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INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE SINCE 1994
NOVEMBER 2025, ₹40

+ Interviews

Aditya Sharma
Head of Process Solutions,
India Region, Merck Life Science

Srinath Venkatesh
MD, India & South Asia,
Thermo Fisher Scientific

Arpit Bhatia
Director, Laborate Pharmaceuticals

NEEDLES, PENS AND PRESSURE
THE GLP-1 CHALLENGE

As GLP-1 therapies transform diabetes and obesity care, demand for prefilled pens and injectors is soaring. Pharma–device collaborations, analytical innovation, and sustainable design will be key to tackle the growing device bottleneck

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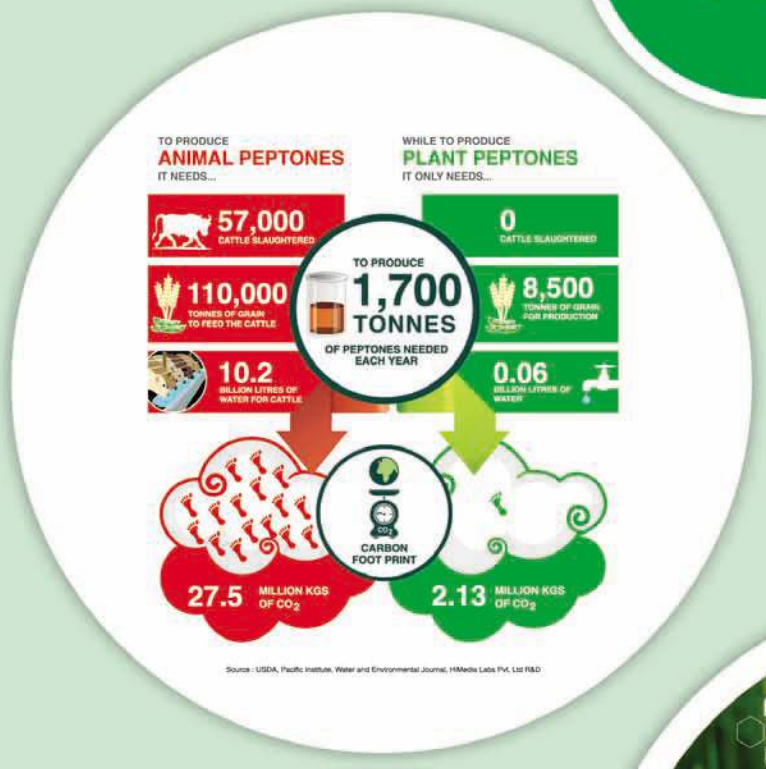

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* Responsible for selection of news under the PRP Act.

Will India pass the cough syrup trust test this time?

While India's CDMOs are well positioned to capitalise on the booming GLP-1 market, the recurring episodes of contaminated cough syrups are warning flags. Loss of semaglutide's key patent in March 2026 will see generics enter the market, putting further pressure on the price. And as manufacturers fight to conserve margins, cutting corners might result in sub-optimal quality.

Our cover story in the November edition, titled, *Needles, Pens and Pressure: The GLP-1 challenge*, highlights how companies are gearing up for this opportunity. The challenge of meeting the increased demand for prefilled pens and injectors will call for deeper pharma–device collaborations, analytical innovation, and sustainable design.

Interestingly, an IQVIA report, titled 'Off-patent semaglutide in 2026: the next revolution in anti-obesity medications', points out that of the over 10 companies filed for Subject Expert Committee (SEC) submissions in India to conduct Phase III studies for semaglutide, seven of them focus on oral versions.

This seems like a differentiation strategy, also anticipating the cold chain challenges of injectable GLP-1s in India. GLP-1 would also address needle-phobia issues.

The IQVIA report points out that Indian companies have begun laying the groundwork for international expansion, referencing Biocon partnering with Biomm who will file and commercialise their off-patent candidate in Brazil.

More recently, Eli Lilly (Lilly), and Cipla announced an agreement to distribute and promote tirzepatide in India under a second brand name, Yurpeak, at the same price as its Mounjaro.

However, the recent incident of cough syrup contamination with diethylene glycol (DEG), which led to the deaths of children in India, resurrects questions and doubts about our commitment to quality and regulatory compliance.

Such lapses undermines India's credibility in global markets and could sour the promise of opportunities like the GLP-1 boom. Following similar incidents in overseas markets in 2022–23, the Central Drugs Standard Control Organisation (CDSCO) had mandated pre-export testing of cough syrups.

And now the same norms are being applied to the domestic market. On October 22, CDSCO mandated a Digital Monitoring System on the Online National Drugs Licensing System (ONDLS) portal for monitoring the supply chain of high risk solvents.

This followed a directive dated October 07, which requested all the States/UTs to take measures to ensure testing before the manufacture and release of cough syrups batches to the market by monitoring during inspections, sensitising the manufacturers through circulars, etc.

Incidents of cough syrup contamination with DEG undermine India's credibility in global markets and could sour the promise of opportunities like the GLP-1 boom

On October 27, the CDSCO released details of the number of batches of cough syrup samples received for testing in Central/State drug testing laboratories. With Health Minister JP Nadda himself asking officials to "end it once and for all," could cough syrup manufacturers finally take this issue seriously?

As December 31, the compliance deadline for Revised Schedule M draws near, it's anyone's guess on how many small and medium manufacturers with a turnover of Rs 250 crore or less, will be ready for the new norms. The industry might lobby for an extension of this deadline but this might be counterproductive, sending the wrong signals.

Many reports highlight the potential of the CDMO opportunity for India but of late, these reports come with caveats. A recent Biobeat report forecasts that CDMOs in China and the US will experience the fastest growth, with mAbs, PROTACs, ADCs and sterile filling expected to drive demand in 2026. In terms of geographic locales, China and the US look best placed to capitalise in the medium term, with India cooling its growth from last year, and Europe remaining more neutral in outlook.

In development, CDMOs in the US, EU, and India are expected to see rising demand from Western innovators. However, Western CDMOs may face increasing pricing pressure from drug pricing reforms, while Indian CDMOs are likely to retain stronger pricing leverage and remain well positioned.

Looking ahead, as per the report, while a few very large CDMOs have benefited from significant GLP-1 revenues, oncology appears to offer greater growth potential for mid- and small-scale CDMO providers. Overall, for CDMOs focused on clinical activities, demand remains stable, with the report forecasting a return to higher growth over the next year.

But it won't take long for the GLP-1 boom to go bust, with many countries competing for the same opportunity. India's MSME pharma manufacturers need to see the short term pain of upgrading to the revised Schedule M as an investment for the future. Without this, they will not figure in future pharma supply chains. Unfortunately, it only takes a few deviant cough syrup makers to change the narrative.

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We can help our customers reach markets faster

Merck Life Science recently augmented its Formulation & Technology Center in Navi Mumbai. On a recent tour of the lab, **Aditya Sharma,** Head of Process Solutions, India Region, Merck Life Science explained to **Viveka Roychowdhury** how the lab plays a pivotal role in supporting Pharma and biopharmaceutical companies in excipient technology, formulation research and drug delivery to result in high-quality products matching the required dissolution, stability, and efficacy profiles. Excerpts from the interview

What's the vision and strategy behind Merck's Formulation & Technology Center in Navi Mumbai, which adds on to the two existing labs in Bengaluru?
We started this lab on a small scale around 10 years ago and recently, in February 2025, expanded to a new modern lab. The whole idea of this Formulation & Technology Center is to help our customers, especially around small molecules, build their formulations. The lab now has modern capabilities to cater to the need for formulators to resolve critical challenges in the drug formulation using Merck excipients.

As formulation development takes time and needs the required expertise, our offer to customers is that if they face challenges in certain formulations and need help, they can come to this lab. And we can bring in our expertise. We have people, we have the lab, so we can utilise the expertise there.

When you talk about helping clients and companies, is it the larger clients, larger companies, or is it the SME sector? Because formulation research, as you said, needs to be kind of done over a period of time. And in the MSME sector, the mid-sized players may not have a full-fledged in-house laboratory.
We have a broad clientele that includes both established multinational corporations and emerging SMEs. Regardless of size, our services are designed to support any organization facing challenges in formulation development, regardless of size. There is a growing trend in the industry where businesses are increasingly outsourcing formulation research to specialised partners like us, particularly those without a dedicated R&D infrastructure.

> There is a growing trend in the industry where businesses are increasingly outsourcing formulation research to specialised partners like us, particularly those without a dedicated R&D

We recently introduced mPredictTM, an AI-powered platform, to meet this need. After the API has been determined, this tool helps clients choose the best excipients for a particular formulation. It makes recommendations for excipient combinations that are most likely to result in a successful formulation by using predictive modeling.

We provide both the digital solution and practical assistance. But if customers also want a proof of concept, to see it in our lab, then we can create the formulation, show it to them and then take it forward from there.

How long would such a project take, from proof of concept to final product?
The final product may take a couple of months depending upon the formulation.

What would be the cost differential between outsourcing formulation R&D work and doing it in-house? Would outsourcing FR&D give enough ROI to prefer outsourcing rather than doing it within the company?
The price of the service would differ, of course, depending on the kind of work it is. But the ROI, in terms of speed to market, is very critical, right? So, for us—with the expertise we have available in the lab—we can help our customers reach markets faster. And this is what this lab enables our customers to do: develop their formulations quickly, without too much trial and error in-house, and move forward with their molecule more efficiently.

So you fail fast earlier and therefore you save time-to-market?
Yes, time to market is faster and the probability of success is faster because the team here in this lab is doing this day in, day out and aided by this AI tool mPredict™, we can provide a much quicker turn around.

Could you illustrate this with examples?
Merck has been working closely with leading biotechnology solution providers for collaborative data analysis in genomics and to ensure data privacy. Merck is also partnering with leading life science research companies to provide equipment and technologies for the manufacturing of monoclonal antibodies (mAbs) and novel modalities.

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Merck is actively working with various leading partners to help build a robust ecosystem that enables emerging biotech firms, smaller companies, and startups to scale rapidly.

Apart from such MOUs, we have also signed agreements with the Department for Promotion of Industry and Internal Trade (DPIIT). We have been working with them to identify a few startups that Merck can mentor, offering expertise and training. If they wish to take their products to different markets, we can consult with them. This is how we are engaging with the government to ensure that we, Merck as an organization—with the government's support and endorsement—can work with the industry, both startups and established players, to help bring products and therapies to market faster.

You mentioned emerging biotechs and start-ups in the biotech space. India's Start-up policy has spurred many emerging biotechs. You've talked about mentoring some of them. What do you feel about the role of India's policy initiatives in this space? How will the Government's Bio-E3 policy impact R&D and manufacturing within this space?

The Bio E3 policy definitely was the starting point, as it began building focus on biotech as an industry. But the recent Research Development and Innovation (RDI) policy is a game changer because the amount that has been allocated Rs 1 lakh crore clearly shows that the government is serious about R&D and innovation.

Within the RDI policy, Rs 20,000 crore will be allocated to several technology sectors of strategic importance, like biotechnology, which is substantial. This is the kind of financial support our startups need because taking a molecule to preclinical and then clinical trials is a very, very expensive endeavor. You need really deep pockets to do that, and that's where most of the molecules or research efforts die in India. So, with this kind of financial support, startups will have access to funding.

Once they get access to funding, the second biggest step is looking for technology and guidance. That is something Merck can provide—and is already doing.

So, I think with the government's policies and the whole ecosystem Merck is trying to create, we will enable these emerging startups to scale up faster.

What are the emerging trends in vaccine manufacturing? Where does India stand?

India is the world's largest vaccine manufacturer and fulfils more than 50% of the world's demand for vaccines. The focus predominantly has been on pediatric vaccines and pentavalent vaccines. With more and more companies expanding their business, we are witnessing a significant shift towards adult vaccines.

Leading companies have grown interest in oncology related vaccines and tremendous progress has been made in areas such as HPV, pneumonia, dengue, malaria. Indian manufacturers are actively launching vaccines targeting these diseases.

The other trend I see is that we now have the ambition to play directly in the established markets, like the US and Europe, with our vaccines. So far, most Indian companies participate in UNICEF, WHO tenders and supply to billions of people in Africa, Asia, Latin America and many other markets.

India holds a significant cost advantage, expertise, and trained manpower. India has been manufacturing vaccines for the past 70-80 years and holds substantial knowledge. Our facilities are all approved by the World Health Organization (WHO) and other premier bodies. India is leading vaccine manufacturers today. We can now realise this ambition through directly selling in US and Europe markets.

India holds a significant cost advantage, expertise, and trained manpower. India has been manufacturing vaccines for the past 70-80 years and bolds substantial knowledge

India is the largest player by volume in vaccines. Do you think that India can make it also in value because with the new generation vaccines, there's new technology like the mRNA vaccines, et cetera. Where does India figure in that space? These are newer technologies and more difficult to replicate. Where does India stand in this space?

Regarding the volume-value play, I would say that because we have been participating in tenders for these pentavalent vaccines, pediatric vaccines which are sold at a very low price, you see very high volumes, and the number of dosages is in billions. But the kind of price that you see is low.

But with these new vaccines, the other vaccines which we are targeting, like pneumonia and HPV, I think the value would definitely grow faster. Second, once we start tapping the US and European markets directly, a lot more value would definitely come in.

New therapies such as mRNA and new technologies would also significantly contribute to the value aspect. Going back to our conversation around start-ups, there are companies in India that are harnessing mRNA as a technology to develop novel products.

So, in working with some established players, some start-ups can further these new therapies through mRNA. I don't know the timelines yet. I see a lot of people debating as to when mRNA would become a very large technology, where you will see several vaccines and products coming out of mRNA. I don't know when that would happen, but I'm sure technology is moving in that direction

How can technology help biopharma companies in India to attain and maintain high standards in drug development and in a sustainable, cost-effective manner? Any advanced technologies that help your clients achieve consistent quality at sustainable cost?

I think the quality standards of Indian pharmaceutical companies, whether its generics, small molecules, vaccines, or biosimilars, are very high. I would say we produce world-class quality products. Forty percent of the US generic requirement is fulfilled by India. If you go to America or Europe, you will see a lot of products from Indian pharmaceutical companies.

So, I think in terms of quality standards, we produce some of the finest, and Merck is definitely working very closely with all leading Indian pharmaceutical players.

Whether it's our excipients, filtration technology, or downstream or upstream purification technologies, all help our customers maintain consistent quality. We have labs in India where we do a lot of validation of the processes. And that is something which helps our customers consistently produce their products.

Apart from that, we have our life science services business, which is BioReliance, acquired earlier by Merck. We provide a lot of services such as lot release criteria, which help customers ensure they consistently deliver top-quality products to their customers globally. The evolving regulatory framework, be it EU GMP or Schedule M, which was implemented recently, helps the Indian industry progress further.

So, I would say that if you look at the way technology has evolved, if you see most of the Indian manufacturers today, they are producing world-quality products and selling to all global markets. If you see, India has the maximum number of USFDA-approved plants outside the US. So, I think we definitely produce the best quality products globally

We talked about advanced therapies and mRNA vaccines, etc. What about GLP-1s? Many companies in India are gearing up for the patent expiries, the first one is coming up in March 2026. Is Merck working on such projects?

That's a very exciting space right now. And if you see, more companies are trying to get a piece of this huge opportunity which has opened up. We are working with many of our customers on different aspects spanning process materials, excipients for these products, formulation development, filter validations, and filtration aspects.

We are also working closely with them to help them build their own applications and formulations, setting the right process and validating the process. It is a very exciting new space which is opening up, and most companies are trying to scale up their business around this.

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Direct-to-Retail will increasingly complement traditional pharma distribution

Arpit Bhatia, Director, Laborate Pharmaceuticals, shares how its retail-first division, Aqualab is reshaping pharma distribution in India with its Direct-to-Retail model. He discusses the brand's rapid scale to Rs 100 crore and its roadmap to Rs 250 crore, in an exclusive interaction with **Viveka Roychowdhury**

Aqualab has crossed Rs 100 crore in just three years, what have been the key drivers behind this growth, and how does the brand plan to achieve the Rs 250 crore target by FY25–26?
Aqualab's journey to Rs 100 crore within three years reflects the strength of a simple yet powerful principle, accessibility through proximity. Our growth has been anchored in three areas: a high-velocity retail network that prioritises last-mile availability, a well-diversified therapeutic portfolio spanning acute and chronic segments, and a strong focus on brand trust built through consistent product quality.

