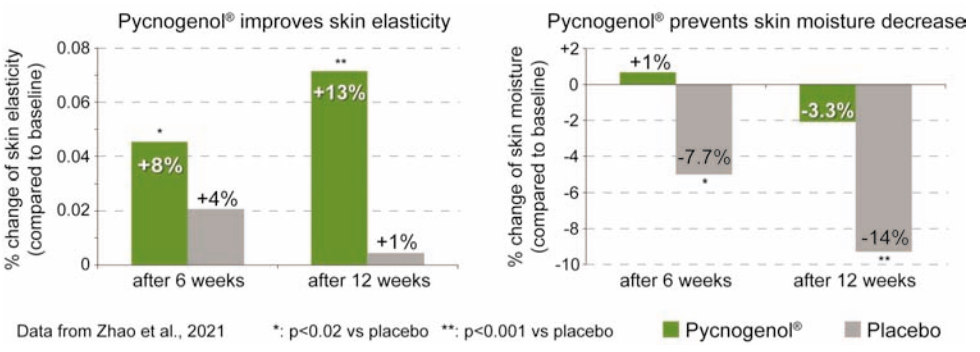
In addition to its effects on skin hydration and elasticity, Pycnogenol® was shown to provide potent photo-protective and melasma-reducing effects from the inside out, contributing to an even skin tone [1, 5, 14-18]. Melasma is a common form of hyperpigmentation and may be caused by UV exposure, female hormones or by predisposed genetic background [20]. In clinical studies, Pycnogenol® reduced the area and intensity of melasma and led to a more regular and even skin complexion [1, 16, 17].

A study with 30 women with melasma reported a more regular and even skin complexion with 22 per cent lower pigment intensity following four weeks intake of Pycnogenol® [17]. Additionally, Pycnogenol® was shown to effectively decrease the area of over-pigmented skin spots by 38 per cent, leading to smaller spots.

It was shown that Pycnogenol® suppresses tyrosinase activity, an enzyme that activates the production of melanin - the pigments, responsible for melasma [14, 15]. These findings of Pycnogenol®'s ability to counteract skin hyperpigmentation were clinically validated in a study, in which Pycnogenol® was shown to significantly lower UV-induced expression of enzymes that are linked to long-lasting pigmentation (5). Pycnogenol® was further shown to increase the resistance of participant's skin to solar UV exposure, needed to trigger skin redness [18]. The results from these studies suggest that Pycnogenol® has photo-protective and melasma-alleviating efficacies.

Beautiful legs with Pycnogenol®

Beautiful legs have been celebrated throughout history, ad-



mired in art, fashion, and culture as symbols of grace and strength. More than just an aesthetic ideal, healthy legs are often a testament to physical well-being and an active lifestyle.

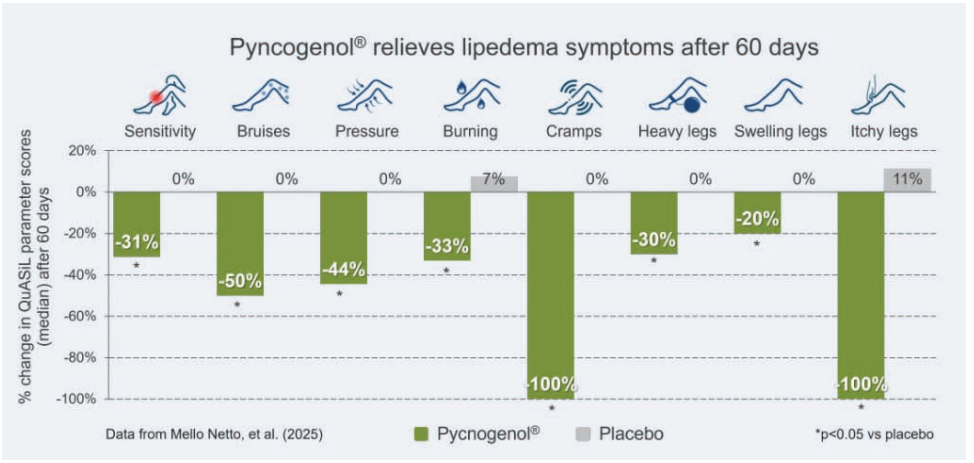
Conditions that alter the ideal silhouette of a "perfect" leg, like lipedema or cellulite are affecting mostly women. Pycnogenol® French maritime pine bark extract as part of a healthy lifestyle has shown to contribute to more beautiful and healthy legs.

Newly published study shows Pycnogenol®'s effects on lipedema

A recently published clinical study investigated the effects of Pycnogenol® supplementation on key symptoms of lipedema, a chronic condition that significantly affects quality of life in women [13]. Lipedema causes an abnormal build-up of subcutaneous fat in the legs and sometimes arms that is not caused by obesity and is resistant to traditional diet and exercise [21]. The condition can be painful and depending on the severity, can greatly affect mental well-being and daily life. Often misdiagnosed, the cause of lipedema is still unknown and unfortunately, there is no consensus treatment described, apart from lymph drainage, compression and physiotherapy to manage the condition.

In the study, one hundred women in their thirties with diagnosed lipedema took Pycnogenol® or placebo for 2 months [13]. The lipedema-related symptom score was reduced by a surprising 29 per cent compared to baseline and was significantly reduced by 32 per cent compared to placebo at the end of the study. In the lipedema-specific questionnaire on quality of life that was used, several parameters were significantly reduced, such as swelling of the legs, heavy legs, tenderness and bruising. In addition, an 8 per cent reduction in body fat and a significant improvement in satisfaction with leg appearance and quality of life compared to placebo was reported at the end of the study.

