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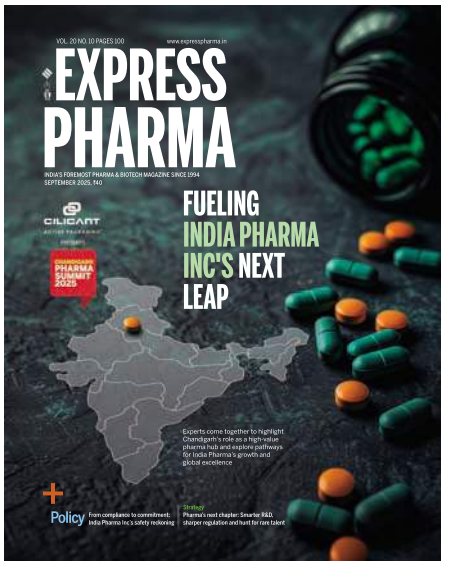
SEPTEMBER 2025, ₹ 40



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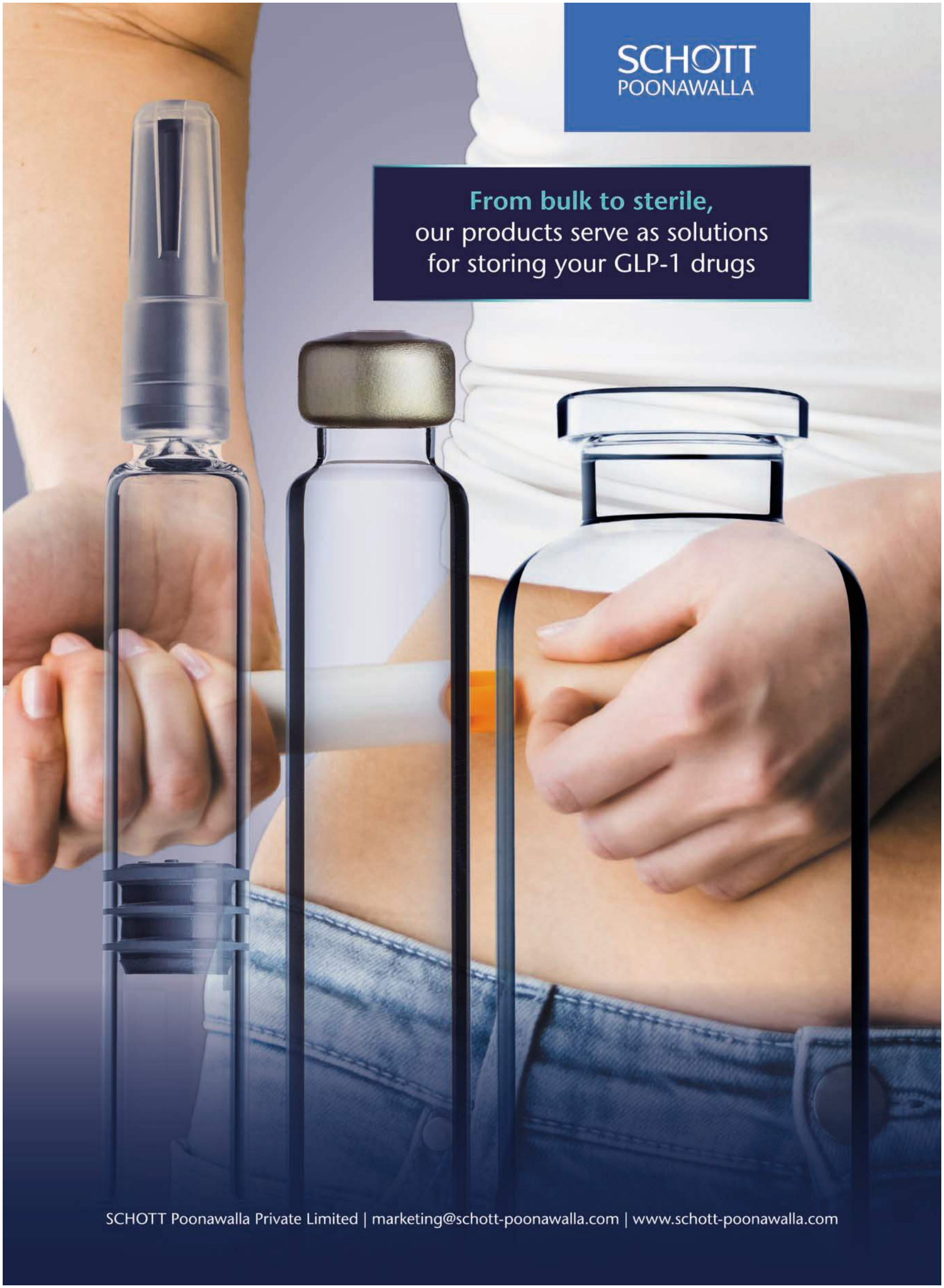
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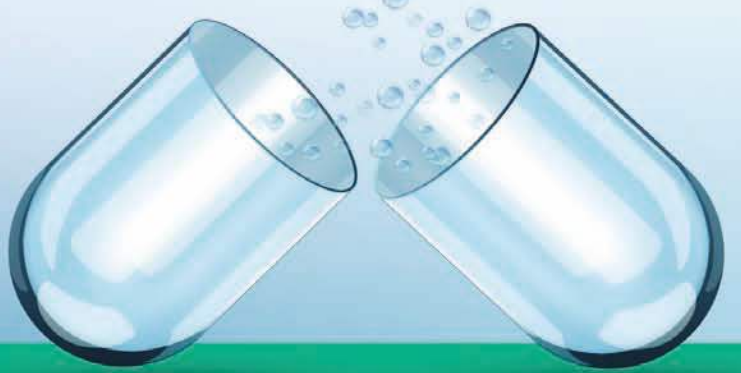