We see Rs 250 crore not merely as a sales target but as a validation of our scalable model. The next phase of growth will be driven by deeper penetration into Tier II and III markets, category expansion in lifestyle and chronic care, and technological investments that bring agility to inventory management and retailer engagement.

What inspired Laborate to create a dedicated Direct-to-Retail division, and how does this model differ from traditional distributor-led pharma sales in India?
The Direct-to-Retail (D2R) model emerged from a simple observation, traditional multi-layered distribution systems often dilute efficiency and delay patient access. By creating a dedicated retail-first division, we bridged that gap. Aqualab enables direct partnerships with pharmacies and medical stores, ensuring consistent product availability, transparent pricing, and better margins for retailers.

Unlike the conventional distributor-led structure, our

D2R model facilitates real-time demand feedback, quicker product rotation, and more personal engagement with retail partners helping us respond faster to changing market needs.

How have non-metro and Tier II–III markets shaped Aqualab's growth story so far? What unique trends or consumer behaviours are emerging from these regions?
Non-metro India has been the real engine of our success. Pharmacies in Tier II and III cities are no longer peripheral; they are now the primary growth centres for affordable and reliable healthcare solutions. We have observed strong demand in therapeutic categories like pain management, antibiotics, and chronic lifestyle diseases.

Retailers in these regions value trust, supply consistency, and relationship-driven service. Our on-ground engagement teams and credit-support mechanisms have helped us build long-term partnerships in these markets.

Can you share how the retail-first model impacts accessibility and affordability for patients, especially in chronic and lifestyle medicine categories?
By removing distribution layers, we've reduced both cost and time inefficiencies. The savings achieved through this model are passed on to the consumer in the form of more competitive pricing while ensuring constant availability even in remote markets.

In chronic therapy segments such as diabetes and hypertension, where uninterrupted access to medication is critical, our retail-first model ensures that pharmacies never face stockouts, improving adherence and outcomes for patients.

> The D2R model will play a significant role in this shift by reducing intermediaries, enhancing transparency, and enabling faster access to medicines

What operational or technological innovations have been instrumental in making this D2R model sustainable and scalable for Laborate?
Aqualab operates on a digitally enabled retail management backbone. We have invested in real-time demand forecasting tools, digital order management systems, and retailer engagement platforms that simplify reordering and communication.

We also use region-specific data analytics to optimise supply chain routes, track sales velocity, and ensure efficient stock replenishment. These innovations have allowed us to scale while maintaining operational precision.

How do you see the Direct-to-Retail approach influencing India's broader pharmaceutical supply chain in the next few years?
India's pharma supply chain is entering a period of transformation, fuelled by digitisation and regulatory streamlining. The D2R model will play a significant role in this shift by reducing intermediaries, enhancing transparency, and enabling faster access to medicines.

As more companies adopt hybrid approaches, blending digital ordering, retailer networks, and data-driven forecasting, we will see a more efficient, patient-centric supply chain ecosystem emerge.

Globally, several healthcare brands are experimenting with direct distribution and patient engagement models. How does Aqualab's strategy compare with international benchmarks?
Globally, brands like Walgreens Boots Alliance in the UK and CVS Health in the US have integrated direct brand-to-shelf strategies to enhance patient engagement. Aqualab's model reflects similar agility, but with a uniquely Indian adaptation, high-touch relationships, flexible payment models, and cost-efficiency suited to regional market realities.

We are creating an ecosystem that balances the scalability of global systems with the relational depth that drives trust in Indian markets.

What role does quality assurance and brand trust play in the success of a direct model, where consumers often engage more closely with the manufacturer's name than with intermediaries?
Trust is non-negotiable. At Laborate, every product under Aqualab adheres to the same rigorous quality standards as our international formulations, backed by EU-GMP, WHO-GMP, and ISO certifications.

When consumers and retailers directly associate with the manufacturer, quality becomes the true differentiator. Our emphasis on transparency, packaging integrity, and consistent supply has helped Aqualab become a name retailers recommend with confidence.

What are some of the key challenges Laborate has faced while scaling the retail-first model, and how have you addressed them?
Building a D2R model required rethinking everything from logistics and credit cycles to on-ground team training. The initial challenge was educating retailers about the long-term benefits of direct engagement versus conventional distributor systems.

We addressed this through dedicated relationship management, faster credit settlements, and reliable after-sales support creating a system where trust could grow organically.

Looking ahead, do you believe Direct-to-Retail could become a mainstream model for Indian pharma? What would need to change policy-wise, technologically, or culturally for that to happen?
Yes, Direct-to-Retail will increasingly complement traditional pharma distribution. For it to become mainstream, three enablers are crucial digital adoption across the retail chain, regulatory support for transparent pricing, and stronger logistics infrastructure for last-mile delivery.

India's healthcare landscape is evolving rapidly, and the D2R model aligns perfectly with the country's vision for accessibility, affordability, and self-reliant growth.

At Laborate, we see this as not just a business model but a step towards democratising healthcare access one retail partnership at a time.

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India is potentially on track to becoming a $300 billion bioeconomy

Srinath Venkatesh, MD, India & South Asia, Thermo Fisher Scientific, shares insights on the drivers shaping India's biopharma growth, the company's role in building innovation capacity, upcoming investments in Hyderabad's Genome Valley, and how partnerships, policy support, and startup collaborations are accelerating India's move up the value chain, in a freewheeling conversation with **Lakshmipriya Nair**

To understand the landscape better, how big is biopharma in India? Where are we headed, and what role does Thermo Fisher play in this journey?
India is potentially on track to becoming a $300 billion bioeconomy. The major shift we are witnessing is from being a largely generics-driven industry — which accounts for about 20 per cent of the world's generics supply — to developing and manufacturing larger molecules and biologics. That's where we see significant momentum, and that's where companies like us play a critical role.

We continue to support generics manufacturers, who remain key customers, but the future opportunity clearly lies in enabling the transition to complex biologics. This shift is being driven by several factors.

First, strong government support through initiatives like PRIP and BioE3 has created an enabling policy environment.

Second, private sector investment is rising. As companies prepare to compete globally, they are raising the bar in quality, R&D, and regulatory compliance, including global approvals like the US FDA.

Third, India has a large talent pool. While not all expertise is specialised yet,

the foundational capability is strong and upskills rapidly once deployed.

And finally, there is a strong national push toward innovation and moving up the value chain.

From our perspective, as this ecosystem evolves, we are well-positioned across the entire biologics value chain. If you break it down into four phases, we operate in all of them:

◆ **Discovery & R&D:** We offer a wide range of analytical and scientific instruments.

◆ **Process development:** We provide comprehensive solutions to build scalable and efficient production workflows.

◆ **Clinical research:** Our teams support clinical trial design, protocol development, packaging, storage, and logistics.

◆ **Manufacturing:** We supply the platforms and technologies to manufacture large-molecule therapeutics.

We don't often highlight it, but our solutions span every step of the biopharma workflow. And with India currently representing only two to three per cent of the global biologics market, despite leadership in generics, moving deeper into biologics is a natural progression. That's where we contribute meaningfully.

What are the opportunities that are unique to India?
Scale and cost advantage, undoubtedly. Take cell and gene therapies, for example — they offer tremendous patient benefits. India's proven record in cost-efficient manufacturing and its scalable talent pool provide a unique advantage in bringing these therapies to market affordably.

I was speaking to someone recently who said that when innovation comes from India, it serves the world, because of our cost competitiveness. Which means we need a stronger innovation ecosystem. Your thoughts?

> Our vision is to become the partner of choice in scaling and enabling the biopharma manufacturing ecosystem. We are expanding our presence through commercial teams, service centers, infrastructure, R&D investments, and localised supply chains

Absolutely. I'll connect that to something we recently announced, a collaboration with Startup India under DPIIT, called the BioVerse Challenge.

The idea is to identify around 500 startups across medtech, biopharma, biophysics, proteomics, etc., and help them scale.

We will mentor about 400 startups offline, and 100 will be brought into our Customer Experience Center (CEC) and Bioprocessing Design Center (BDC) in Genome Valley, Hyderabad, for hands-on support.

The BDC is being set up with the Government of Telangana, and the CEC is our own facility. Startups will get access to infrastructure, equipment, and technical expertise, essentially the ecosystem needed to accelerate innovation.

And how are the startups being selected?
The applications are invited through the DPIIT Startup India portal. Startups share the problem they are addressing, market relevance, and feasibility. An advisory board of academicians and industry leaders evaluates them. The top 100 receive hands-on training; the others receive structured mentorship.

When will the new Hyderabad facilities be ready? Can you share the scale of investment at these facilities?
Within this year. They are at an advanced stage and we expect to announce in Q4.

We won't be sharing numbers at this stage. But broadly, for the BDC it's largely equipment and people, and for the CEC it includes infrastructure, space, and solutions. It is a significant investment across both.

What is Thermo Fisher's five-year plan for India?
Our vision is to become the partner of choice in scaling and enabling the biopharma manufacturing ecosystem. We are expanding our presence through commercial teams, service centers, infrastructure, R&D investments, and localised supply chains. Beyond biopharma, the CEC will also support semiconductors and clean energy workflows. You'll see a stronger, more embedded on-ground presence.

Any new partnerships?
We continue to partner across the ecosystem — with the Government of Telangana, DPIIT, CFSL Ahmedabad, CCAMP, and Atal Incubation Centres, among others. These partnerships combine our technical expertise with institutional scale and reach.

Are more centers planned after Hyderabad?
Not immediately. These are experience and workflow centers, not manufacturing sites. Our manufacturing footprint is already national — in Maharashtra (Chakan and Pune), near Amarnath, and in Bengaluru.

What challenges do you encounter in the Indian market?
The need for more specialised skills, especially in emerging areas like CGT, and continuously evolving regulatory pathways. These are natural in a growth market, not roadblocks. Our ongoing investments address these areas.

How is Thermo Fisher supporting MSMEs, especially in a cost-sensitive environment?
Many MSMEs are already our customers — for example, in air quality monitoring solutions. While the market is price-conscious, customers value high-technology solutions when we demonstrate clear value and reliability.

How has your supply chain evolved post-pandemic?
We've increased local stocking and localised manufacturing for several products. We've also strengthened our service capabilities and spare-part availability. Faster response and reliable service have been key.

One final question — tariffs and geopolitics. How are you managing customer concerns?
We stay transparent, stay close to our customers, and continue doing what we do best. We adjust where needed and remain committed to supporting our customers consistently.

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18 edition of CPHI & PMEC India 2025 to be held from 25–27 Nov 2025 at IEML, Greater Noida

The event will bring together 2,000+ exhibitors and 35,000+ industry professionals

Organised by Informa Markets in India, the 18th edition of CPHI & PMEC India 2025 is scheduled from November 25-27, 2025, at the India Expo Mart, Greater Noida, Delhi NCR. The event will bring together over 2,000 exhibitors and 35,000+ industry professionals, buyers, and investors from India, Southeast Asia, and across the globe. As India's pharma industry gears up for robust expansion, the sector's total market size is projected to reach $130 billion by 2030 and an impressive $450 billion by 2047, highlighting the country's growing role as a global pharma powerhouse.

Yogesh Mudras, Managing Director, Informa Markets in India

CPHI & PMEC India is a global platform for pharma sourcing and innovation, connecting over 50,000 professionals from 120+ countries. The 2025 edition will feature the complete pharma value chain under one roof, encompassing formulations, APIs, excipients, packaging, machinery, and contract services, offering unparalleled opportunities for business networking, B2B matchmaking, and market insights.

Yogesh Mudras, Managing Director, Informa Markets in India, said, "The Indian pharmaceutical industry has evolved into one of the most dynamic and innovation-driven sectors globally, recognised for its world-class capability in producing affordable generics and life-saving vaccines. Ranking third in pharma production by volume and contributing around 1.72 per cent to the national GDP, the sector continues to play a pivotal role in driving economic growth and global healthcare accessibility. With the Union Budget 2025–26 proposing an allocation of over Rs 5,268 crore to the Department of Pharmaceuticals, marking a nearly 29 per cent increase from the previous year, the government's continued focus on strengthening R&D, infrastructure, and capacity building further reinforces India's vision of becoming a global hub for pharma innovation. Against this backdrop, CPHI & PMEC India 2025 serves as an ideal platform for strengthening collaboration, knowledge exchange, and strategic partnerships that will shape the future of India's pharma landscape."

The upcoming edition will focus on key industry themes such as API self-reliance, sustainability, digitalisation, and exports, highlighting India's transition toward innovation-driven growth. The event will showcase cutting-edge solutions in clean manufacturing, ESG compliance, and Pharma 4.0 technologies, aligning with the evolving needs of a future-ready pharma ecosystem. Visitors can expect exciting product launches and breakthrough technology innovations, highlighting India's growing capability in sustainable and high-value pharma manufacturing.

CPHI & PMEC India 2025 will welcome international exhibitors from China, Italy, Germany, Switzerland, and South Korea, among others, strengthening cross-border collaborations and export opportunities.

This year's edition will also host the Pharma Leaders Roundtable, Women in Pharma Roundtable, the CPHI Pharma Awards, and the Pharma Connect Congress, offering a platform for policy dialogues, leadership exchange, and innovation-driven discussions.

The three-day event will also feature a comprehensive line-up of knowledge-led conferences and leadership dialogues, designed to drive strategic discussions and actionable insights for the pharma community. Key sessions will explore themes such as business sustainability in a shifting geopolitical landscape, reimagining innovation and manufacturing to enable transformative and affordable medicines, and enhancing patient centricity beyond GMP compliance. Further, high-level panels will delve into charting the roadmap to meet sustainability goals and incorporating green design principles in pharma packaging and logistics to reduce carbon footprint, reflecting the industry's collective vision towards responsible growth, innovation, and global competitiveness.

The event will see participation from leading exhibitors such as Dr. Reddy's Laboratories, Hetero Labs, Oceanic Pharmachem, Akums Drugs & Pharmaceuticals, Morepen Laboratories, MSN Laboratories, Capsugel Healthcare, Biocon, and Jubilant Ingrevia. On the machinery side, PMEC India will feature top players including ACG Pam Pharma Technologies, Cadmach Machinery, Ace Technologies & Packaging Systems, Parle Global Technologies, Klenzaids Contamination Controls, Gansons, Elmach Packages (India), NPM Machinery, and Snowbell Machines.

Supported by key industry associations such as Pharmexcil, International Pharmaceutical Excipients Council (IPEC) India, Bulk Drug Manufacturers Association of India (BDMAI), and Organisation of Pharmaceutical Producers of India (OPPI), along with participation from regulatory authorities and policymakers, the 2025 edition reinforces its position as a credible platform for policy advocacy, industry collaboration, and sustainable business growth.

With its global reach, comprehensive exhibit profile, and strong focus on innovation, CPHI & PMEC India 2025 continues to strengthen India's role as the pharmacy of the world, fostering meaningful partnerships and charting the next phase of growth for the pharma industry.