Pycnogenol®'s benefits on

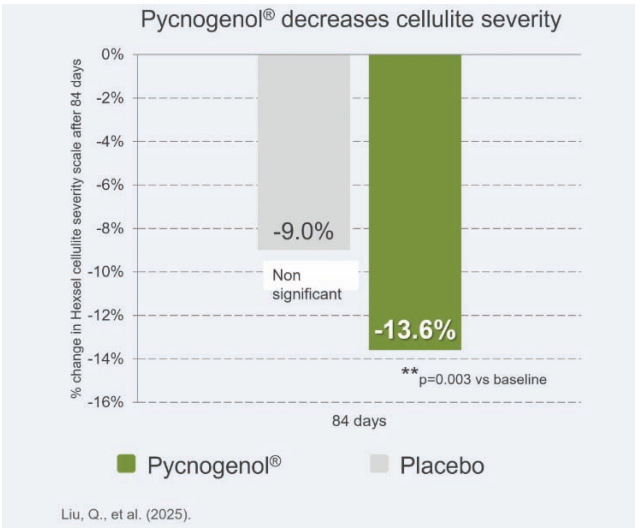


Lipedema stem from its antioxidant [9, 22-27] and anti-inflammatory properties [4, 28, 29], which help strengthen blood vessel walls [9-11] and improve microcirculation [6-8]. These effects are particularly relevant for lipedema, where impaired circulation contributes to chronic swelling and tissue discomfort.

Pycnogenol®'s efficacy on cellulite

Cellulite is a very common cosmetic skin condition of the legs, affecting 80-90 per cent of women [30]. It is linked to dermal structure and vascular changes, causing subcutaneous fat within connective tissue to push up the skin leading to dimpled and bumpy skin on the thighs, hips, buttocks and abdomen (30).

A recent study revealed that Pycnogenol® significantly decreases cellulite severity [12]. The double-blind placebo-controlled study included 60 women who either took Pycnogenol® or placebo for 3 months. Cellulite severity was significantly reduced by 13.6 per cent in the Pycnogenol® group, according to the Hexsel cellulite severity score, a clinically valuated assessment tool, evaluating five key morphological features of cellulite, such as skin surface alterations and sagging skin. In addition, upper thigh circumference was significantly reduced by 2.07 cm after the 3 months of Pycnogenol® intake compared to a reduction of 0.9 cm in the placebo group. Skin roughness was decreased by 32 per cent and skin smoothness was increased by 11.2 per cent after



Pycnogenol® supplementation.

Pycnogenol® French maritime pine bark extract is a safe, natural and evidence-based solution to support smooth and healthy skin. Pycnogenol® improves skin hydration and skin elasticity and reduces skin fatigue. Additionally, Pycnogenol® provides photo-protection and reduces melasma, contributing to an even and healthy skin tone. New research shows that Pycnogenol® not only helps to increase leg beauty but also reduces the symptoms of lipedema and cellulite. For more information on how Pycnogenol® helps support smooth and healthy skin, please visit www.pycnogenol.com .

Article written by Dr. Franziska Weichmann, Manager of Scientific Communications and Product Development at Horphag Research.

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Ensuring Pharma compliance with testo data measurement technology

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

Ensuring end to end climate monitoring – Testo Data Loggers

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

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

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

Data compliance for audits and inspections

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

Service & Calibration made easy

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

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

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

Waters receives CE mark for BD BACTEC FXI Culture System under EU IVDR

Next-generation blood culture system records ~3-hour faster detection time and introduces automated blood volume measurement

Waters Corporation announced the launch of the Waters omniDAWN™ Multi-Angle Light Scattering Photometer, part of the Wyatt Technology portfolio.

Waters Corporation announced that the BD BACTEC FXI Culture System has received CE marking under the European Union's In Vitro Diagnostic Regulation (IVDR), enabling commercialisation in Europe. The development marks a milestone in the company's clinical microbiology portfolio expansion.

The BD BACTEC FXI System is a fully automated blood culture system designed for bloodstream infection diagnostics in microbiology laboratories. Clinical study data show that the system delivers a mean time to detection approximately three hours faster, representing around a 15 per cent reduction compared to the previous generation BD BACTEC FX System. This supports earlier detection of pathogens and initiation of targeted antimicrobial therapy in patients with suspected bloodstream infections and sepsis.

In 2021, sepsis-related deaths represented 31.5 per cent of total global deaths, with studies indicating that each hour of delay in antibiotic administration is associated with increased odds of mortality.

"In the context of sepsis, diagnostics are critical to supporting informed clinical decision-making and ultimately improving antimicrobial stewardship and patient care," said Rafael Cantón, Ph.D., Head of Clinical Microbiology, University Hospital Ramón y Cajal – IRYCIS, Madrid. "Based on our experience during clinical trials,

the BD BACTEC FXI System reflects a mature and robust approach to blood culture diagnostics, with a clear focus on system reliability, ease of use, and laboratory workflow."

The system introduces automated gravimetric measurement of individual blood culture vial volume. This feature confirms sample collection quality in each bottle processed. Studies indicate that up to 85 per cent of blood culture vials are inappropriately filled in routine clinical practice, which impacts diagnostic accuracy. By confirming blood volume in each vial, the system addresses pre-analytical variability and supports adherence to recommended collection practices.

The BD BACTEC FXI System is designed for high-throughput microbiology laboratories and includes automated workflows such as vial loading, unloading, incubation, and detection alerts. It supports automated loading of up to 60 vials at a time and module capacities of 480 and 960 vials.

"The BD BACTEC FXI Culture System represents a significant advancement in automated microbiology, combining speed, automation, and scalability to support laboratory modernisation," said Jianqing Bennett, Senior Vice President, Waters Advanced Diagnostics, Waters Corporation. "This system strengthens our position in clinical microbiology and expands our ability to address the growing global demand for faster, more reliable infectious disease testing."

Waters Corporation stated that it has reinforced its manufacturing supply chain by diversifying sourcing, strengthening supplier partnerships, and improving operational processes while maintaining quality standards.

The BD BACTEC FXI Culture System will be showcased at ESCMID Global 2026 in Munich. The system is currently available in Europe and Japan, and the company is pursuing regulatory approvals in other markets.

The BD BACTEC FXI System and BD BACTEC Blood Culture Vials are manufactured by Becton, Dickinson and Company or its affiliates.

Waters launches omniDAWN MALS Photometer for UHPLC and UPLC workflows

Extended-range detector enables molar mass and size measurement for large molecule characterisation

Waters Corporation announced the launch of the Waters omniDAWN™ Multi-Angle Light Scattering Photometer, part of the Wyatt Technology portfolio.

The device is designed for Ultra High Performance Liquid Chromatography and Ultra Performance Liquid Chromatography workflows and features 18 angles of detection.

The omniDAWN Photometer is the first extended-range multi-angle light scattering detector for UHPLC and UPLC workflows, providing molar mass and size measurements.

The system delivers chromatographic run times up to four times faster and supports a ten-fold extension in UPLC-compatible sizing from approximately 50 to 500 nm in radius.

It also reduces sample consumption by 30–50 per cent and solvent use by approximately 40 per cent.

Waters stated that the system enables characterization of protein aggregates, viral vectors, lipid nanoparticles, and advanced materials. It reduces reliance on column calibration standards and supports biosimilarity studies, antibody-drug conjugate characterisation, and viral vector analytics.

Rob Carpio, Senior Vice President, Waters Analytical Sciences, Waters Corporation, said, "Advances in UHPLC and UPLC separations for complex biologics and newer modalities have outpaced detector technology, until now. The omniDAWN MALS Photometer brings extended-range multi-angle light scattering to modern separations. This means our customers can move faster while maintaining the resolution, robustness, and depth of characterization needed to accelerate the discovery, development, and quality control of next-generation therapies."

The system integrates with Waters UPLC systems and columns and is designed to reduce dispersion while maintaining analytical performance. It supports run times up to four times faster than conventional HPLC workflows.

Waters stated that the system supports detection of monomers, aggregates, and fragments with higher resolution and sensitivity.

Stacey Louie, Associate Professor, Department of Civil and Environmental Engineering, University of Houston, said, "Extending the capabilities of multi-angle light scattering to UHPLC and UPLC analysis will enable absolute molar mass measurements, paired with faster and more flexible separations. This represents a critical leap forward in MALS-based analyses, empowering us to better understand the structure of complex materials across drug delivery and environmental nanotechnology applications, ultimately supporting improved health outcomes."

The omniDAWN Photometer is powered by ASTRA™ Software and integrates multi-angle light scattering with ultraviolet and refractive index detection. The software is compliant with 21 CFR Part 11 and EU Annex 11 standards and will be compatible with Waters Empower™ Software later.

The product will be available globally in summer 2026.

To learn more or request a demo, visit www.wyatt.com/omniDAWN

Dock Shelters from Gandhi Automations Pvt Ltd – safe & environmentally friendly

India's No. 1 Entrance Automation & Loading Bay Equipment Company, Gandhi Automations, offers a complete range of Dock Shelters available for every requirement and environment.

Dock Shelters are installed mainly to seal the gap between the building and the vehicle in such a way that when the Sectional Overhead Door is opened, goods and personnel are protected against the harsh weather conditions outside. Dock Shelters provide a seal between the internal and external environments, thus assisting in the reduction of energy consumption. The savings in energy costs are considerable.

Retractable Dock Shelters

The retractable PVC front panels Dock Shelter is commonly used. With its simplicity and efficiency, it guarantees a constant return on investment. These are available for dock-level installation or for ground-level installation for the protection of doors without docks. The front panels are made of high-resistance black PVC reinforced with a double weave of polyester that works like a spring in order to seal the vehicles of different shapes. The flaps are flexible and have very high wear and tear resistance. Designed to retract under the shock of any possible wrong maneuvers of the docking vehicles and extend when the vehicle drives away.

Cushion Dock Shelters

Due to its high insulation factor, the Cushion Dock Shelter is the ideal solution for controlled temperatures. The three cushions are made of elastic polyurethane foam and covered with PVC-coated polyester fabric, supporting the vehicle pressures and perfectly sealing the three sides, including the space between the opened rear doors and sides of the vehicle. The two vertical cushions have continuous overlapped anti-friction limpets, allowing for the up-and-down heavy friction of the vehicle on its suspensions during the loading. It is available with a fixed or adjustable horizontal top cushion, adjustable to the different vehicle heights.

Inflatable Dock Shelters

Inflatable Dock Shelter is the best solution for insulating and improving the working environment. It can be rapidly inflated with a fan, and it creates perfect insulation between the vehicle and the loading bay, sheltering from cold, rain, wind, dust, and humidity. The Inflatable Dock Shelter is made of polyester fabric, PVC-covered, a material resistant to hot temperatures and bad weather conditions. Inflatable Dock Shelters provide the most versatile seal available to service the widest variety of truck and trailer configurations. Contrary to other types of dock shelters, the vehicle does not push towards the shelter; instead, the shelter is inflated around the vehicle.

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Romaco's sustainable blister packaging line at interpack

At this year's interpack, the Romaco Group will present its sustainable Unity 600 high-speed blister packaging line, featuring – for the first time – the PF 75 stretch bander. With this exhibit, the pharmaceutical machinery manufacturer is demonstrating its expertise in the primary, secondary and tertiary packaging of solid dosage forms.

Unity600 blister packaging line

Unity 600 blister packaging line

Powerful, sustainable and flexible – the double-lane, high-speed Unity 600 blister packaging line by Romaco Noack packages a wide variety of tablets and capsules with outstanding speed and reliability. The product range of this monobloc extends from very small and lightweight blisters to extremely large and heavy packs up to 145 mm long and 90 mm wide. This blister line with rotary sealing and a continuous motion cartoner achieves a maximum output of 600 blisters and 350 cartons per minute. The packaging line has proven to be exceptionally versatile in its processing of different types of packaging: apart from producing standard PVC/aluminum or aluminum/aluminum blisters, the technology is also suitable for handling climate-friendly blister foils made of mono-materials such as PET and PP. Dispensing with multilayer laminated blister foils not only reduces the carbon footprint of each blister, but also makes it easier to sort and recycle the discarded packs.

More sustainable

The sustainable system design of the Unity 600 cannot fail to impress: the innovative transfer unit that conveys the die-cut blisters to the cartoner has been engineered to operate without the need of energy-intensive vacuum. Instead, after their removal from the blister machine, the blisters are safely transported on a conveyor belt and fed directly into the stack transfer unit, where they are securely stacked from the bottom up. Moreover, this highly automated transfer solution is capable of identifying any gaps in the process via software and compensating for these directly. As a result, there is no longer any need to hold back good blisters for the stacking unit, which in turn enables the tracking and tracing of blisters from the point of product feed onward.