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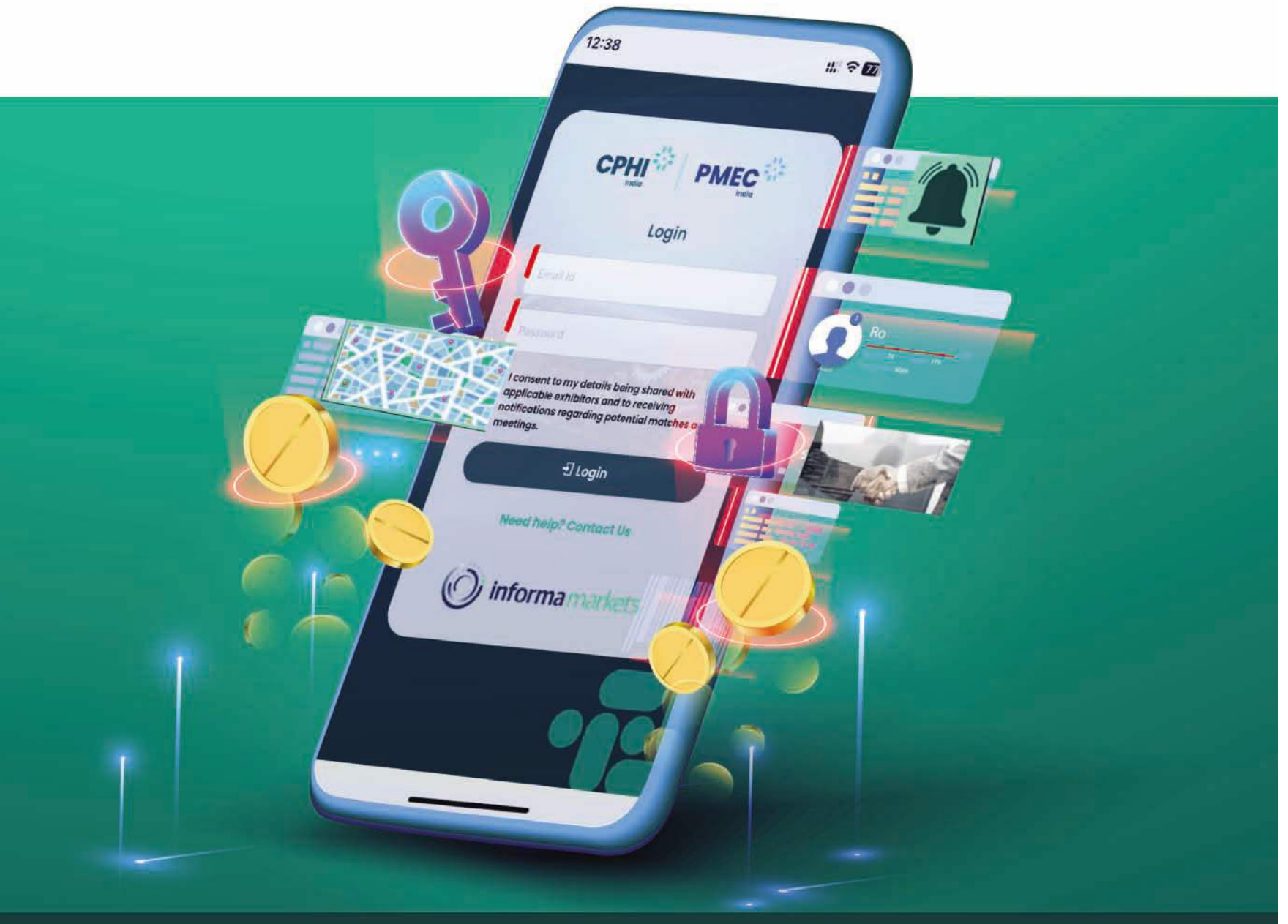

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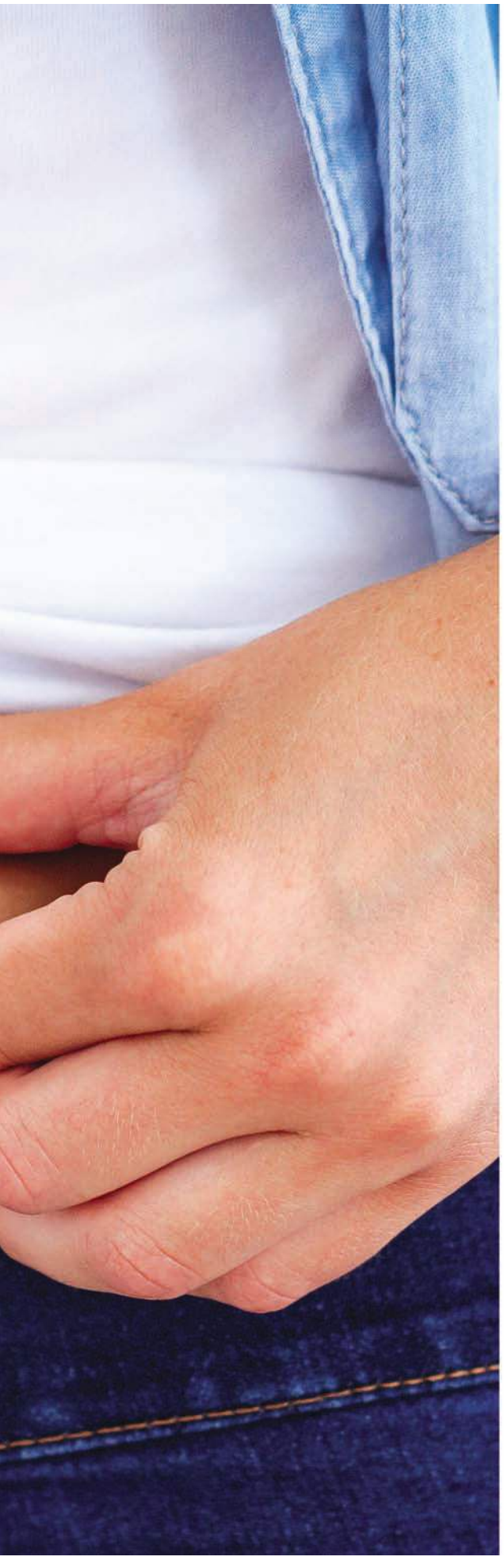


NEEDLES, PENS AND PRESSURE

THE GLP-1 CHALLENGE

As GLP-1 therapies transform diabetes and obesity care, demand for prefilled pens and injectors is soaring. Pharma–device collaborations, analytical innovation, and sustainable design will be key to tackle the growing device bottleneck

By Kalyani Sharma

The rapid global adoption of GLP-1 based therapies, developed for diabetes and now also used for weight management, has reshaped the pharma landscape. Drugs like semaglutide and tirzepatide are seeing a surge in demand. However, this is creating a critical bottleneck in the supply of the active drug itself, but also in the availability of the medical devices to administer it.

The essential components of these therapies include prefilled pens, cartridges and autoinjectors. The surge in usage and prescriptions is pushing manufacturers to scale up production. As the global pharma prepares for the entry of generic versions, once the key patent expires, the device ecosystem's planning and strategy on its readiness will define how accessible and sustainable this revolution will be.

The global weight loss drug boom

The last few years have witnessed a dramatic transformation in the perception and uptake of GLP-1–based therapies. Once confined to diabetes management, these drugs are now leading a new era of metabolic care.

Selena Yu, Senior Medical Analyst, GlobalData explains, “Rising global rates of obesity and type II diabetes, coupled with growing public awareness of GLP 1R agonists, are fueling expansion in the weight loss drug market. Originally developed for patients with type II diabetes (with or without obesity), GLP-1R agonists are increasingly prescribed for obesity alone. Public interest has surged since 2019—Google searches for 'Ozempic' peaked in August 2025.”

Yu notes that while off-label use accounts for a sizeable share of drug use, those users largely do not overlap with the obese patient population. “For obese patients, the first line of treatment is lifestyle intervention, where medical professionals aid patients to lose weight with a healthy diet and exercise. In 2024, 94 per cent of obese patients in the 7MM (US, 5EU, and Japan) are using methods such as lifestyle intervention, diet, and exercise to manage weight, as shown in Figure 1. If the patients can lose 5 per cent or more of their weight and show improvements in other health targets like blood pressure and glucose, they will continue utilising lifestyle intervention. However, if obese patients are not successful, intense behavioral treatment or pharmacotherapy is used. 5.59 per cent of the obese population in 2024 uses GLP-1R agonists in the 7MM, and this is expected to grow to 12.11 per cent of the obese population in 2033.”

The rising patient base and rise in prescriptions have created a cascade across the ecosystem-from formulation innovation to delivery systems.

According to Yu, “The pipeline products database on the Medical Intelligence Center (MIC) already features 16 devices targeting obesity and type II diabetes with GLP 1R agonists, as many ditch injections altogether. New approaches, from microneedle transdermal patches to implantable slow-release systems, are being engineered to deliver GLP-1R agonists steadily over time.”

“Additionally, these types of devices may have reduced injection frequency, which improves adherence, and with easier drug delivery systems, there’s a smaller learning curve, which also increases patient compliance”, she adds.

Yu also cautions that, “It's hard to say if drug delivery device manufacturers will 'keep pace' with this growing market, as this market really depends on partnerships made with pharma companies producing GLP 1R agonists. Major aspects for manufacturers to consider are, do their manufacturing partner, OEMs and CMOs have facilities in the US to offset tariffs, do they currently have manufacturing capabilities, or is this

It's hard to say if drug delivery device manufacturers will 'keep pace' with this growing market, as this market really depends on partnerships made with pharmaceutical companies producing GLP 1R agonists

Selena Yu
Senior Medical Analyst,
GlobalData

The rise of single-use pens brings sustainability into focus. As environmental expectations grow, reusable and recyclable delivery systems are gaining traction

Nandakumar Kalathil
Country General Manager - India,
Agilent Technologies

India combines scale manufacturing, cost advantage, and a deep pharmaceutical talent pool. That extends to device supply chains (needles, syringes, components) and to oral dosage form manufacturing

Harshad Lalwani
Founder,
Hummsa Biotech

The anticipated surge in demand is primarily fueled by the expiration of patents for semaglutide in over 100 countries... This development is expected to lead to the introduction of generic versions, making these therapies more accessible and affordable

Neeraj Sharma
CEO and Managing Director,
OneSource Specialty Pharma

something that requires to be scaled up, which can take months to years."

Drug innovation to delivery innovation

The success of GLP-1 therapies has inflated the pharma innovation-from molecular design to the engineering of safer and more sustainable delivery systems.

Nandakumar Kalathil, Country General Manager - India, Agilent Technologies, highlights, "The global healthcare landscape is evolving rapidly with the widespread adoption of GLP-1 receptor agonists—therapies originally developed for type 2 diabetes that are now transforming obesity management. As prescriptions for drugs like semaglutide and tirzepatide surge, attention is shifting from drug availability to a critical enabler - the medical devices required to deliver these therapies safely, sustainably, and at scale."

He mentions that prefilled and reusable injection pens have emerged as the preferred delivery method, offering precision, convenience, and improved patient adherence. However, this surge in demand is testing the resilience of device supply chains and raising important questions around sustainability, regulatory compliance, and readiness for scale.

Industry forecasts project the market to exceed $100 billion by 2029, driven by expanded therapeutic indications and the anticipated launch of oral formulations.

Kalathil stresses, "This momentum presents both opportunity and urgency for pharmaceutical and device manufacturers to ensure delivery systems can keep pace with demand while maintaining safety, sustainability, and regulatory integrity."

The complexity of these devices often involving multilayer packaging, elastomeric seals, and polymeric components, also heightens the need for robust analytical validation. "As GLP-1 therapies scale, the complexity of delivery devices often involving multilayer packaging, elastomeric seals, and polymeric components requires rigorous analytical validation to ensure patient safety and regulatory compliance by identifying and controlling extractables and leachables (E&Ls) that may migrate from device materials into the drug product.", Kalathil adds.

Kalathil shares that, "Agilent supports this critical need with GLP-compliant analytical workflows that help manufacturers validate materials, assess E&Ls, and meet global regulatory standards. Our LC/MS, GC/MS, and ICP-MS platforms provide trusted answers across the product lifecycle, enabling safe and compliant scale-up."

Beyond compliance, sustainability is emerging as a major differentiator. "The rise of single-use pens brings sustainability into focus. As environmental expectations grow, reusable and recyclable delivery systems are gaining traction. This shift presents an opportunity for pharma–device collaboration, where analytical science guides material selection, impurity profiling, and lifecycle assessments", says Kalathil.

Agilent, he adds, is also exploring "circular economy models and green lab certifications to further reduce environmental impact, ensuring that innovation goes together with responsibility."

With India rapidly evolving as a biopharma manufacturing hub, Kalathil points out that the country is "well-positioned to support global supply chains for GLP-1 therapies."

Capacity, challenges and collaboration

For manufacturers, the biggest challenge is the rising demand for GLP-1 therapies with sufficient device capacity.

Harshad Lalwani, Founder, Hummsa Biotech, explains, "GLP-1–based therapies have moved from diabetes into broad metabolic care and obesity, with rapid adoption. The market is diversifying beyond weekly injectables into new delivery forms—including orals (both peptide and small-molecule) and combo regimens. Two realities now coexist: (i) unprecedented demand, and (ii) supply strain not just on drug substance, but also on delivery systems (pens, autoinjectors, fill-finish)."

He further stresses that, "Device capacity is a real bottleneck: pen bodies, springs, needles, cartridges, and aseptic fill-finish all sit on long lead times and specialized lines. As more products launch (including after loss-of-exclusivity waves in some markets), device demand rises further."

According to Lalwani, "The mitigation is multi-pronged: platform hardware, multi-sourcing, earlier device–pharma collaboration, and therapeutic modalities that don't require a pen, notably, orals. From a systems view, every patient on an oral reduces device load and environmental footprint."

Lalwani believes that India has a strong role to play in this transformation. "India combines scale manufacturing, cost advantage, and a deep pharmaceutical talent pool. That extends to device supply chains (needles, syringes, components) and to oral dosage form manufacturing. For innovators like us, India enables capital-efficient development: CMC, stability under Zone IVb, and rapid tech transfer. Strategically, India can both expand device capacity and lead in oral GLP-1 manufacturing, easing supply constraints and improving access."

Scaling up and expanding capacity to meet global demand

While innovators focus on next-generation formulations, contract manufacturers and CDMOs are racing to expand capacity and build resilient, end-to-end ecosystems capable of supporting large-scale production.

Neeraj Sharma, CEO and Managing Director, OneSource Specialty Pharma, outlines, "The global market for GLP-1–based therapies is experiencing unprecedented growth, given the increasing incidence of Type 2 diabetes and obesity and its efficacy in the management of both diseases. The competition is expected to further intensify with key drugs like semaglutide expected to go off patent in 2026."

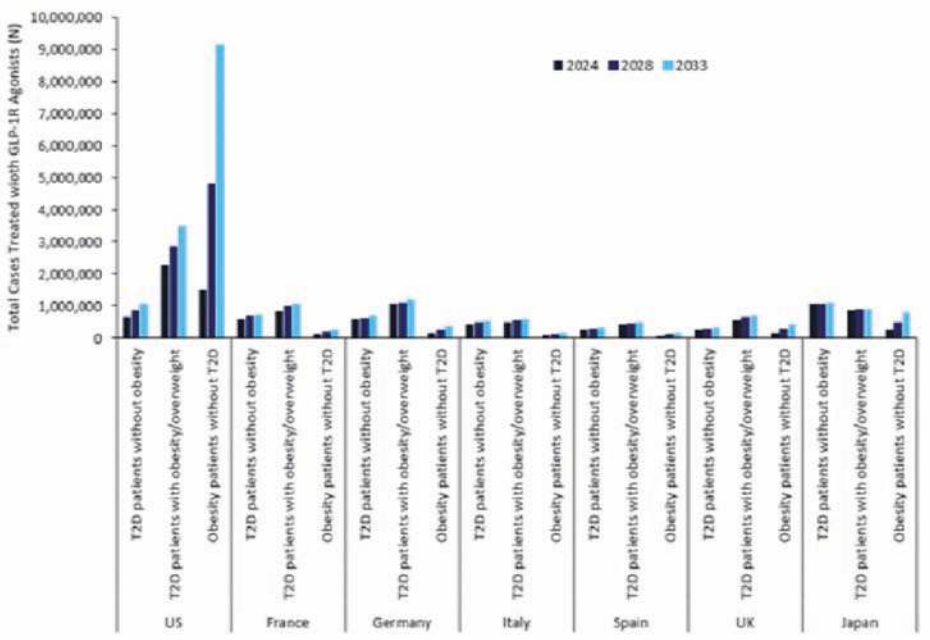
Sharma also opines that for CDMOs, this evolution demands far more than drug synthesis; it requires large-scale, compliant, and efficient production of complex, patient-ready combination products."

Recognising industry-wide constraints around API sourcing, primary packaging, and device availability, the company has taken proactive measures. "To ensure uninterrupted supply and agility, we have built a resilient ecosystem with multiple qualified vendors across each critical component. This approach, coupled with our robust capabilities, scalable capacity, and regulatory strength, enables OneSource to reliably support customers through the evolving GLP-1 landscape."

According to Sharma, the surge in demand will be driven by the impending wave of generics. "The anticipated surge in demand is primarily fueled by the expiration of patents for semaglutide in over 100 countries...This development is expected to lead to the introduction of generic versions, making these therapies more accessible and affordable."