The bottom line is that the new Unity 600 achieves energy savings of up to 45% compared to its predecessor. This is also thanks to the installation of Venturi systems at points where vacuum is technically necessary – for example during the pick-up of cartons and leaflets. The comparatively small and low-maintenance Venturi pumps emit significantly less heat than conventional vacuum pumps, considerably cutting the amount of energy needed to air condition the cleanrooms. In addition, the blister packaging line features an intelligent standby function, which dramatically reduces the machine's base load without any negative effects on OEE (overall equipment effectiveness). For sustainability reporting, the Unity 600 is also equipped with an energy monitor, which measures the machine's electricity and air consumption as well as its CO2 emissions.

As a first, at interpack the Unity 600 will be exhibited in line with the new PF 75 stretch bander.

PF 75 stretch bander

The new PF 75 stretch bander boasts an exceptionally compact design with a very small footprint of approximately 2 m². This allows the final packaging machine to be flexibly integrated into any pharmaceutical and nutraceutical packaging line, even when space is at a premium. The stretch bander is designed to handle up to 450 cartons at the infeed and is therefore compatible with the fastest Romaco cartoner. For product changes, a single format part merely needs to be replaced – no tools required. All other settings can be entered conveniently on the HMI panel and easily adjusted on a few machine components. The GMP-compliant machine design is clearly laid out and easy to see into, shortening cleaning processes and enabling rapid line clearance. Cartons are bundled to better organize the retail units and to ensure greater stability during case packing. This also increases storage capacity per pallet and ultimately reduces transport costs. The launch of the PF 75 stretch bander marks a strategic step in rounding out Romaco's end-of-line packaging range. Manufactured by Romaco's long-standing technology partner, SPH Group, the machine is a key component of the supplier's packaging lines. Thanks to the integration of this ergonomic, low-maintenance technology, the pharmaceutical and nutraceutical industries benefit from seamless end-to-end solutions from a single source – covering the entire production chain.

PF75 stretch bander

PC 4350 continuous motion cartoner

The Romaco Promatic PC 4350 continuous motion cartoner was developed as a secondary packaging unit for the Unity 600 blister packaging line and meets all the requirements for integration in the high-performance monobloc. It achieves a maximum output of 350 cartons per minute. Its positive carton opening system eradicates any friction, enabling very gentle handling of packaging materials. In addition, counter-vacuum is used to prevent unstable cartons from collapsing again after they have been erected. In the PC 4350, the stacks of blister packs are fed into the open cartons from the rear. The entire insertion area is therefore easily viewable and accessible – a major advantage for GMP-compliant cleaning and fast line clearance. What's more, for the first time the leaflet folding module is positioned in the running direction and not on the front. This layout ensures extremely short distances for transporting patient information leaflets, further enhancing process reliability, per-

Wide range of applications from one stop solution supplier Romaco

formance and efficiency. In case of a pre-folded leaflet feeding unit, a greater magazine capacity can be granted, without compromising operator ergonomics. Furthermore, the cartoner's fail-safe design makes sure that solely verified products are released for the next production step. As well as blisters, the PC 4350 also packs plastic bottles, glass vials, strips, tubes and numerous other products.

All from one source – one stop solutions by Romaco

In addition to its packaging technologies, one stop solutions supplier Romaco will be presenting further innovations from its processing portfolio at interpack. These include the fully automated MAXIMUS 400 tablet coater, which comes with a multitude of intelligent features. Also on show for the first time is the KTS 840 tablet press, which was specially engineered for compressing three-layer tablets in the nutraceutical and food industries. Furthermore, Romaco is showcasing its laboratory expertise with live demonstrations of the VENTILUS® Lab fluid bed processor and the KTP 1X compaction simulator.

On show at interpack in Dusseldorf (Germany) from May 7 to 13, 2026 (Hall 16, Booth D22).

Strong partnerships

Romaco joins forces with industry partners to reveal further insights into its portfolio: the KTS 1000 high-speed press will be exhibited in line with the BHS continuous wrapping machine from Theegarten-PACTEC for tableting and packaging stock cubes. In the food and confectionery sector, this technology is currently the best performer in the market. (Hall 1, Stand B51)

Span Inspection Systems demonstrates its latest camera control system using the example of the universal, intermittent motion N 760 blister packaging machine from Romaco. This inspection system is used for quality control and reliably detects various parameters, such as presence, color, shape, breakage, etc. of the tablets or capsules during primary packaging. (Hall 15, Stand C11)

For more information on Romaco, visit our website and social media channels: www.romaco.com – Showroom – LinkedIn – YouTube

Romaco Group

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

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

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

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

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Standardisation vs customisation in single-use systems for bioprocessing: What do biopharma companies need?

Priyabrata Pattnaik, CEO, Ami Polymer highlights the balance between standardisation and customisation in single - use systems in biopharma manufacturing

Single-use systems (SUS) have transformed liquid handling in biopharma manufacturing, enabling flexibility, reducing cleaning validation burdens, accelerating changeovers, and supporting faster facility deployment. From media and buffer bags to sterile connectors, tubing manifolds, mixing systems, and final fill assemblies, disposable technologies have become integral across upstream, downstream, and fill-finish operations.

Yet as adoption matures, biopharma manufacturers face a persistent paradox: should they rely on standardized single-use components and systems designed for broad applicability, or invest in customized, application-specific assemblies optimized for unique process requirements? This is not merely a procurement decision. It influences operational efficiency, supply resilience, quality assurance, cost structure, and strategic manufacturing agility. The answer is rarely absolute. What biopharma companies really need is not standardization or customization alone, but a risk-based framework for selecting the right balance.

The case for standardisation

Standardized single-use systems refer to off-the-shelf, broadly available assemblies or components built around common configurations. Examples include standard tubing sets, predefined manifold designs, universal bag platforms, and vendor catalogue components.

The greatest strength of standardization is simplicity. From an operational perspective, standardized systems are easier to implement and use. Operators become familiar with repeatable configurations, reducing training requirements and minimizing assembly errors. Standard workflows also improve procedural consistency, especially in multi-site or global manufacturing networks where harmonization matters.

Inventory management is another major advantage. Fewer unique part numbers simplify planning, reduce SKU proliferation, and lower the burden on warehousing. Safety stock strategies become easier to manage, and demand forecasting tends to be more accurate.