He highlights that OneSource is investing significantly to prepare for this growth. "OneSource Specialty Pharma is investing approximately $100 million to expand its drug-device facilities, increasing cartridge filling capacity from 40 million to 200 million units over

FIGURE 1: TARGET POPULATION TREATED WITH GLP-1R AGONISTS, 7MM (N)



Source: GlobalData

the next 18–24 months. This strategic investment strengthens OneSource's position as a reliable partner capable of supporting large-scale GLP-1 programs worldwide."

At the same time, the company is closely tracking innovation trends. "Emerging advancements such as once-a-month dosing, reusable or more sustainable delivery systems, and cost-efficient options driven by mass manufacturing will further transform patient access and adherence," Sharma explains.

He sees India as a clear beneficiary of this expansion. "India, known as the pharmacy of the world, has a significant opportunity to play a pivotal role in the GLP-1 space... With the growing global demand for weight loss drugs, Indian CDMOs must leverage these strengths to scale up device manufacturing, focusing on cost-efficient, high-quality drug delivery systems that can serve both the large domestic market and emerging global economies."

Convergence of sustainability and scalability

The rise in demand has put a spotlight on environmental sustainability. The disposal of single-use injection pens globally raises concerns about plastic waste and life-cycle impact.

As Kalathil points out, "The rise of single-use pens brings sustainability into focus. As environmental expectations grow, reusable and recyclable delivery systems are gaining traction."

This combination of sustainability and scalability can drive deeper collaboration between pharma and device companies.

The India advantage

India is emerging as a preferred hub for both pharma and medical devices, offering a strategic advantage in the GLP-1 race. The cost-competitiveness, increasingly mature regulatory environment and large talent base can serve both domestic and international demand.

As Sharma points out, "The country possesses end-to-end expertise from API development and drug manufacturing at scale to strong government support creating a robust foundation for growth."

Lalwani echoes this sentiment, "For innovators like us, India enables capital-efficient development: CMC, stability under Zone IVb, and rapid tech transfer. Strategically, India can both expand device capacity and lead in oral GLP-1 manufacturing, easing supply constraints and improving access."

The localisation of device production could enable quicker market response time by reducing dependence on imported components.

Way forward

All expert perspectives point toward a future where the success of GLP-1 therapies depends on how strong our engineering and logistics are.

To sustain its momentum, the GLP-1 revolution will require pharma–device collaborations, analytical innovation, and sustainable design, which will be key to tackling the growing device bottleneck. Can the device supply keep up with the demand? If India's manufacturing ecosystem, coupled with meaningful global collaboration, rises to the challenges, then the answer might be yes.

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Reimagining cold chain: How IoT secures every pharma mile

Swarup Bose, Co-founder and CEO, Celcius Logistics points out that as the demand for temperature-sensitive medicines surges, maintaining an unbroken cold chain has never been more critical. IoT is emerging as the game-changer that ensures every vial and vaccine arrives potent, safe, and on time

Did you know that nearly 25 per cent of vaccines are wasted each year due to poor temperature control?1 Behind this alarming statistic are real stories – a child missing a lifesaving dose, a diabetic struggling without effective insulin, or a family paying for treatment that no longer works. Temperature fluctuations during storage and transit make the pharmaceutical cold chain one of the most brittle links in healthcare delivery. With millions of lives depending on temperature-sensitive medicines, flawless cold chain logistics aren't just about reducing waste; they're about safeguarding patient safety and ensuring every dose, from lab to life, fulfills its purpose.

Rising importance of pharma cold chain

The foundation of healthcare logistics is made up of pharmaceutical cold chains, which guarantee the safe delivery of vaccines, biologics, insulin, and other temperature-sensitive medicines. Cold chains, as opposed to traditional supply chains, need to keep manufacturing plants, pharmacies, and hospitals in challenging environmental conditions. Any slip-up, whether due to poor refrigeration, delayed shipping, or human error, can reduce the potency of a drug, resulting in monetary losses, fines from the government, and above all — patient risk.

Conventional cold chain procedures are under more and more strain due to the rising demand for biologics, vaccines, and specialty medications. To meet the demands of contemporary healthcare, real-time monitoring, predictive maintenance, and end-to-end visibility are now crucial.

The IoT advantage in cold chain

The Internet of Things (IoT) is transforming cold chain management by connecting sensors, trackers, and cloud platforms to enable continuous monitoring of shipments. Smart sensors measure temperature, humidity, and location data, generating real-time insights that allow logistics teams to respond instantly to any deviations.

These systems enable proactive intervention to stop spoiling by sending out automated alerts if conditions deviate from safe ranges. In addition to reducing human error, automated data logging produces precise, audit-ready records for regulatory compliance. Every pharma product is kept safe, effective, and traceable from manufacturing to delivery owing to real-time monitoring.

Supply chain integration with emerging tech

Emerging technologies are further strengthening the IoT-led cold chain. Instead of dense, one-size-fits-all systems, companies are layering specialised tools. AI and analytics use historical and real-time data to forecast demand and optimise delivery routes. This reduces spoilage and ensures efficient inventory management. Blockchain provides an immutable record of handling conditions, ensuring traceability and product integrity. It allows stakeholders to verify authenticity and compliance at every stage. GPS and telematics enable live tracking of shipments and monitoring of environmental conditions, offering transparency to regulators and allowing timely intervention if issues arise.

By integrating these solutions, businesses can transform fragmented cold chain operations into cohesive, intelligent networks that adapt to challenges in real time.

Regulatory compliance and data integrity

Pharmaceutical regulations, including Good Distribution Practice (GDP) and Good Manufacturing Practice (GMP), demand strict adherence to precise storage and transportation conditions to ensure drug safety and efficacy. IoT platforms play a critical role in simplifying compliance by continuously monitoring temperature, humidity, and other environmental parameters, generating automated reports, and maintaining secure, tamper-proof digital records. These systems allow companies to identify and address deviations in real time, reducing the risk of regulatory breaches.

In addition to ensuring adherence to both global and local regulations, IoT-enabled data provides accurate, immutable audit trails that make inspections faster and less resource-intensive. By leveraging such technologies, pharmaceutical companies can confidently demonstrate compliance while strengthening trust with regulators, healthcare providers, and, ultimately, patients who rely on safe and effective medicines.

Building future-ready pharma supply chains

The future of pharmaceutical logistics relies on supply chains that are intelligent, responsive, and robust. IoT-enabled solutions ensure operational efficiency while cutting energy use and costs, making the entire cold chain more sustainable. Predictive maintenance, automated alerts, and real-time monitoring safeguard product integrity, prevent spoilage, and optimise warehouse and transport resources.

Pharma logistics can build supply chains that are safer, smarter, and more transparent by adopting IoT and emerging technologies. Real-time monitoring and management of every shipment, from the production floor to the pharmacy shelf, improves operational effectiveness, patient safety, and regulatory compliance.

With rising global demand for temperature-sensitive medicines, IoT-enabled cold chain solutions have become indispensable. They ensure every product reaches its destination intact, preserving potency, reducing waste, and lowering costs, while strengthening the healthcare ecosystem. Beyond efficiency, securing every mile of the pharma supply chain is about trust and responsibility. It's not just technology at work; it's the protection of patient lives worldwide.

1. https://www.rejigdigital.com/blog/iot-cold-chain-management-pharma/

Strategic shifts in pharma hiring and why it matters

Roop Kaistha, Regional Managing Director, APAC- AMS highlights the evolving talent strategies in pharma and reveals how hiring is becoming a core lever for innovation, resilience, and global competitiveness

The pharmaceutical sector is operating in an increasingly complex environment. Regulatory scrutiny, rising input costs, and global pricing pressures are impacting profitability across the board. At the same time, companies are under pressure to secure highly skilled talent capable of driving scientific and commercial performance. This mounting pressure is forcing pharma players to rethink their recruitment models through measurable changes that reflect both operational constraints and strategic intent.

Cost pressures are reshaping talent decisions

Indian pharmaceutical firms, especially those focused on generics, are navigating steep margin compression. The combination of declining prices in key export markets and proposed tariffs on active pharmaceutical ingredients has placed financial strain on many companies. Industry data suggests Indian pharma profitability has declined between 20 per cent-30 per cent over the past few years. This has prompted cost containment measures that include budget freezes, hiring slowdowns, and workforce rationalisation.

Recruitment is being recalibrated to focus on business-critical roles with direct value contribution. Companies are placing greater emphasis on role justification, prioritising hires with specialised skills or strategic impact. Hiring timelines have become shorter in high-need areas while lateral hiring in support functions has been delayed or scaled back.

In parallel, hiring intent rose from 47 per cent in 2024 to 52 per cent in H1 2025 across metro cities like Bengaluru, Hyderabad, and Chennai. This intent is driven by demand for clinical data analysts and medical transcriptionists fueled by greenfield and brownfield GCCs in the sector.

Global hiring momentum remains uneven across regions

Across the global pharma and MedTech landscape, external hiring began slowly in 2024. While activity improved during the middle of the year, several regions including the United States, the United Kingdom, and parts of the Asia Pacific region are now reporting a decline in job postings. In contrast, markets such as India, Latin America, and the EMEA region have shown increased demand. In India specifically, job demand rose by 48 per cent in the first half of 2025 , with pharmaceutical roles accounting for more than 7,000 of the 8,600 job postings per month. This disparity reflects the influence of local market conditions, investment cycles, and regional regulatory frameworks on talent planning.

Sanofi's Hyderabad Innovation Center is a case in point. It plans to double its headcount from 1,000 to 2,600 by 2026, focusing on data science and clinical trial documentation.

Hybrid work models are expanding gradually

Across corporate India, hybrid work is now common in several sectors. Surveys indicate that more than 44% of companies follow a hybrid structure, with a smaller share operating entirely remotely. In pharma, uptake of flexible work arrangements has been slower due to the physical infrastructure required for research and manufacturing.

Even so, there has been an increase in flexibility for functions such as regulatory affairs, corporate strategy, medical writing, pharmacovigilance, and information technology. Companies are piloting hybrid formats for eligible roles where compliance and productivity can be maintained. Location-neutral recruitment is gaining ground in select functions, particularly in cities with strong scientific and technical talent availability.

By July 2024, 20 per cent of all job postings across industries in India were hybrid or remote, up from just 0.9 per cent in 2020. Among larger enterprises, 38.6 per cent of new hires are now being made in hybrid roles.

R&D talent is driving a clear hiring trend

Scientific hiring in the Indian pharma sector has grown consistently over the last two years. A number of global workforce solution providers reported annual growth of 15 per cent - 20 per cent in research and development-related recruitment. The highest demand is concentrated in oncology, diagnostics, and digital health. Hiring has increased across levels, from CXO appointments to technical leaders and mid-career specialists.

Companies are building domestic research teams while also attracting talent with international experience. However, research investment remains comparatively lower than that of global peers. Indian companies typically invest a smaller share of sales into research and file fewer patents per billion dollars of revenue. Senior executives reported a 20 per cent increase in CXO-level hiring, a 35 per cent increase at senior levels, and a 50 per cent increase at junior and mid-levels.

In 2025, India's pharma, healthcare, and life sciences (PHLD) sector is witnessing a sharp rise in demand for digital and technology-driven skills, with healthcare and pharma job postings growing 62 per cent year-on-year and mid-level IT roles increasing by 31 per cent, particularly for professionals skilled in digital transformation tools such as electronic health record (EHR) systems. Key areas of demand include AI/ML, data analytics, health informatics, cloud platforms, DevOps, and digital health, with many pharma firms now adopting hybrid or multi-cloud systems. IoT and blockchain technologies are enhancing supply chain transparency and responsiveness. Upskilling remains a major focus, with significant investments in digital training and widespread skill gaps in AI/ML expertise. Hyderabad has emerged as a leading life sciences hub, attracting ?54,000 crore in investments since December 2023 and creating 200,000 jobs. Global leaders including Eli Lilly, Amgen, MSD, Zoetis, Evernorth, and Olympus have chosen the city as their preferred GCC base, with Eli Lilly planning to hire 1,500 professionals in AI, cloud, and automation by 2026–27.

While the outlook for research talent appears positive in India, this momentum is uneven globally. Forecasts indicating growth in research roles have not translated into broad-based job creation in mature markets. In the United States and the United Kingdom, sev-

eral companies have initiated layoffs throughout the year. The gap between projections and actual hiring reflects a more cautious approach driven by fiscal and regulatory uncertainties.

Digital tools are making recruitment more effective

A growing number of pharmaceutical companies is adopting digital hiring platforms and data-based screening tools. According to a study, by the end of 2024, approximately 52 per cent of Indian pharma and healthcare firms had implemented artificial intelligence-supported tools in their recruitment processes. These include structured resume screening, behavioral assessments, and standardised video interviews.

In fact, 75 per cent of Indian recruiters are now allocating significant portions of their budgets to AI recruitment platforms.

Firms that have invested in digital recruitment infrastructure report notable benefits. Hiring costs have declined, hiring timelines have shortened, and quality of hire has improved. Platforms such as LinkedIn, HireVue, and Pymetrics are being used to enhance candidate experience and increase sourcing reach. Digital tools continue to gain traction even in a slower job market, indicating a focus on efficiency and quality over scale.

Per LinkedIn's 2025Talent Trends, companies in India with strong employer branding (including in pharma) have achieved a 50 per cent reduction in hiring costs and a 28 per cent lower turnover rate.

Additionally, younger professionals now expect streamlined recruitment experience. Around 82 per cent of job seekers in this segment consider a company's technological capability and innovative mindset to be a key factor in their decision-making process.

Talent strategy is becoming a growth enabler

Pharmaceutical companies are integrating talent decisions more closely with business priorities. Rather than simply filling vacancies, the focus is now on identifying professionals who can support drug development, regulatory readiness, and international expansion.

Hiring decisions are increasingly made with input from business and technical leads, alongside the human resources team. The use of campus partnerships, talent analytics, and competency mapping is on the rise. Companies are also investing in mobility programs and skill development initiatives to retain and repurpose internal talent.

The evolving structure of drug portfolios is playing a role in shaping talent decisions. Global pharma is placing more focus on high-cost specialty drugs, including treatments for rare diseases and complex conditions. This realignment is influencing recruitment strategies. In response to stricter pricing controls in key markets, including the United States, companies are taking a more selective approach to research investments and hiring. Legislation such as the Inflation Reduction Act, which enables Medicare to negotiate drug prices, may affect funding for innovation and lead to narrower hiring requirements.

Conclusion

Pharma recruitment is becoming more intentional, data-informed, and closely tied to operational outcomes. Companies are learning to manage budget pressures while still building strength in priority areas. Recruitment is no longer viewed as an administrative function but as a contributor to product development, compliance, and global competitiveness. As the sector enters the next cycle, companies that focus on clarity, long-term capability, and consistent execution in their talent strategy will be positioned to deliver meaningful results.

Shaping the next gen of global pharmacists: Preparing students for AI, data and precision medicine

Dr Supriya Shidhaye, Principal, Vivekanand Education Society's College of Pharmacy, Mumbai highlights that by modernising curricula, embracing technology, and nurturing globally aware professionals, we can ensure that the next generation of Indian pharmacists leads confidently in a world where medicine, data, and humanity converge

The pharmacy profession is at a defining crossroads. The rapid integration of artificial intelligence (AI), data analytics, and precision medicine is transforming every layer of healthcare — from drug discovery and clinical decision-making to patient monitoring and policy design. Pharmacists today are no longer limited to dispensing medicines; they are becoming interpreters of data, partners in clinical research, and active contributors to personalised care.

As healthcare systems move toward digitalisation and individualisation, the role of the "global pharmacist" is being redefined. For Indian pharmacy education and practice to remain globally competitive, it must evolve beyond conventional pharmaceutics and pharmacology, integrating emerging disciplines such as informatics, genomics, nanomedicine, and 3D printing. This transformation will prepare students to work at the intersection of technology and therapeutics.

AI, data science, and precision medicine: The new drivers of healthcare

AI and big data analytics have already begun reshaping the pharmaceutical value chain — from molecule design and clinical trials to pharmacovigilance and patient adherence. Reports from the World Health Organisation (WHO) and the International Pharmaceutical Federation (FIP) underline that digital intelligence improves decision-making, enhances drug safety, and streamlines healthcare delivery.

In research and development, AI-based algorithms are capable of predicting drug–drug interactions, identifying adverse effects, and optimising dosing regimens. They enable in silico drug design, significantly reducing both time and cost in early discovery stages. Similarly, pharmacogenomics — the foundation of precision medicine — is transforming therapy by aligning drug choice and dose with a patient's genetic profile. This ensures that treatment is both efficacious and safe, minimising the trial-and-error approach that has traditionally characterised drug therapy.