Supply resilience is often stronger with standardized systems. Because standard components are generally produced at higher volume and used by multiple customers, suppliers often prioritize capacity and continuity for these products. In periods of supply disruption—an issue exposed dramatically during the pandemic—standard components may offer more sourcing alternatives or second-source options.

Cost can also favour standardization, particularly in routine operations. Economies of scale usually reduce per-unit pricing, and lower engineering involvement means reduced design qualification and change control effort. Validation packages may also be more mature, accelerating deployment.

Quality assurance benefits from standardization as well. Established products typically have deeper extractables data, more robust change notification processes, and longer performance histories. This can simplify supplier qualification and regulatory justification.

But standardization has limits. A standard system may not fit a process optimally. Operators may compensate through workarounds, excess tubing lengths, unnecessary connection points, or overbuilt assemblies. What appears simpler on paper may introduce inefficiencies in practice. In some cases, forcing

a unique process into a standard design creates hidden operational risks.

The case for customisation

Customized single-use systems are purpose-built assemblies designed around a process or facility's specific needs. These may include bespoke manifolds, unique bag geometries, integrated sensor placements, specialized flow paths, or assemblies configured to fit equipment layouts.

Customization's biggest advantage is process fit. A well-designed custom assembly can improve ease of operation dramatically. By integrating multiple steps into a single assembly, reducing operator interventions, or optimizing ergonomic layout, customized systems can reduce handling errors and shorten execution times.

For complex processes, customization can also improve process performance. Tailored designs may minimize hold-up volume, improve product recovery, reduce contamination risk, or accommodate challenging process parameters that standard systems cannot. There can be quality advantages too. A custom assembly designed to eliminate unnecessary connections or simplify critical transfers may reduce risk points. In high-value biologics manufacturing, even small reductions in contamination or product loss risk can justify customization.

In some cases, customization may reduce total operating cost despite higher unit prices. While a custom assembly may cost more to purchase, it may save labour, reduce deviations, improve batch success, or eliminate multiple standard components that otherwise need separate management.

However, customization comes with trade-offs. Inventory management often becomes more difficult. Each dedicated design adds unique SKUs, often with lower usage frequency and more complex forecasting. This can increase obsolescence risk, especially in volatile development pipelines.

Supply risk may also rise. Custom assemblies can create dependency on specific suppliers, longer lead times, and reduced sourcing flexibility. A highly specialized assembly may be difficult to replace quickly during disruptions. Cost can escalate beyond purchase price. Engineering time, qualification studies, design reviews, validation documentation, and ongoing change control all add lifecycle cost. Companies often underestimate these hidden costs.

Quality assurance can also become more resource-intensive. Every custom configuration may require additional scrutiny for extractables assessment, supplier controls, and design changes. If customization proliferates without discipline, QA complexity can become unmanageable.

The real paradox: Optimisation vs complexity

The core paradox is that standardization reduces complexity but may sacrifice optimization, while customization improves optimization but can introduce complexity. Too much standardization may create operational inefficiency. Too much customization may create organizational chaos. Neither extreme serves biopharma well. The real challenge is distinguishing where process differentiation creates value and where it merely creates variation.

When standardisation is the better choice

Standardisation is often ideal when:

1. Processes are mature and repeatable. Commercial products with stable operations often benefit from standardized assemblies.

2. Operations span multiple sites. Network harmonization strongly favours standard components.

3. Supply resilience is critical. If continuity of supply outweighs incremental optimization, standardization reduces risk.

4. High-volume, lower-complexity fluid handling is involved. Routine media, buffer, and intermediate transfers often do not justify custom designs.

5. When organizations are early in SUS adoption and companies building foundational single-use capabilities often benefit from starting standardized before adding complexity.

6. Cost and inventory control are major priorities. Standardization supports leaner supply chain management.

In these situations, "good enough" standardized solutions often outperform over engineered custom alternatives.

When Customization Is the Better Choice

Customisation is often justified when:

1. Process requirements are unique or technically demanding. Complex cell therapies, advanced biologics, or difficult downstream operations may re-

quire tailored solutions.

2. Product value is extremely high. For processes where product loss carries major financial consequences, optimization may outweigh added system complexity.

3. Standard systems introduce clear operational risk. If standard components force workarounds, increase interventions, or compromise ergonomics, customisation may reduce risk.

4. Closed processing or contamination control requirements are stringent. Custom integrated assemblies may improve assurance.

5. Facility or equipment layouts create unique constraints. Physical fit sometimes necessitates custom design.

6. Labour reduction or automation integration is strategic. Custom systems may better support advanced manufacturing goals.

In these cases, customisation can be a risk-reduction strategy rather than a complexity burden.

What biopharma companies really need: Controlled customisation

Increasingly, the industry is moving toward a middle path: controlled customisation built on standardized platforms. This approach standardizes core building blocks—tubing platforms, connector families, bag films, sensor technologies, and design rules—while allowing targeted customisation at the assembly level.

Think of it as modular design rather than unrestricted customization. This model offers several advantages:

1. Standardized components preserve supply resilience.

2. Modular customisation enables process fit.

3. QA complexity remains manageable.

4. Inventory proliferation is constrained.

5. Suppliers can support designs more efficiently.

6. Change control becomes more structured.

This is often where mature organizations achieve the best balance.

A risk-based decision framework

Rather than asking - standard or custom, biopharma companies need to ask strategic questions, not the tactical questions.

1. Does customisation solve a real process problem or simply reflect preference?

2. Does the operational benefit outweigh added supply and quality complexity?

3. What is the lifecycle cost, not just purchase price?

4. What supply risk does this design introduce?

5. Can the need be met through modular configuration rather than full customization?

6. Does this choice support long-term platform strategy?

Conclusion

The debate between standardization and customisation in single-use systems is not about choosing one philosophy over another. It is about aligning system design with process risk, operational needs, and business strategy. Standardisation brings simplicity, scalability, supply resilience, and control. Customisation brings optimization, flexibility, and process-specific performance.

Biopharma companies do not truly need one or the other exclusively. They need disciplined decision-making about where standardisation creates value, where customisation is justified, and where modular hybrid approaches deliver both. In practice, the most effective organizations standardize by default, customize by exception, and govern both through a risk-based framework.

That is how the paradox is resolved—and how single-use systems deliver not just flexibility, but sustainable manufacturing advantage.