The arrival of 3D printing adds another layer of personalisation. A 2023 study by Serrano et al. highlighted how 3D printing enables the fabrication of tailored dosage forms and implants for specific patient needs. The FDA-approved 3D-printed tablet Spritam® (levetiracetam) stands as a milestone, demonstrating the feasibility of custom-designed oral formulations. Moreover,

"polypills" that combine multiple drugs in a single dosage form have shown improved adherence for patients with chronic conditions.

Together, AI, data analytics, pharmacogenomics, and 3D printing are shaping a future where pharmacists will design and deliver truly individualised therapy.

Bridging the educational divide

Based on these global advancements, Pharmacy council of India (PCI) is redefining a Curriculum that focuses on AI, pharmacogenomics, or informatics. The future graduates are expected to be strong in pharmaceutical sciences, with preparedness for data-driven and technology-enabled healthcare environments as an outcome of new curriculum.

The FIP Development Goals (2021) call upon institutions worldwide to embed digital health literacy, ethical data use, and interprofessional collaboration into their curricula. These competencies are essential to equip graduates for an era where pharmacists interact with machine-learning systems, genomic data, and digital health platforms.

India's pharmacy colleges and universities must therefore reimagine their academic structures. This requires:

◆ Curriculum integration of data science, AI applications, pharmacogenomics, and digital therapeutics.

◆ Faculty upskilling, so educators can confidently teach and mentor students in these emerging domains.

◆ Collaborations with industry, regulatory bodies, and research institutes, enabling real-world exposure to AI-driven drug design, nanomedicine formulation, and data-based pharmacovigilance.

◆ Such reforms will align Indian pharmacy education with Industry 4.0, fostering a workforce capable of contributing to the global pharmaceutical and healthcare ecosystem.

Reimagining the curriculum: The three pillars of future-ready pharmacy education

To create globally competent pharmacists, the training must rest on three interlinked pillars:

◆ **Digital and data competence**

Pharmacy graduates should be skilled in interpreting clinical and pharmacological data, analysing health informatics, and using AI tools in decision support. Add-on Courses or certificate courses in data analytics, bioinformatics, and AI-based drug discovery, supplemented by simulation-based learning and case studies, will nurture analytical and evidence-based thinking with its application to pharmaceutical and clinical sciences.

◆ **Technological adaptability and innovation**

Hands-on exposure to 3D printing, nanotechnology, and advanced biopharmaceutical manufacturing can empower students to design innovative dosage forms and personalised therapies. Training modules should include practical demonstrations, industry-linked projects, and entrepreneurship cells that promote innovation in digital and precision healthcare.

◆ **Global and ethical perspective**

As pharmacy practice becomes increasingly borderless, students must understand international regulatory frameworks, ethical dimensions of AI, and global standards in data security and patient confidentiality. Add-on Courses on pharmacy law, bioethics, and global health policy will instill responsibility in using technology for equitable healthcare access.

Policy support and academic innovation in india

The National Education Policy (NEP 2020) provides a strong foundation for this transformation. It advocates multidisciplinary learning, flexibility, and innovation, encouraging institutions to become incubators of critical thinking and entrepreneurship. Pharmacy colleges can leverage NEP's vision by offering interdisciplinary electives — such as AI in drug discovery, digital therapeutics, or genomics-based precision medicine — in collaboration with engineering, data science, and medical schools.

Further, the Pharmacy Council of India (PCI) can play an enabling role by updating model curricula, incentivising faculty development, and promoting industry-academia linkages. Continuous professional development in digital health, supported by short-term certification courses and international collaborations, can ensure sustained competence among practicing pharmacists as well.

The vision ahead: The global pharmacist

The pharmacist of tomorrow will combine scientific depth with digital intelligence. They will be able to decode genomic information, operate AI-assisted systems, and use 3D bioprinting to deliver patient-specific therapies. Beyond technical proficiency, these professionals must embody adaptability, curiosity, and ethical responsibility — qualities essential in a fast-evolving healthcare landscape.

Ultimately, AI, data science, and precision medicine are not replacements for human judgment but extensions of it. The pharmacist's role will continue to center on ensuring that medicines — and now, data-driven insights — are used safely, effectively, and compassionately.

As India positions itself as a global pharma and healthcare innovation hub, the country's pharmacy educators hold a critical responsibility. By modernising curricula, embracing technology, and nurturing globally aware professionals, we can ensure that the next generation of Indian pharmacists leads confidently in a world where medicine, data, and humanity converge.

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How HVAC is evolving from utility to critical quality enabler

Once viewed as a background utility, HVAC systems have become crucial to pharmaceutical manufacturing — enabling contamination control, regulatory compliance, and sustainability. With the rise of global standards like EU GMP Annex 1 (2023) and the growing push for digitalisation and energy efficiency, HVAC is no longer just about temperature and humidity control. It is now a core pillar of quality assurance and contamination risk management

HVAC is emerging as a strategic pillar in pharma quality, compliance, and sustainability

Over the past decade, the role of HVAC systems in pharmaceutical manufacturing has evolved from being a utility function to becoming a core enabler of product quality, compliance, and sustainability. This transformation has been driven by the twin forces of stricter global regulatory frameworks and rapid technological advancement.

With the revision of standards such as EU GMP Annex 1 (2023), WHO TRS updates, and US FDA guidance, the pharmaceutical industry has witnessed a paradigm shift from conventional temperature and humidity control to a risk-based contamination control approach. HVAC systems are now viewed as a vital component of the overall quality assurance strategy — ensuring environmental integrity, cross-contamination prevention, and adherence to Good Manufacturing Practices (GMP).

Over the years, innovations such as low-leakage AHUs, energy-efficient chillers, high-efficiency filtration, variable air volume systems, and smart automation have redefined performance benchmarks. The integration of IoT, data analytics, and AI-based monitoring has also enabled real-time validation, predictive maintenance, and enhanced data integrity — critical for regulatory compliance.

Jayant K Patekar – President, ISHRAE Mumbai Chapter

HVAC system design in pharma is increasingly focusing on green technologies, adaptive airflows, and optimised energy recovery solutions

Another key driver of change has been sustainability. With global pressure to reduce carbon footprints and improve energy efficiency, HVAC system design in pharma is increasingly focusing on green technologies, adaptive airflows, and optimised energy recovery solutions without compromising cleanroom performance.

Throughout this period of change, ISHRAE has played a pivotal role in bridging the gap between engineering, compliance, and sustainability. Through initiatives such as Pharma Connect, ISHRAE Mumbai Chapter has created a vibrant knowledge-sharing platform that brings together regulators, consultants, and manufacturers. The Society continuously supports its pharma members through technical training, advocacy initiatives, and publication of design guidelines, helping them align with evolving standards while adopting best practices.

As India strengthens its position as the pharmacy of the world, the synergy between pharma and HVAC professionals — nurtured by ISHRAE — continues to shape safer, cleaner, and more sustainable manufacturing environments.

Because in today's pharma world, when HVAC breathes right — Pharma thrives.

Digital technologies are quietly transforming HVAC into an intelligent compliance partner

Over the last decade, HVAC standards in pharmaceutical manufacturing have undergone a quiet revolution. Earlier, design intent revolved around temperature, RH, and air changes to meet Schedule M and WHO GMP norms. Today, validation and continuous monitoring have taken centre stage. Global guidelines like EU GMP Annex 1, US FDA, and Schedule M now emphasise contamination control, data integrity, and lifecycle quality.

India's ambition to move from "Pharmacy to the world" to "World leader in pharmacy" has intensified the need for global alignment. Tighter supply-chain scrutiny and lessons from pandemic disruptions have driven clients to demand digital traceability of every cubic metre of clean air.

With AI-enabled Building Management Systems and cloud-based monitoring becoming common, HVAC design is shifting from paperwork-driven setups to smart, responsive environments that learn from data and maintain compliance with far greater ease. Every cubic metre of clean air must now come with its own audit trail.

Technology is gradually transforming how HVAC systems are designed and operated. Sensors and digital monitoring now provide continuous data on temperature, humidity, pressure, and filter condition — helping engineers spot early warning signs.

B Gautham Baliga, Director, Opal HVAC Engineers

Artificial intelligence and machine learning are still in early adoption but are beginning to analyse operational data, predict equipment faults, and suggest energy-optimisation actions. CFD modelling and digital-twin tools allow designers to visualise airflow and contamination risks before fabrication, reducing rework and validation time.

In India, the movement toward smart, connected HVAC systems has clearly begun, though much remains manual. The goal is to evolve from data collection to intelligent interpretation — where technology becomes an assistant to the engineer, not a replacement.

Cleanrooms demand strict temperature, humidity, and pressure stability — but this precision consumes enormous energy. The focus is now on reducing this load without affecting GMP compliance. Modern facilities are adopting high-efficiency chillers with magnetic-bearing compressors and strong part-load performance. Low pressure-drop filters are gaining recognition, as filter resistance alone can drain thousands of kilowatt-hours annually. Precision air-distribution and hydronic design — correct duct sizing, balanced airflows, and optimal pump heads — minimises hidden losses while maintaining uniformity.

Heat-recovery systems such as run-around coils and energy-recovery wheels are used wherever cross-contamination risks permit. AI-based analytics for energy tracking are still emerging but hold promise for the near future. The sector is learning that sustainability begins with good engineering — each Pascal of saved pressure drop and each recovered kilowatt counts toward a cleaner, more efficient plant.

The pharma HVAC sector continues to face familiar challenges — high energy cost, complex validation, microbial risks, and documentation overload. The response so far has been steady and practical. Most facilities still rely on periodic manual checks, but continuous monitoring using calibrated sensors is becoming more common, reducing human error. A few progressive plants have introduced cloud-based monitoring for validation reports, though AI and IoT remain at an early stage.

Moisture and mold control now receive stronger attention through improved psychrometric design, coil hygiene, and air-balancing practices. Upskilling maintenance and HVAC staff is another vital focus. Overall, the Indian pharma industry is moving — step by step — from reactive maintenance to preventive, data-informed operation, laying the foundation for more reliable and sustainable facilities.

As Indian pharma modernises, HVAC systems are quietly becoming smarter, cleaner, and more efficient. The transformation is evolutionary, not revolutionary — yet it is reshaping the very air that ensures product safety. The next leap will come from merging engineering rigour with digital intelligence, where every cubic metre of conditioned air supports both compliance and sustainability.

Unified standards and smarter design are key to unlocking next-generation HVAC performance

Current HVAC design relies on a diverse, and sometimes confusing, array of guidelines issued by regulatory bodies such as WHO, EU GMP, ISO 14644, ISPE Baseline, and ASHRAE/ISHRAE. Furthermore, specific equipment has its own dedicated guidelines, including Eurovent/AHRI for Air Handling Units (AHU) and EN779, ASHRAE 52.2, and ISO 16890 for air filters.

This multiplicity of standards, particularly those governing filter testing—each with its unique methodology—can lead to designer confusion in selection and correlation. There is a pressing need for the unification of these standards, and for the outdated versions to be formally phased out to create a clearer regulatory environment.

Amit Pawar, Manager, HVAC, Biopharmax India

Technology shaping the next generation of HVAC:

The era where energy consumption was secondary has passed. The future of HVAC is being driven by technologies focused on optimisation and efficiency:

◆ **Artificial Intelligence (AI):** AI is poised to play a crucial role in future systems by analysing actual load profiles of buildings and industrial plants, leading to the optimum selection and sizing of equipment capacity.

◆ **High-efficiency equipment:** Technological advancements are influencing the selection of more efficient components, such as magnetic bearing chillers and Electronically Commutated (EC) motors.

◆ **Enhanced dehumidification:** New solutions now achieve necessary dehumidification requirements with lower regeneration temperatures, significantly contributing to overall energy savings.

◆ **Control systems:** Modern chiller plant management systems and variable pumping systems equipped with inbuilt pump curve intelligence are providing superior control and system optimisation.

◆ **Sustainability and Environmental Control:** Recognising HVAC systems are major energy consumers, manufacturers must move from traditional rules of thumb toward optimised design parameters.

◆ **Optimising air flow:** The Air Changes Per Hour (ACH) is often over-designed due to the fear of non-compliance with particle count requirements. Similarly, the selection of internal conditions (temperature and relative humidity) must be optimal, as unnecessarily low RH requirements demand disproportionately high energy costs.

◆ **Sustainable practices:** Manufacturers are increasingly adopting Variable Air Volume (VAV) systems and Energy Recovery Systems (ERS). Retrofitting existing systems with more efficient components is a common strategy to add value without increasing capital expenditure.

Major industry challenges:

To fully realise the potential of next-generation HVAC, the industry must address several significant challenges:

◆ **Awareness and education:** There is a critical need for mandatory education and awareness programs regarding energy efficiency and technological advancements across all segments: manufacturers, designers, and suppliers.

◆ **Standards unification:** As noted, the unification of diverse standards is essential to eliminate chaos and provide clear regulatory guidance.

◆ **Over-design:** Over-designing HVAC systems, often due to limited forecasting of product and subsequent system requirements, leads to significant operational inefficiencies.

◆ **System bypassing:** Even when sophisticated systems are implemented, their efficiency is often compromised or entirely bypassed due to a lack of proper training, illiteracy regarding the system's function, or general ignorance on how to operate the smart technology correctly.

Contamination control and HVAC must evolve together through training and technology

The HVAC system is not simply a utility in a pharma facility — it is a key enabler of Contamination Control Strategy. As pharma manufacturing evolves, the HVAC design, operation and monitoring must evolve in parallel.

In the next five years, HVAC systems will become smarter, more energy efficient, more flexible, more instrumented, and more tightly integrated into contamination control frameworks. To future-proof the systems, the companies must adopt a risk-based CCS, design for flexibility/modularity, prioritise monitoring/data integration, balance compliance with sustainability, maintain rigorous qualification and lifecycle management, and build reliability and resilience into the system.

Sant Advani, Secretary, Contamination Control Society of India

Contamination control strategy has taken giant strides in the last few years and HVAC is trying to keep up by introducing new standards. Cleanroom design was governed by thumb rules for many years and being the "Prima Donna" it was rarely questioned. It was only with the advent of 'Energy Efficiency' that the empirical rules were challenged.

HVAC standards have kept pace thanks to the efforts of ISO and ASHRAE. In India ISHRAE and the Contamination Control Society of India have contributed greatly to this effort. HVAC standards are being constantly updated to keep up with the new trends and this will accelerate sharply with AI leading the way. Pharma companies should have continuous ongoing training programmes to familiarise their QA,QC and operating staff with new developments and standards like EUGMP Annex 1 (2022).

Guaranteeing continuity of medicine supply through AI innovation

Hari Kiran Chereddi highlights how AI is transforming pharma supply chains to ensure uninterrupted medicine availability

Whenever we speak of pharmaceutical innovation, we often focus on novel molecules or path-breaking therapies. The COVID 19 pandemic has revealed a lot of cracks in our supply chains and that lifesaving medications are only as good as the supply chains that deliver them. Disruptions, geopolitical tensions, demand uncertainties or logistics breakdowns can leave them futile. This is where AI has stepped in as the 'silent' push to provide continuity, predictability and thereby creating resilient global pharmaceutical supply networks.

From reactive to predictive supply chains

Classic supply chains were meant to respond to demand fluctuations, disruptions, or shortages. AI has turned that on its head. Armed with predictive analytics and real-time data, pharma firms can now anticipate disruptions well in advance and act on them.

Algorithms powered by AI/ML (Machine Learning) draw from massive sets of data across procurement cycles, customs clearance delays to hospital usage patterns and thereby predict changes much in advance before the shortage occurs. Companies can thereby reallocate inventories in real time and shuffle production cycles just in time.

AI as the new compliance engine

In an era where compliance isn't optional, AI isn't merely automating processes it's raising trust to the next level. Sophisticated models now track every data point of a batch journey from API synthesis through to final shipment checking documentation, monitoring deviations, and anticipating non-conformance risk far before an audit flag is raised.

This compliance layer upfront guarantees that regulatory integrity is never broken, even when speed and scale are. The payoff: accelerated regulatory reviews, minimised manual interventions, and, ultimately, seamless market supply.

The power of real-time intelligence

Because ultimately, continuity of medicine supply is not about responding quicker — it's about anticipating better

The real potential of AI comes from linking intelligence and execution together. By combining real-time streams of data temperature records, geolocation of shipments, utilisation at plants, and order fill rates businesses are gaining an always-on layer of visibility.

AI-powered "Intelligence Engines" are there not to just track live operations but also to run simulations of potential bottlenecks allowing our teams to respond before a supply risk becomes real. This type of forward-looking intervention is what turns resilience from a defensive stance into an operating ethos.

Automation: The bridge between reliability and scale

In addition to forecasting and visibility, automation is emerging as the deciding bridge to scale. Robotic process automation (RPA) and AI-fuelled documentation tools are reducing batch release times, automating quality reviews, and cutting redundancies throughout the supply continuum.

As these processes continue to learn from AI systems, they're becoming ever more autonomous able to self-correct documentation mistakes, optimise delivery routes, and even readjust procurement priorities based on changing market or regulatory inputs.

Creating a future of predictive availability

The future of pharmaceutical logistics will not be shaped by warehouses or fleets, but by smartness. Firms that view data as a strategic asset and not an operational derivative will dominate the next wave of reliability for the supply of medicine.

For us at HRV Pharma, this is not a technology tale alone; it's a philosophy of change. By leveraging India's manufacturing breadth and AI-powered orchestration, we're making fragmentation into flexibility and volatility into visibility.

Because ultimately, continuity of medicine supply is not about responding quicker — it's about anticipating better.

And that's precisely what AI enables.

AI and real-world evidence: The next frontier in clinical research

As AI meets real-world evidence, clinical research is moving beyond controlled trials into the realm of real-life data. The result is a smarter, faster, and more equitable path to better healthcare, highlights **Dr Seema Pai,** President, Indian Society for Clinical Research

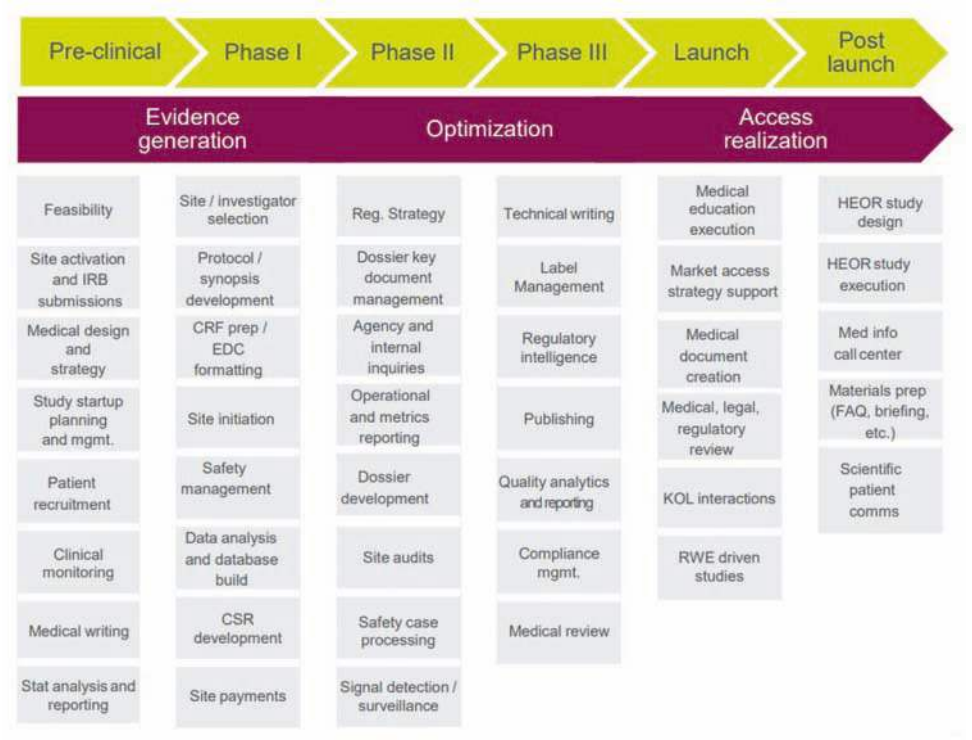
In the rapidly evolving world of clinical research, few developments hold as much promise—or provoke as much debate—as the convergence of artificial intelligence (AI) and real-world evidence (RWE). While AI has already transformed industries from finance to logistics, its ability to analyse, interpret, and act on vast datasets in real time is now redefining how we design, conduct, and scale clinical research. For India, a country with immense patient diversity, digital health penetration, and growing R&D infrastructure, this convergence presents a transformative opportunity.

The shift from hypothetical to real-world

Traditionally, randomised controlled trials (RCTs) have been the gold standard in establishing drug efficacy and safety. However, they are time-consuming, expensive, and often limited in population diversity. Real-world evidence—derived from sources like electronic health records (EHRs), insurance claims, wearable devices, and mobile health platforms—offers a complementary approach. When powered by AI, RWE can reveal patient behaviours, treatment outcomes, and adverse events in ways that RCTs simply cannot.

India is uniquely positioned to lead this shift. With over one billion mobile phone users and increasing adoption of digital health tools, there is a growing trove of real-world data waiting to be structured and analysed. AI models can mine this data to detect patterns, predict outcomes, and optimise interventions with speed and precision.

In their recent article in ISPOR – Parexel, one of the world's largest clinical research organisations (CROs) has clearly outlined some key areas where one could use AI in clinical development as follows:



Clinical trials reimagined

There are numerous promising use cases where AI is already making an impact. For instance, AI can optimise trial protocol design by identifying ideal inclusion/exclusion criteria and predicting patient outcomes using historical and synthetic datasets. Platforms like TrialGPT and Criteria2Query have demonstrated up to 80 per cent time savings in patient screening by using natural language processing (NLP) to analyse EHRs and match patients to trials more accurately.

AI also enables the creation of virtual control arms—synthetic groups based on RWE that can reduce or eliminate the need for placebos in certain trials. This not only improves ethical considerations but also accelerates trial timelines. In oncology, algorithms are now predicting tumour responses and survival rates with increasing accuracy, supporting better endpoint definition and adaptive trial design.

Pharmacovigilance and post-market surveillance

Real-world data is equally critical post-approval. Pharmacovigilance—a cornerstone of patient safety—is being revolutionised by AI tools that scan unstructured data like case reports, scientific literature, and social media to detect adverse events faster. AI-powered literature monitoring tools have achieved sensitivity rates as high as 97 per cent in screening for relevant safety signals.

Moreover, predictive analytics can identify at-risk populations and flag drug-drug interactions before they occur, transforming pharmacovigilance from a reactive to a proactive discipline. In India, initiatives like the Comprehensive Loss to Follow-Up and Mortality Prediction (CLAMP-TB) system for tuberculosis care show how AI can enhance patient safety and treatment adherence even at scale.

Ethical guardrails and regulatory evolution

However, innovation must be met with responsibility. AI models are only as good as the data they're trained on. Biases in datasets can lead to exclusionary outcomes, particularly in India's diverse population. This makes the case for explainable AI (xAI), robust anonymisation techniques, and the inclusion of human oversight in algorithmic decision-making.

On the regulatory front, India is making encouraging progress. While the Central Drugs Standard Control Organ-

isation (CDSCO) has yet to publish formal AI guidelines, the Indian Council of Medical Research (ICMR) released ethical guidelines for AI in healthcare in 2023. These emphasise transparency, bias mitigation, and accountability—principles that must underpin every AI-powered clinical decision.

The integration of AI and RWE is not a replacement for traditional clinical research but an evolution. It opens up new paradigms—decentralised trials, real-time monitoring, population-level insights—that were previously inaccessible. It's a future where patient safety is proactive, data is democratised, and trials reflect the true complexity of real-world conditions.

Regulatory guidelines are being developed to help shape the applications of AI across the healthcare ecosystem. EMA and USFDA have been at the forefront to highlight use of AI responsibly.

EMA states: "... the use of exceptionally great numbers of trainable parameters arranged in non-transparent model architectures introduces new risks that need to be mitigated both during model development and deployment to ensure the safety of patients and integrity of clinical study results. Also, as the overarching approach is inherently data-driven, active measures must be taken to avoid the integration of bias into AI/ML applications and promote AI trustworthiness..."

FDA states: ..."There are also concerns with using algorithms that have a degree of opacity, or algorithms that may have internal operations that are not visible to users or other interested parties. This can lead to amplification of errors or preexisting biases in the data. We aim to prevent and remedy discrimination — including algorithmic discrimination, which occurs when automated systems favor one category of people over other(s) — to advance equity when using AI/ML techniques."

Because the future of clinical research isn't just about discovering new molecules—it's about discovering better ways to deliver health.

The landscape is fast-evolving and collaborative efforts between AI experts and healthcare professionals and other industry stakeholders can enhance outcomes. Training /grounding these algorithms with data still requires human oversight. Adapting to the evolving regulatory landscape ensures AI system safety and efficacy; AI is positioned to accelerate clinical development and enhance patient access with continued stakeholder collaboration across the healthcare ecosystem.

Kyasanur Forest Disease - How far is a regulatory approved vaccine?

Dr Priyabrata Pattnaik, Former Deputy MD, Indian Immunologicals, informs about the Kyasanur Forest Disease (KFD), a zoonotic viral hemorrhagic fever endemic to parts of India, particularly along the Western Ghats and discusses the current status of developing a regulatory-approved KFD vaccine in India

Kyasanur Forest Disease (KFD) is a tick-borne viral hemorrhagic fever endemic to parts of India, particularly in Karnataka and neighboring states such as Kerala, Tamil Nadu, and Goa, along the Western Ghats. The KFD virus belongs to the Flavivirus genus within the Flaviviridae family. Its vectors commonly include Haemaphysalis spinigera, Dermacentor, and Ixodes ticks. The disease, also known as "monkey fever," has a fatality rate of three to five per cent. Developing a more effective vaccine is therefore critical for public health.[1,2]

A regulatory-approved KFD vaccine for humans is still several years away. While an older, formalin-inactivated vaccine existed (not formally approved by Indian authorities), it demonstrated limited efficacy and has been discontinued[3]. The new and more promising vaccine candidate is being developed by Indian Immunologicals (Hyderabad) in collaboration with the Indian Council of Medical Research (ICMR)–National Institute of Virology (NIV), Pune.

This inactivated, adjuvanted vaccine—based on KFD virus strain NIV 164187 isolated by ICMR–NIV—is scheduled to enter Phase 1 clinical trials in India before the end of 2025[4].

As of October 2025, the inactivated KFD vaccine candidate has completed preclinical single- and repeat-dose toxicity and immunogenicity studies. Based on these data, the vaccine was found to be safe, well-tolerated, and immunogenic. The sponsor has proposed a first-in-human study involving two doses (≥18 µg per dose), administered 28 days apart in healthy volunteers (aged 18–49 years) residing in endemic areas. The trial will assess seroconversion rates as the primary endpoint, with exploratory analyses comparing immunogenicity among subgroups stratified by baseline flavivirus serostatus. Participants will be followed for 366 days for safety and immunogenicity outcomes. A Data and Safety Monitoring Board (DSMB) report will be submitted after 57 days to the Central Drugs Standard Control Organisation (CDSCO) before initiating Phase II trials. The vaccine candidate is currently undergoing developmental and reproductive toxicology (DART) studies. Recruitment of female volunteers will commence after DART completion [5].

Until 2022, a formalin-inactivated vaccine produced by the Karnataka Government's Institute of Animal Health and Veterinary Biologicals (IAHVB) was used in endemic areas. However, it was discontinued due to several major drawbacks[6]:

- **Limited efficacy:** Protection was moderate and waned over time.
- **Production challenges:** The vaccine was derived from a mouse brain–passaged virus, leading to supply constraints.
- **Strain mismatch:** Circulating KFDV strains diverged genetically from the strain used in vaccine production, reducing effectiveness.
- **Regulatory noncompliance:** The vaccine and its manufacturing facility did not meet current Good Manufacturing Practice (cGMP) standards and lacked CDSCO approval [7].

The earlier vaccine showed 62.4 per cent efficacy with two doses and 82.9 per cent with boosters, but waning immunity and production issues limited its usefulness[8,9]. Due to suboptimal protection, it was discontinued in October 2022. Recent ap-

proaches—including vesicular stomatitis virus (VSV)-based live-attenuated platforms[10,11], subunit vaccines targeting recombinant envelope domain III [12], and in silico-designed multi-epitope constructs—have shown promising immunogenicity and protection in preclinical models [13].

Developing a regulatory-approved KFD vaccine presents several technical and clinical challenges. KFD occurs sporadically; in 2024, Karnataka reported 2,567 suspected cases, of which 103 were confirmed [14,15]. Transmission peaks between January and April16, and by mid-2025, 175 confirmed cases had been reported[17]. Conducting a full-scale Phase III clinical trial is challenging because vaccine efficacy must be evaluated while the virus is actively circulating—something that occurs only during limited seasonal windows. Thus, completing such trials could take several years.

Women living near the Western Ghats are particularly vulnerable, as they often enter forested areas for firewood collection and other livelihood activities, exposing them to Ixodes ticks that transmit KFDV from infected bonnet macaques. Considering the complications observed in other flavivirus infections (e.g., dengue, Zika), DART studies are critical for demonstrating vaccine safety in female laboratory animals. Given the urgent need for a regulatory-approved KFD vaccine, emergency authorisation by Indian authorities may be considered based on Phase I and II clinical data, supported by nonhuman primate challenge studies (bonnet macaques) and DART results from two animal species.

Another major constraint in developing a fully regulatory-compliant KFD vaccine is its limited commercial potential. Between 2000 and 2018, IAHVB produced 1.28 million doses at a cost of Rs 20–30 ($0.22–0.33) per dose[18]. The estimated annual domestic demand is approximately 0.5 million doses, with virtually no private market. The government would likely remain the sole purchaser, using the vaccine for annual immunisation in high-risk areas or maintaining stockpiles for emergency use.

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AI in pharma: Disruption, displacement, and a new digital dawn

Dr Rajendra Pratap Gupta, Chairman of the Academy of Digital Health Sciences and Former Advisor to the Health Minister of India, highlights how artificial intelligence is redefining pharma — from workforce structures and business models to the very definition of what a pharmaceutical company will be by 2032

"By 2030, pharma will not just be about pills — it will be about platforms, patients, and predictive algorithms."

Artificial intelligence (AI) is no longer a futuristic buzzword in pharmaceuticals and healthcare;it is reshaping jobs across the value chain. From R&D to sales, from patient engagement to regulatory filings, the industry is in the middle of a silent revolution. The consequences? A mix of job displacement, job transformation, and job creation.

The mixed picture: Loss, transition, and opportunity

The most visible casualties will be traditional field force roles — medical representatives, sales teams, and administrative staff dependent on manual processes. Automation of repetitive tasks and AI-driven engagement platforms mean that the size of field teams will shrink dramatically.

At the same time, AI is spawning new jobs in specialised areas: data science, bioinformatics, digital health management, and clinical informatics. Global Capability Centres (GCCs) in India's tech hubs will be the crucibles for these opportunities.

In R&D, the story is one of transition, not elimination. AI will accelerate drug discovery, predictive modeling, and patient recruitment for trials. But this will require large-scale reskilling of the existing workforce.

The scale of disruption will be profound. "By 2030–32, the pharmaceutical industry will shed nearly half a million workforce."

No longer mere sellers of drugs, the leaders of tomorrow will be providers of digital therapies, predictive care, and patient platforms. The real winners will not be those who cling to headcounts, but those who reimagine workforce strategy, invest in learning, and partner with digital health training providers

Yet the net outlook is not bleak. The jobs of the future will be higher value, technology-enabled, and global in scope.

In my view, 'forward-looking healthcare and life sciences companies will have far more 'agents' than 'humans'; That's the future."

AI across the pharma value chain

Where exactly will AI bite deepest — and where will it create?

◆ **Drug discovery & development:** AI will design molecules, model clinical outcomes, and identify patients for trials.

◆ **Manufacturing:** Predictive maintenance, automated quality control, and AI-optimised supply chains will become the norm.

◆ **Marketing & sales:** AI-driven healthcare professional (HCP) engagement, personalised content generation, and predictive analytics will replace cold calls.

◆ **Patient care:** AI diagnostic assistants, treatment recommenders, and chatbot-based patient support will transform care delivery.