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CPHI Middle East and BIO Middle East to position Saudi Arabia as life sciences hub

2026 summit in Riyadh to bring pharmaceutical and biotechnology sectors under unified platform

CPHI Middle East and BIO Middle East 2026 will position Saudi Arabia within the global life sciences sector with international industry participation confirmed for the inaugural edition.

The events will take place from 14–16 December 2026 at the Riyadh Exhibition and Convention Centre, Malham, Saudi Arabia. The summit is held under the patronage of the Ministry of Health and will bring together pharmaceutical, biotechnology and life sciences stakeholders.

Exhibitors confirmed include Boston Oncology, Johnson & Johnson, Fakeeh Care Group, M42 Arabia and Sinovac Holding Group.

Saudi Arabia's pharmaceutical market is projected to reach USD 15.6 billion by 2030, up from USD 11.8 billion in 2024. Biotechnology is projected to contribute more than USD 34 billion to Saudi Arabia's non-oil GDP by 2040, representing 3 per cent of total GDP.

CPHI Middle East and BIO Middle East will be co-located in Riyadh in December 2026, bringing together global pharmaceutical and biotechnology stakeholders under Saudi Arabia's life sciences strategy

H.E. Eng. Fahad Abdulrahman AlJalajel, Minister of Health, said, "The National Biotechnology Strategy outlines a comprehensive roadmap to address critical health challenges, accelerate medical advancements, and enhance patient care. With this strategy, we will leverage the power of genomics, precision medicine and advanced therapeutics to transform healthcare and improve the lives of people across the nation."

Mohaned El Mahgoub, Vice President of Tahaluf, the event organisers, said, "CPHI Middle East and BIO Middle East 2026 editions are expected to welcome more than 60,000 visitors, 1,000 exhibiting brands and 400+ speakers from more than 100 countries, making it the most comprehensive life sciences gathering ever hosted in the region. Across three days, attendees will engage in strategic panels, technical deep dives, investment forums, scientific sessions, workshops and highlevel ministerial engagements. The event will also introduce the BIO partneringONE® platform to the Middle East for the first time, enabling targeted one-to-one meetings designed to accelerate licensing deals, collaborations and market entry strategies for global and regional companies."

Global medicine spending is projected to reach USD 1.6 trillion in 2025. The sector is being driven by developments in AI-enabled drug discovery, precision medicine and advanced therapeutic modalities.

Saudi Arabia's National Biotechnology Strategy, launched in 2024, aims to position the country as a global biotechnology hub by 2040. It includes targets such as creating more than 11,000 jobs, localisation of vaccine and biopharmaceutical production, and development in genomics, precision medicine and research.

BIO Middle East will focus on next-generation therapies, cell and gene therapy, digital and data-driven R&D, clinical trial innovation, vaccine development, biomanufacturing and supply chain systems. It will also include innovation pitches and workshops under the EBD Academy for partnering and commercialisation.

CPHI Middle East will cover APIs, CDMOs, packaging, logistics, manufacturing technologies, regulatory alignment and workforce development. It will also include forums such as the Women in Pharma Forum and CPHI Academy.

The co-location will include areas such as a Deals Hub, Investor Programme, Saudi Biotech Garden and roundtables on AI drug discovery, rare diseases, oncology and regulatory systems.

Registration for the summit is open. Further details, including the full agenda and exhibitor information, are available at *www.cphimiddleeast. com and www.biomiddleeast. com.*

PRUV® -The original Sodium Stearyl Fumarate

JRS Pharma's PRUV® is the original sodium stearyl fumarate (SSF) introduced in the market over 20 years ago

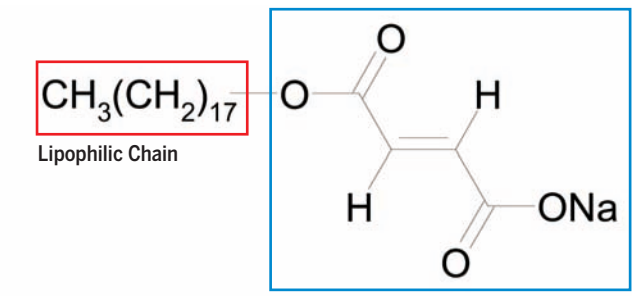
Pharma lubricants are the inactive agents i.e. excipients added into tablet and capsule formulations in a very small quantity (usually 0.25-5.0 % w/w) to improve the processing properties of formulations. They decrease the friction at the interface between tablet's surface and the die wall during the compression and ejection phase of the tableting so that the wear on punches and dies are reduced. They prevent sticking of tablets to punch faces as well as sticking of capsules to dosators and tamping pins. In terms of powder flow, lubricants can improve the flowability of blends and aid unit operations [1].

A good balance between hydrophobic and hydrophilic moieties in PRUV® (Sodium Stearyl Fumarate) makes it an ideal lubricant [2].

Common lubricants used in drug development

Most of the lubricants used in the pharma processes are boundary lubricants. Certainly, metallic salts of fatty acids such as magnesium stearate; stearic acid and sodium salt of fatty acid such as sodium stearyl fumarate are the most common ones.

A. Fatty acid esters: Fatty acid esters, including glyceride esters (glyceryl monostearate, glyceryl tribehenate, and glyceryl dibehenate), sugar esters (sorbitan monostearate and sucrose monopalmitate) and alcohol ester of stearic alcohol with fumaric acid, including sodium stearyl fumarate are often used as lubricants. In particular, sodium stearyl fumarate and glyceryl dibehenate are effective lubricants to replace magnesium stearate when the latter hampers dissolution and has chemical incompatibility issues. Relative to magnesium stearate, sodium stearyl fumarate has similar lubrication efficiency with a higher optimal concentration (around 2%, w/w). In addition, the use of sodium stearyl fumarate does not affect compressibility [1].



Lipophilic Chain

Hydrophilic chain

B. Metallic salts of fatty acids: Use of the metallic salts of fatty acids as lubricants has a long history in the pharma industry and they are still the most dominant class of lubricants. Magnesium stearate, calcium stearate and zinc stearate are the three common metallic salts of fatty acids used [1].