◆ **Regulatory & compliance:** Natural language processing (NLP) systems will handle documentation, pharmacovigilance, and adverse event reporting.

◆ **Operations:** From inventory management to robotic process automation, AI will streamline routine tasks.

The rise of new roles

The AI revolution is not only eliminate jobs — it will create a new cadre of pharma professionals:

◆ Certified digital health professionals to run digital transformation programs

◆ AI pharma strategists to identify integration opportunities.

◆ Clinical data scientists to unlock trial and real-world evidence.

◆ AI ethics & compliance officers to ensure regulatory safety.

◆ Pharmacovigilance AI specialists to monitor safety signals.

◆ Precision medicine coordinators to personalise therapy.

◆ AI-Human interface trainers to help humans and algorithms collaborate.

These jobs demand hybrid skills: clinical knowledge plus AI fluency, regulatory awareness plus digital literacy.

India's unique AI story

India sits at a fascinating intersection.

◆ **Cost advantage:** GCCs in Bangalore, Hyderabad, and Pune will expand, creating high-skilled AI jobs even as field operations shrink.

◆ **Regulatory lag:** India's evolving AI framework gives innovators a window to experiment before strict compliance kicks in.

◆ **Tier 2/3 cities:** Smaller towns, home to much of the sales force, will face sharper job displacement — reskilling here is critical.

◆ **Generics focus:** Unlike Western innovators, Indian firms will first apply AI in manufacturing and supply chains rather than new molecule discovery.

◆ **Talent pipeline:** IITs and tech schools are churning AI engineers, but pharma-specific AI skills remain scarce, requiring academia-industry collaboration.

If Indian pharma does not invest now, it will cede its leadership just like Intel ceded to OpenAI.

Preparing the workforce: From MR to AI-assisted advisor

The iconic Medical Representative (MR) role is already under threat. Doctors in the near future will not prioritise physical samples and brochures when AI-driven digital detailing can provide precise, personalised insights. Future MRs will be fewer, but far more strategic — data-savvy, digitally fluent, and focused on digital therapeutics rather than pills.

To manage this transition, pharma firms must:

◆ **Reskill at scale:** Partner with academies to train staff in digital health, AI, and data.

◆ **Enable internal mobility:** Shift field staff into digital roles such as patient engagement coordinators.

◆ **Roll out AI gradually:** Start with AI assistants, not replacements.

◆ **Communicate transparently:** Tell employees which roles will evolve, which will fade, and where new opportunities lie.

◆ **Reward learning:** Incentivise employees to upskill with promotions, certifications, and financial rewards.

"The key is treating this as workforce transformation, not just a technology upgrade."

Investment gap: India vs global

Global pharma majors like Pfizer, Roche, and Novartis are investing hundreds of million dollars annually in AI, with 3–7 per cent of R&D budgets dedicated to machine learning. India, in contrast, spends a fraction — a few million dollars annually, often on basic analytics rather than true AI.

This gap represents both a risk and an opportunity. Indian firms that invest boldly now — like Lupin Pharma and Dr Reddy's, which have launched digital therapeutics — will shape the next decade. Those that hesitate risk becoming acquisition targets.

Will smaller players survive?

The short answer is NO. But, if we look at the details,

◆ Top 20–30 firms will invest in proprietary AI and widen their lead.

◆ Mid-tier firms will survive by adopting vendor solutions.

◆ Over 1,000 small firms may struggle due to poor data hygiene, lack of AI talent, and no budgets for experimentation.

Yet disruption cuts both ways. "A smaller pharmaceutical company can upend the game by launching a new molecule and even acquire a conventional giant." This possibility makes the industry's future less predictable and more exciting.

The road ahead

The timeline for AI adoption in India will likely unfold in three waves:

◆ **1–2 years:** Early adopters scale pilots in analytics, supply chains, and pharmacovigilance.

◆ **3–4 years:** Mass adoption by mid-sized firms. Workforce transformation accelerates.

◆ **5–7 years:** Full integration, with AI embedded across discovery, development, and delivery.

In the United States, pharma-AI partnerships are racing ahead. India lags by about five years, but could leapfrog in operational AI due to its generics and manufacturing dominance.

Final Word: From pills to platforms

AI is not just about replacing jobs. It is about redefining what pharma companies are. No longer mere sellers of drugs, the leaders of tomorrow will be providers of digital therapies, predictive care, and patient platforms.

The real winners will not be those who cling to headcounts, but those who reimagine workforce strategy, invest in learning, and partner with digital health training providers.

"By 2032, the pharmaceutical industry will not look anything like it does today. The question is: will your company be ready to lead, or will it be left behind?"

India's biopharma industry charts the road from biosimilars to innovation

Express Pharma hosted the maiden **Biopharma Leadership Conclave 2025** and brought together industry leaders to discuss how India can move from being the world's leading producer of generics and biosimilars to becoming a hub for innovative, affordable, and high-quality biologics and advanced therapies

L-R: Dr Santosh Taur, Director – Medical Affairs, Pfizer ; Dr Vishal Pavitrakar, Sr Director – Global Regulatory Affairs – CMC, Alvotech; Dr Venkata Ramana, Chief Scientific Officer, Reliance Life Sciences; Dr Mukesh Kumar, Chief Scientific Officer, CLINEXEL; Dr Dakshesh Mehta, Independent Biopharma Professional; Sonia Gandhi, DGM & Head (Regulatory Affairs & Policy Advocacy), BIRAC; and Nitin Damle, Executive VP & Chief Innovation Officer, Sun Pharma Advanced Research Company

Global health needs are changing fast. New challenges such as complex diseases, rare conditions, and personalised treatments are reshaping how therapies are developed and delivered. Technology is also transforming discovery and manufacturing. This shift opens a new window of opportunity for biopharma in India.

To explore this potential, *Express Pharma* hosted the Biopharma Leadership Conclave 2025, under the theme, '*The future of biopharma: Made in India*'.

Held at Hilton Garden Inn, Pune Hinjawadi, the conclave brought together industry leaders, entrepreneurs, researchers, innovators and ecosystem partners to discuss how India can move from being the world's leading producer of generics and biosimilars to becoming a hub for innovative, affordable, and high-quality biologics and advanced therapies.

The conclave covered a wide range of themes including India's innovation pathway, digital transformation, biopharma funding, Manufacturing 4.0, regulatory harmonisation etc.

India's move beyond biosimilars

The day opened with a panel moderated by Dr Dakshesh Mehta, Independent Biopharma Professional. The panelists included Nitin Damle,

Executive VP and Chief Innovation Officer, Sun Pharma Advanced Research Company; Sonia Gandhi, DGM & Head (Regulatory Affairs & Policy Advocacy), BIRAC; Dr Mukesh Kumar, Chief Scientific Officer, CLINEXEL; Dr Venkata Ramana, Chief Scientific Officer, Reliance Life Sciences; Dr Vishal Pavitrakar, Sr Director-Global Regulatory Affairs-CMC, Alvotech and Dr Santosh Taur, Director-Medical Affairs, Pfizer.

The session, titled '*From biosimilars to breakthroughs: India's innovation pathway*', focused on how India can move up the value chain, from being a manufacturing powerhouse in biosimilars to becoming a true innovation hub for biologics and large molecules.

Panellists observed that India's foundation in bioprocessing, analytical sciences, and clinical execution provides a strong base for expansion into novel entities.

However, they agreed that India must strengthen translational research infrastructure, offer sustained support for biotech start-ups, and ensure predictable regulatory pathways to accelerate innovation. The conversation also underlined the importance of bridging academia and industry, ensuring lab discoveries are developed into commercial products faster.

A shared view was that innovation must remain affordable and accessible for Indian and global patients alike.

Clinical development strategies for emerging biotech

The event also saw several focused sessions. One was by Dr Mukesh Kumar, Chief Scientific Officer, CLINEXEL, who discussed how smaller biotech companies can design clinical development programmes more efficiently. He stressed on adaptive trial design, the use of real-world data, and early regulatory engagement. Collaborating with CROs, academic networks, and international partners, he noted, can help smaller firms scale their programmes faster and reduce costs. The session highlighted that clinical strategies should connect directly with market access and affordability goals.

The digital leap in biopharma manufacturing

Next, followed a panel discussion that explored how digital tools are transforming biopharma manufacturing. Moderated by Dr Sudeep Kumar, COO, Techinvention Lifecare, the panel featured Prof Samir Kulkarni, Head; Department of Biological Sciences and Biotechnology, Institute of Chemical Technology, Mumbai; Usman Ali Ansari, Sr Manager (Biotech DS Production Department), Bharat Serums and Vaccines; Dr Peddireddy SR, GM-Manufacturing & Development-Mabs & Vaccines, Serum Institute of India; Prashant Chawla, Sr GM, Biological E; Pankaj Gour, Sr GM and Head of Manufacturing Science and Technology (MSAT), Enzene Biosciences; Shital Jain, Deputy GM, Serum Institute of India and Mukesh Patale, Group Lead, MSAT, Dr Reddy's Laboratories, Biologics Unit, Hyderabad.

The discussion focused on automation, predictive analytics, and electronic batch records as the next frontier in improving compliance and process consistency. Many organisations, the panel noted, are transitioning through hybrid models, blending traditional and digital systems during the transformation phase.

The need for a digitally fluent workforce was highlighted repeatedly. Participants agreed that digitalisation is not just a technology upgrade, but a shift in culture and skills within the organisation.

Smarter systems, intelligent processes

A technical session led by Garet Jacob Fernandes, Product Manager, Smart Intelligent Process Software, showcased Aseptsoft: Smart Intelligent Process Software, a platform designed to bring intelligence and efficiency to biopharma process management.

He informed that Aseptsoft enables digital process mapping, automated documentation, traceability, and validation alignment. It aims to shorten tech-transfer and scale-up timelines, allowing faster movement from lab to plant. The session illustrated how software-driven process design can make manufacturing more transparent, standardised, and inspection-ready.

Reviving a critical need: anti-snake venom therapeutics

Dr Anil Yadav, Technical Director, Raut Serums India, presented the next session, highlighting developments in anti-snake venom production, a critical yet often underfunded therapeutic segment in India.

The presentation traced the journey from traditional serum-based treatments to highly purified, standardised antivenom formulations that meet WHO and Indian Pharmacopoeia 2022 standards.

The session also noted the need for better supply mechanisms and region-specific formulations, given India's diversity of snake species. It was an example of how biopharma innovation can also serve public health priorities.

Functional characterisation in mAbs

Sheetal Raut, Sr Manager & Bioassay Team Lead, Advanced Biotech Lab, Ipca Laboratories, presented on the importance of functional characterisation in biosimilar development.

These studies are key to both regulatory approval and lifecycle management, ensuring continued similarity even when manufacturing changes occur.

The presentation highlighted that robust analytical and functional data form the backbone of regulatory confidence and product reliability.

Quality, compliance and inspection readiness

The concluding panel, moderated by Prasun Guha, Head & VP – Regulatory Affairs (Biologics), Dr Reddy's Laboratories; Dr Yashwant Chavan, MD, geneOmbio Technologies; Dr Shuvankar Ballav, Manager and Lead - Regulatory Affairs (ABL), Ipca Laboratories and Jayachandran Ramalingam, DGM- Biosimilars QC, Serum Institute of India.

This session titled, '*Quality and compliance: Powering global leadership in biopharma*' focused on building a culture of compliance. Panellists said that quality is no longer just about regulatory obligation, it is about trust, reliability, and competitive advantage. They stressed the importance of data integrity, robust documentation systems and proactive internal audits.

The discussion concluded that continuous inspection readiness is essential for India's credibility as a global biopharma supplier.

A new phase of growth

The Biopharma Leadership Conclave 2025 made it clear that India's biopharma story is entering a new phase. With its scientific talent, manufacturing scale and cost advantage, India is well-positioned to lead in biologics and advanced therapies. However, achieving this will require stronger partnerships, smarter investments, and agile regulation.

Dr Mukesh Kumar, Chief Scientific Officer, CLINEXEL

Garet Jacob Fernandes, Product Manager, Smart Inteligent Process Software

Dr Anil Yadav, Technical Director, Raut Serums India

Sheetal Raut, Sr Manager and Bioassay Team Lead - Advanced Biotech Lab, Ipca Laboratorie

L-R: Dr Dakshesh Mehta, Independent Biopharma Professional (MODERATOR); Nitin Damle, Executive VP and Chief Innovation Officer, Sun Pharma Advanced Research Company; Sonia Gandhi, DGM & Head (Regulatory Affairs & Policy Advocacy), BIRAC; Dr Mukesh Kumar, Chief Scientific Officer, CLINEXEL; Dr Venkata Ramana, Chief Scientific Officer, Reliance Life Sciences; Dr Vishal Pavitrakar, Sr Director-Global Regulatory Affairs-CMC, Alvotech; Dr Santosh Taur, Director-Medical Affairs, Pfizer

L-R: Dr Sudeep Kumar, COO, Techinvention Lifecare (MODERATOR); Prof Samir Kulkarni, Head; Department of Biological Sciences and Biotechnology, Institute of Chemical Technology, Mumbai; Usman Ali Ansari, Sr Manager (Biotech DS Production Department), Bharat Serums and Vaccines; Dr Peddireddy SR, GM-Manufacturing & Development-Mabs & Vaccines, Serum Institute of India; Prashant Chawla, Sr GM, Biological E; Pankaj Gour, Sr GM and Head of Manufacturing Science and Technology (MSAT), Enzene Biosciences; Shital Jain, Deputy GM, Serum Institute of India; Mukesh Patale, Group Lead, MSAT, Dr Reddy's Laboratories, Biologics Unit, Hyderabad

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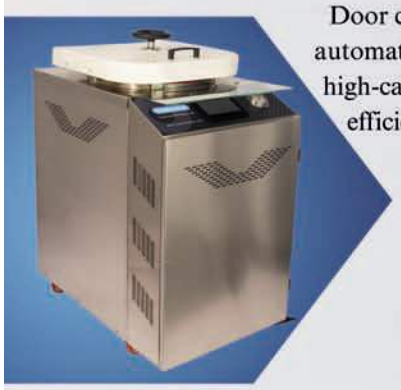
Technical Specifications

Temperature Range	20.0°C To 60.0°C
Temperature Accuracy	±0.1°C
Humidity Range	20% To 95% RH
Humidity Accuracy	±1% RH

Autoclaves - Steam Sterilizers



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Technical Specifications

Temperature Range	Ambient To 134°C
Temperature Accuracy	± 0.1°C
Operating Pressure	0 To 30 PSI
Pressure Display	Dial Gauge/Digital
Pressure Resolution	1 PSI

Our Products

- BOD Incubator
- Deep Freezer
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- Low Temperature Freezer
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- Photo Stability Chamber
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- Seed Germinator
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- 30+ Countries
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CONTACT US

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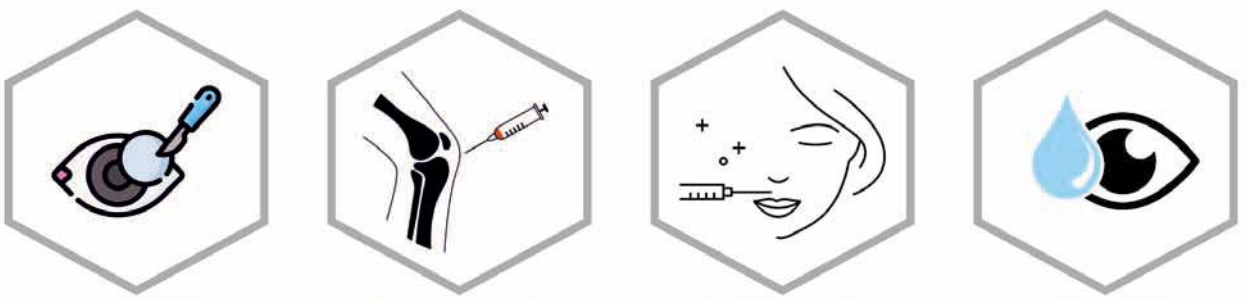
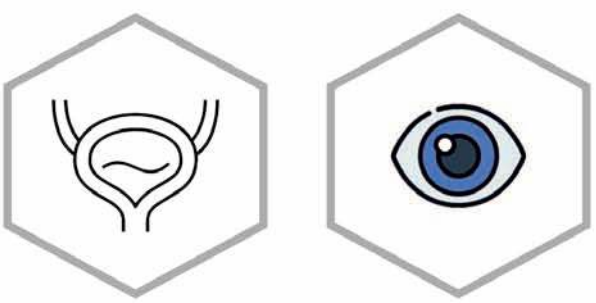
	Grade	Intrinsic viscosity (m^3/Kg)	Molecular weight (M.Dal)
Bioburden	GS-40	0.39 - 0.99	**0.15 to 0.49**
	GS-100	1.00 - 2.49	**0.50 to 1.60**
	GS-200	2.50 - 3.31	**1.61 to 2.31**

Key Specifications :

- Non-Animal origin, produced by Microbial fermentation
- Parenteral grade with BET/ MLT specs
- GMP (ICH-Q7) Controlled
- USP, EP, JP, BP Compliance Grades
- US-DMF, CEP, J-DMF, K-DMF available
- Indian API Registration
- HALAL Certified
- Covers wide range of Intrinsic Viscosity (1.00 to 3.4 m^3/kg) & Molecular Weight (500 – 2200 kDa)
- Customised grade can be offered as per requirement



Cataract | **Knee Injection** | **Dermal Filler** | **Eye Drops**



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

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ImaSteriConnect™

Aseptic Single-use Fluid Transfer Connector

Ami Polymer®

Reliable. Easy. Sterile. Even in Non-Sterile Environments.

Introducing **Ami Polymer's Sterile Connector** – engineered for secure, clamp-free connectivity in critical pharmaceutical and biopharmaceutical manufacturing steps. Designed with a genderless interface and robust construction for worry-free performance.

Key Features

- Genderless, universal design
- No need for clamps, fixtures, or tube welders
- Seamless transition between 1/4" to 3/4" tubing
- Operator-friendly, ergonomic structure

Technical Specs

- **Sterilization:** Gamma stable up to 50KGy
- Body Material: USP Class VI Polycarbonate
- Seal Material: USP Class VI Platinum-Cured Silicone
- Sizes Available: 1/4", 3/8", 1/2", 3/4" Hosebarbs

Applications

- Aseptic fluid transfer
- Bio-reactor line integration
- Sterile processing series connections

Benefits

- Simplifies single-use system integration
- Reduces operator error
- Confidence in sterile fluid transfer
- One part number – both halves

PROSOLV® 730: Directly compressible carrier for lipophilic ingredients

Nearly 90 % of molecules in the discovery pipeline and 40 % of drugs with market approval are poorly water soluble.

Poor aqueous solubility can lead to low bioavailability resulting in insufficient plasma levels.

Oil-based preparations of these APIs, as well as oily APIs in general, present challenges in terms of solid dosage form manufacturing.

PROSOLV® 730 was designed to provide a solution to the formulation of BCS class II and IV APIs. It enables the formulation of lipidic APIs or API-loaded lipid systems by facilitating the adsorption of oil, creating a free-flowing, compactible system that can be further formulated.

PROSOLV® 730 is a co-processed, high-functionality excipient comprising

MCC
SILICA
COPOVIDONE

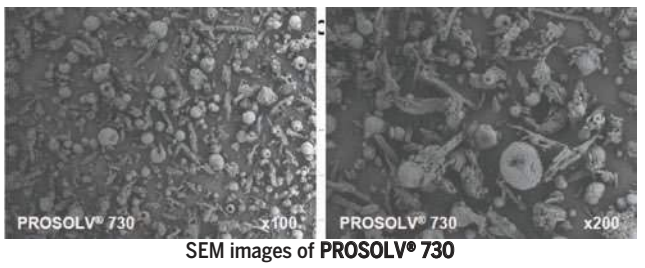
Lipophilic actives have practically no solubility in water.
They can be dissolved, however, in many non-aqueous media, including a wide range of different oils and organic solvents.

PROSOLV® 730 readily adsorbs and integrates oily APIs or API dissolved in non-aqueous liquids.

Oil-loaded **PROSOLV® 730** is a free- flowing powder that is suitable for capsule filling as well as for direct compression of tablets.

PROSOLV® 730 quickly releases the oil in the form of a fine mist of droplets. The API partitions into the aqueous phase and becomes available for absorption.

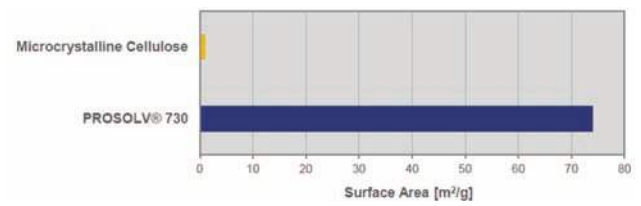
How does **PROSOLV® 730** work



SEM images of **PROSOLV® 730**

Specific surface area

PROSOLV®730 presents a 70 plus times greater specific surface area than Microcrystalline Cellulose.



Physical Properties of PROSOLV® 730

- ◆ High oil binding capacity
- ◆ White, free-flowing powder
- ◆ Chemically inert
- ◆ Non-soluble
- ◆ Excellent compactability
- ◆ Enhanced lubrication efficiency
- ◆ Improved blending properties
- ◆ Over 70 times greater specific surface area than regular Microcrystalline Cellulose (MCC)
- ◆ Coprocessed excipient with no chemical bonding between ingredients

PROSOLV® 730 has four main functions:

1) Oil adsorption in Direct compression
2) Converting Soft gel capsules into DC tablets
3) Dissolution enhancement
4) Modified release

Oil adsorption in direct compression

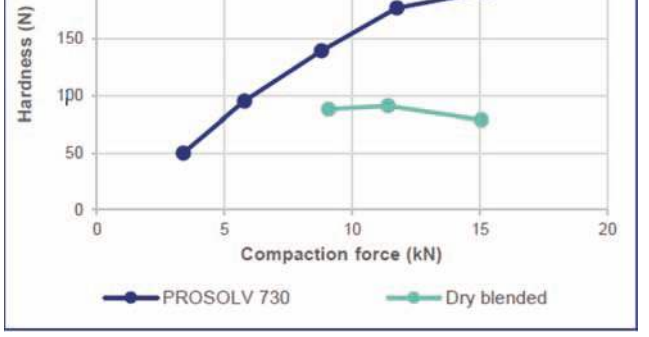
PROSOLV® 730 can adsorb oils up to 25% of its own weight (4:1 ratio), converting oil into powder and allowing its tableting

Even when fully loaded, it is a free flowing powder that can be directly compressed or encapsulated

PROSOLV® 730 excipients alone

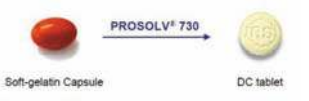
Oil loaded **PROSOLV® 730** tablets have more than 2 times the hardness than those that are made from a blend of the individual components of **PROSOLV® 730** and the oil.

PROSOLV® 730 25 % oil loaded



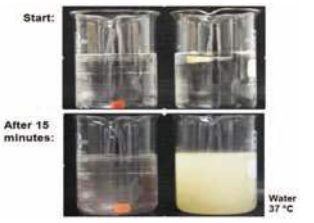
Converting Soft gel capsules into DC tablets

PRO SOLV® 730 enables direct compression of oily APIs or APIs dissolved in oil.



After reformulating with **PROSOLV® 730**, the need for costly soft-gel encapsulation was eliminated.

Thanks to its structure, **PROSOLV® 730** is able to release the oil in an aqueous medium and facilitate its dissolution without the need for any additional ingredients.



Dissolution enhancement

PROSOLV® 730 can adsorb lipophilic APIs dissolved in oil enabling dissolution enhancement depending on the API properties.

Loratadine is a second-generation antihistamine classified as a BCS class II drug (low solubility, high permeability). Therefore, the challenge is to increase its solubility as it is the major obstacle in its absorption. In this case study, the solubility of two formulations using **PROSOLV® 730** are compared to a commercial OTC formulation.

In this case, 100% API-release is reached up to 6 times faster when using **PROSOLV® 730**.

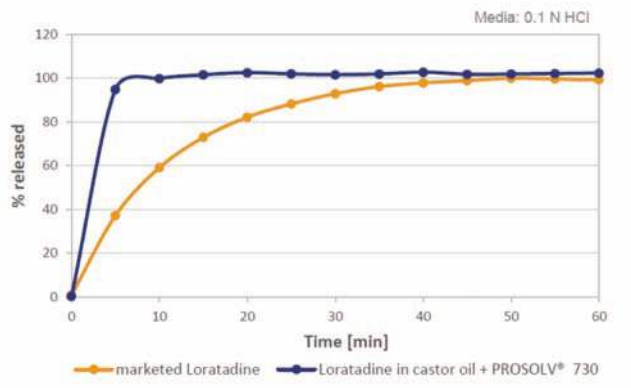
Modified release

PROSOLV® 730 can adsorb lipophilic APIs dissolved in molten lipid carriers. This enables modified release of the API.

Formulation consisting of Loratadine, LUBRITAB® (hydrogenated vegetable oil), **PROSOLV® 730**, PRUV®

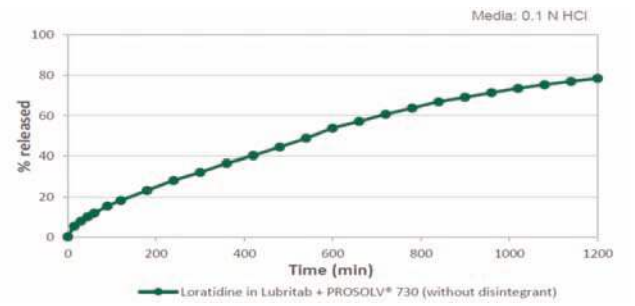
80% of drug release achieved in a near zero order release profile (extended release) for up to 20 hours.

Unlike conventional lipophilic matrix formulations, **PROSOLV® 730** helps building sustained release formulations by elevating the proven concept of a hydrophobic matrix to an easy-to-use directly compressible dry powder formulation, which may be easily coated without any adhesion problems.



Compared with other methods for solubility enhancement, PROSOLV® 730 offers the following advantages:

- ◆ Enables processes at room temperature
- ◆ Organic-solvents-free process
- ◆ Costly-polymer-free formulation
- ◆ Emulsifiers-free formulation
- ◆ Gelatine-free formulation
- ◆ Cost-effective manufacturing techniques
- ◆ Ease of handling
- ◆ Streamlined production



Regulatory information

1) EXCiPACT™ cerified
2) Components are Generally Recognized as Safe (GRAS)
3) **PROSOLV® 730** is derived from non-GMO trees
4) GMP compliant
5) Listed in the USP Inactive Ingredients Database as microcrystalline cellulose, colloidal silicon dioxide, and copovidone
6) **PROSOLV® 730** is a high-quality co-processed excipient compliant with international pharmacopoeial standards, food regulations, and GMP requirements. It provides a reliable option for pharmaceutical and food and nutraceutical applications while meeting stringent safety and compliance standards.

Author
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Technical Manager,
JRS Pharma India
Email id:
Suyesh.kale@jrsindia.com

ImasteriConnect™ – Redefining Sterile Fluid Connection

In the fast-moving world of modern bioprocessing, every connection counts. Sterility, safety, and efficiency are no longer just operational goals — they are the backbone of successful therapies, vaccines, and advanced biologics. Any compromise in fluid transfer can lead to costly downtime, contamination, or even the loss of an entire production batch.

That's why ImasteriConnect™ was developed — a breakthrough sterile fluid transfer technology that combines simplicity, reliability, and compliance into one powerful solution. Designed for today's demanding bioprocessing environments, ImasteriConnect™ ensures that sterile connections are no longer a challenge, but a seamless part of your workflow.

What Makes ImasteriConnect™ Unique?

ImasteriConnect™ is purpose-built to address the most critical challenges faced by operators and engineers in the field. Its innovative features go beyond traditional connectors to provide a new benchmark in sterile connectivity:

◆ **Genderless Design** – A single connector fits all, eliminating the complexity of maintaining multiple SKUs and reducing inventory costs.

◆ **Twist-to-Lock Mechanism** – Simple, tool-free, and intuitive. Operators can establish connections in seconds, reducing training needs and minimizing the risk of errors.

◆ **Aseptic, Airtight Seal** – Every connection maintains sterility and protects product integrity, ensuring batch safety.

◆ **Gamma Sterilized & Ready-to-Use** – Supplied sterile, the connectors can be immediately integrated into aseptic processes, streamlining workflows.

◆ **cGMP Compliant** – Designed and manufactured in accordance with global regulatory standards for biopharmaceutical production.

Why It Matters

In bioprocessing, the smallest details can determine the biggest outcomes. ImasteriConnect™ delivers measurable benefits at every stage of production:

◆ **Superior Sterility Assurance** – Leak-proof, validated design prevents contamination and protects sensitive materials.

◆ **Enhanced Efficiency** – Operators can complete sterile connections up to 50% faster compared to conventional systems, improving productivity.

◆ **Reduced Operational Costs** – Simplified inventory management, minimized downtime, and decreased training requirements contribute directly to cost savings.

◆ **Improved Safety** – Secure, spill-free connections protect both personnel and valuable products, reducing the risk of accidents.

◆ **Universal Compatibility** – Seamlessly integrates into a wide range of bioprocess systems, from upstream to downstream, across applications like vaccines, cell therapy, filtration, and fill-finish.

Applications across Bioprocessing

ImasteriConnect™ is engineered for flexibility, making it suitable for diverse applications in biopharmaceutical manufacturing:

◆ **Cell & Gene Therapy** – Provides sterile and reliable transfer of delicate and high-value materials, where contamination is not an option.

◆ **Vaccine Manufacturing** – Maintains product purity and consistency during critical steps such as media preparation and drug formulation.

◆ **Media Preparation & Fill-Finish** – Simplifies complex aseptic workflows and ensures sterility during final product handling.

◆ **Filtration & Bioreactors** – Enables airtight, sterile connections that support consistent performance and scale-up reliability.

By offering a universal sterile connection solution, ImasteriConnect™ helps accelerate innovation in life-saving therapies while reducing operational challenges.

Certifications & Quality Assurance

Quality and compliance are at the heart of ImasteriConnect™. Each connector is backed by rigorous testing and certification to meet the most demanding requirements of global bioprocessing.

◆ **cGMP Compliant** – Manufactured under strict Good Manufacturing Practice guidelines.

◆ **Gamma Sterilized** – Supplied sterile, eliminating the need for in-house sterilization and saving valuable process time.

◆ **Validated Materials** – Constructed from biocompatible, chemically resistant polymers that have been tested for safety, performance, and regulatory compliance.

This ensures that every ImasteriConnect™ product you use is not only effective, but also fully aligned with industry standards.

Key Product Features at a Glance

◆ **Genderless Design** – One connector for all, simplifying logistics and operations.

◆ **Twist-to-Lock Mechanism** – Fast, tool-free, and error-free connections every time.

◆ **Aseptic & Airtight Seal** – Guarantees sterility and product integrity.

◆ **Universal Compatibility** – Seamless integration into upstream, downstream, and final fill processes.

◆ **Enhanced Safety** – Leak-proof performance that minimizes contamination risks and protects operators.

Written by:
Suresh Rathod
Assistant manager,
Bioprocess marketing & sales
Suresh.r@amipolymer.com
Contact No - 6357077083

Ensuring Clean Room Integrity with Prime Clean Reset High-Speed Doors: Minimizing Air Permeability and Leakages

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

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

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

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

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

Prime Clean Reset, our high-speed door is designed specifically for clean rooms. This innovative solution is engineered to meet the stringent requirements of controlled environments, ensuring exceptional performance and reliability. Designed with precision to meet the stringent requirements of controlled environments, Prime Clean Reset is the epitome of performance and reliability, ensuring that your clean room operations consistently meet the highest standards of regulatory compliance and product integrity.

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

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

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

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

◆ **Low Air Permeability:** Designed to maintain low air permeability in pressurized rooms with both positive and negative air pressure.

◆ **Compact Design:** The doors are designed to fit inside the columns, with a self-supporting construction that minimizes air leakage.

◆ **Customizable Transparency:** They can be equipped with transparent PVC horizontal sections or vision windows for visibility.

◆ **Specialized Side Guides:** The special side guides ensure a tight integration of the curtain, providing high leak tightness.

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

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

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

For further information on our high-speed doors offering, contact:
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Off : +91 22 66720200 / 66720300 (200 lines)
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