C. Fatty acids: Fatty acids are also common lubricants used in the pharma industry with stearic acid as the most popular one. Chemically, stearic acid is a straight-chain saturated monobasic acid found in animal fats and in varying degrees in cotton seed, corn and coco. The commercial material of stearic acid has other minor fatty acid constituents such as myristic acid and palmitic acid [1].

D. Inorganic materials and polymers: Inorganic materials and polymers are also used as lubricants when magnesium stearate cannot be used. In terms of inorganic materials, talc (a hydrated magnesium silicate (Mg3Si4O10(OH)2), is often used as a lubricant or as a glidant in formulations. Talc provides some essential lubricity for pharma operations because of its hydrophobicity and weakly bonded sheet structure [1][6].

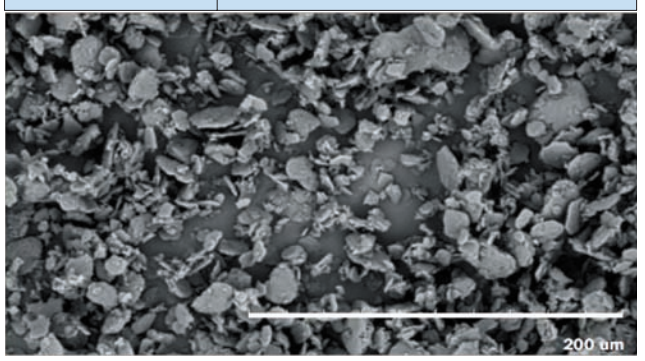
Mechanism of lubrication:

There are four lubrication mechanisms: [1]

1. Hydrodynamic lubrication,
2. Elasto-hydrodynamic lubrication,
3. Mixed lubrication, and
4. Boundary lubrication.

As their names imply, the first three mechanisms are related to the usage of liquid lubricants to some extent. In the pharma industry, boundary lubrication is the most common mechanism functioning in unit operations.

Typical properties of PRUV®: [5]	
pH	About 8.5 (10% aqueous solution at 90°C)
Saponification value	142.2-146.0
Moisture	<5.0%
Solubility	0.5mg/100 ml at 25°C/
	10 g/100 ml at 80°C
	20 g/100 ml at 90°C
Melting point	224-245°C



SEM Picture of PRUV®

For boundary lubrication, a lubricant typically forms layers/film between surfaces or at interfaces to reduce friction, where the penetration of the lubricant into surface asperities occurs. Structurally, the lubricants commonly used for boundary lubrication are long chain molecules with active end-groups. The typical end-groups include:

1. –OH (long chain alcohol);
2. –NH2 (long chain amine);
3. –COOH (long chain fatty acids); and
4. Metal ions such as Mg2+.

Considerations for selecting a lubricant

There are many factors to be considered for selecting an appropriate lubricant for preparing solid dosage forms, including low shear strength, being able to form a durable layer covering the surface/particles, non-toxic, chemically compatible with APIs and other components in the formulation, low batch-to-batch variability, and having minimum adverse effects on the performance of the finished dosage forms. [1][3]

In addition, the optimal concentration and mixing time are also needed to be taken into consideration when selecting a lubricant because both of these two parameters greatly affect the performance of pharma products and processes. [1][6].

After understanding what are lubricants, commonly used lubricants in pharma formulation, mechanism of lubricants and considerations for selecting the best lubricant, let's focus on more detail regarding PRUV® (Sodium Stearyl Fumarate) lubricant from JRS Pharma.

PRUV® (Sodium Stearyl Fumarate) characteristics:

- ◆ Highly efficient lubricant and anti-adherant
- ◆ More water-soluble than Magnesium stearate
- ◆ Well-defined particle size and specific surface area
- ◆ High melting point (230°C)
- ◆ Lamellar structure
- ◆ High purity and batch-to-batch consistency

How PRUV® works?

- ◆ **PRUV®** reduces inter-particulate friction during tablet manufacturing while acting as a boundary lubricant in the formulation.
- ◆ **PRUV®** facilitates lubrication during blending through shearing.
- ◆ **PRUV®** is more hydrophilic, dissolution is not compromised wherever facing dissolution issue with magnesium stearate.
- ◆ **PRUV®** goes beyond lubrication and it also accelerates dissolution.

Applications of PRUV®

PRUV® can be used in dry granulation as well as wet granulation technology to avoid sticking of intra-granular blend to roller or RMG wall. PRUV® can also be used in capsule dosage by reducing friction between the particles. PRUV® is a perfect lubricant for high-speed tableting/continuous manufacturing because it is less sensitive to heat. PRUV® can also be used in hot melt

extrusion due to its higher melting point (224-245°C).

Following are the case studies of PRUV® to evaluate the effect on physio-chemical properties on tablet dosage form [4].

In this study, the effect of different lubricants on Acetaminophen formulation was studied. Acetaminophen API blended with PROSOLV SMCC HD 90 for 15 min and afterwards blended with sieved lubricants for three minutes. Different lubricants like PRUV, Magnesium stearate, stearic acid and sodium stearate are used. Tablets were compressed to 800 mg weight. tablet.

Magnesium stearate is the most widely used lubricant in the pharma industry. Hence, PRUV® is compared with Magnesium stearate in the following section:

PRUV® helps to avoid API incompatibilities and enhances API stability. With a few exceptions, PRUV® can be applied to any formulation for lubrication, particularly those in which API stability or tablet taste is compromised due to magnesium stearate. Magnesium cation (Mg2+) is electrophilic, it interacts with the free electrons of an API and forms insoluble salts. This is one of the many causes of API incompatibility with magnesium stearate. [4]

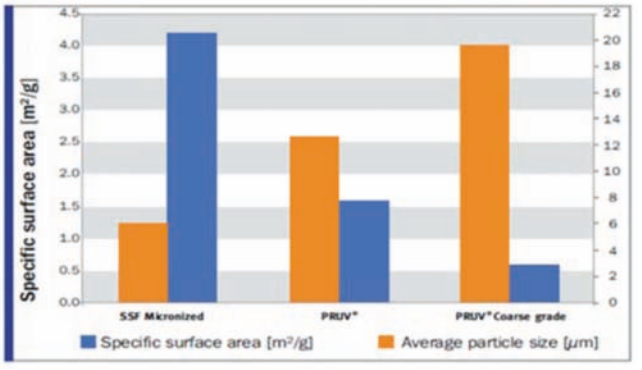
Ingredients	Quantity (%)	Quantity (mg/unit)
Acetaminophen	62.5%	500 mg
PROSOLV® SMCC HD 90	35.5%	248 mg
Lubricant	2.0%	16 mg
Total	**100.0%**	**800 mg**

Electrostatic Properties: Magnesium stearate shows higher voltage and retention time than PRUV®. Low electric charge and retention improve lubricant dispersion during blending. As a result, PRUV® due to its low voltage and retention can be considered a superior lubricant with improved lubricant uniformity.

PRUV® was carefully designed to consistently deliver the following functional characteristics:

Grade	D(50)	BET
SSF Micronized	7.6	4.2 m^2/g
PRUV®	13.6	1.6 m^2/g
PRUV® CG (Coarse Grade)	20.4	0.6 m^2/g

PARTICLE SIZE AND SPECIFIC SURFACE AREA FOR DIFFERENT GRADES OF SSF[4]



◆ Tight particle size distribution
◆ Well-defined specific surface area
◆ Reproducible particle morphology

The outstanding performance of PRUV® is based on its well-controlled particle size and shape. Following studies show the effect of deviating from the ideal values.

Conclusion:

Beyond tablet lubrication properties of PRUV®:

It shows:

◆ Improved API stability
◆ Superior blending properties
◆ Faster disintegration
◆ Faster dissolution times

The choice of lubricant can influence the quality of the tablets as well as the dissolution rates. Since APIs tend to be less water-soluble and difficult to compress, choosing the right lubricants continues to become an even more important task.

Most commonly available lubricants are very hydrophobic and thus increase dissolution times significantly. In such cases, a less hydrophobic lubricant can help to decrease the dissolution times as well as increase the API release.

PRUV® Sodium Stearyl Fumarate complies with Ph.Eur., NF and JPE. It has the ideal particle size and specific surface area to offer a perfect balance between all functionality aspects. It is the preferred choice over magnesium stearate in terms of improving disintegration time and dissolution.

Furthermore, different particle sizes are available, which help to fine tune tablet formulation resulting in the desired dissolution profiles.

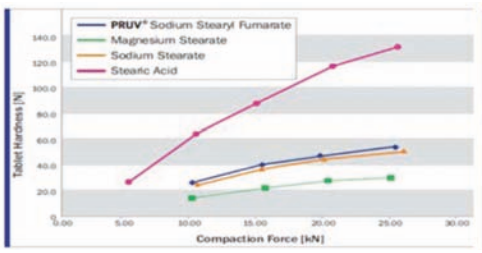
Regulatory status of PRUV®:

◆ Ph.Eur., NF, JPE, GRAS status
◆ C-DMF is available for PRUV®
◆ Non-animal origin
◆ BSE/TSE-free
◆ GMO-free
◆ OVI-free (USP<467>) and conforms to the residual solvents requirement of Ph.Eur.(5.4) and USP <467>
◆ QBD dossier available
◆ Elemental impurity statement available

LUBRICANTS: PRUV® (SODIUM STEARYL FUMARATE), MAGNESIUM STEARATE, STEARIC ACID, SODIUM STEARATE)

Tablet Hardness/Compactability

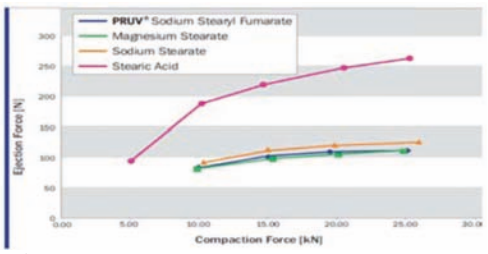
In this study, the effect of different lubricant on tablet hardness was evaluated



Observation: The kind of lubricant used had a significant influence on the hardness of the tablets. While tablet lubricated with stearic acid resulted in the highest tablet hardness, those made from magnesium stearate exhibited the lowest hardness. Tablets made from PRUV show intermediate hardness.

Lubrication efficiency

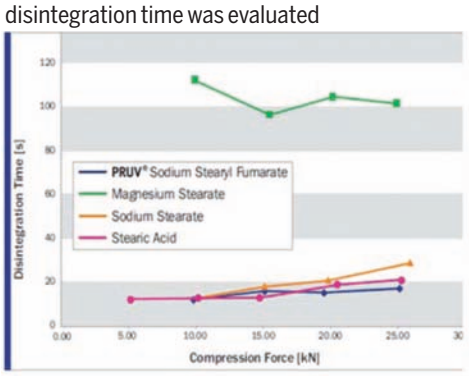
In this study, the effect of lubrication efficiency of different lubricants was evaluated



Observation: As for compactibility, a similar trend observed in the ejection forces. The tablets lubricated with stearic acid showed the highest ejection forces, while magnesium stearate was found on the lower end of the ejection force spectrum. Tablets made with PRUV exhibited the same low ejection forces as compared to magnesium stearate.

Disintegration time

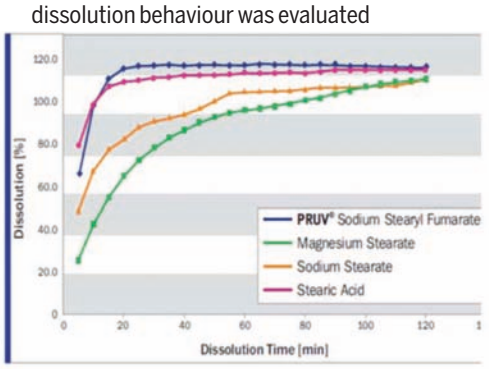
In this study, the effect of different lubricant on disintegration time was evaluated



Observation: Tablets lubricated with magnesium stearate needed by far the longest time for disintegration. All other tablets were found to have disintegration times in the same range

Dissolution behaviour

In this study, the effect of different lubricants on dissolution behaviour was evaluated



Observation: Tablets containing magnesium stearate showed by far the slowest dissolution rates. Sodium stearate and stearic acid-lubricated tablets released the API much faster. The faster drug release was observed for tablets lubricated with PRUV®

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Scan the QR code for more details regarding PRUV® from JRS Pharma.

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