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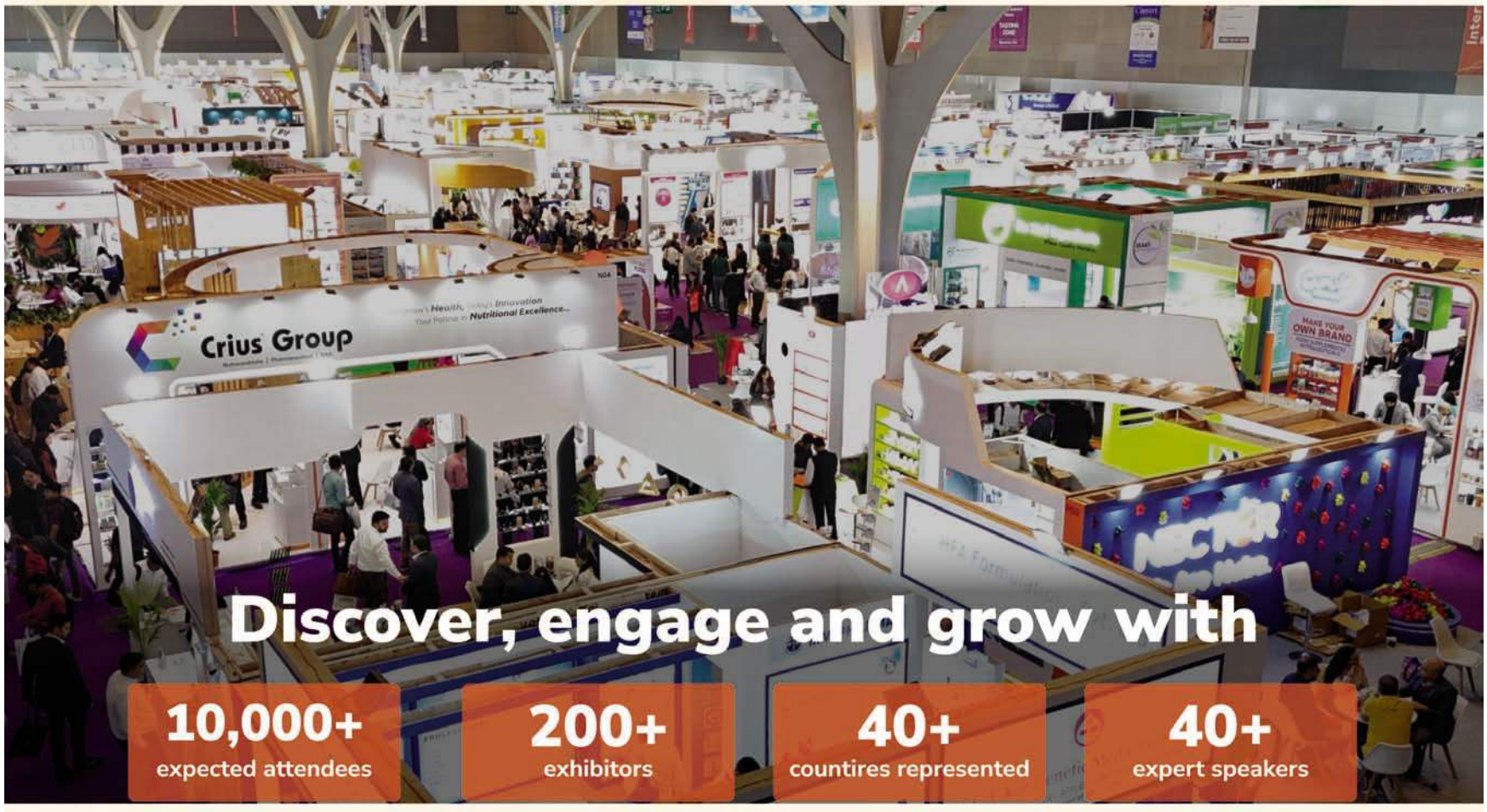

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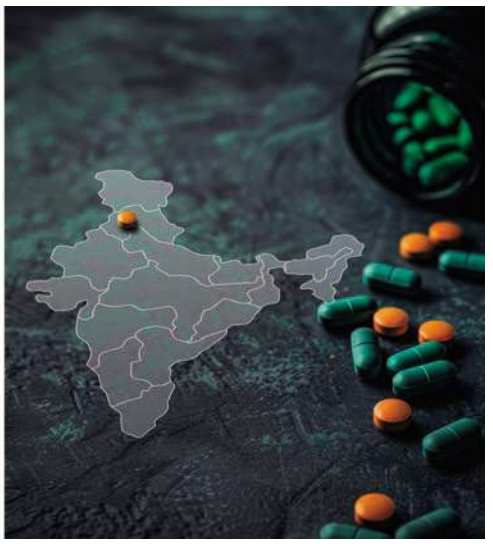

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Tariff turbulence sparks a reset

In the battle of wills between the world's oldest and biggest democracies, lie the seeds of change. With the 25 per cent reciprocal tariffs joined by 25 per penalty tariffs, India has to find a way to survive 50 per cent tariffs which came into effect on August 27, 2025. All sectors are adapting to this change, and India's biopharma leaders are already building a new playbook. Turning a challenge into an opportunity, they are pivoting to other markets like the EU, Africa and other geographies with new purpose and aggression.

For example, Aurobindo Pharma is reportedly the front runner in a race to acquire Zentiva, which would give it an enviable expanded footprint in the EU. In an interview to CNBC-TV18, Aurobindo CFO, Santhanam Subramanian explained that Zentiva fits into their strategic plans as it is based in Europe, but it was too premature to comment on possible outcome of ongoing discussions. He also commented that there was nothing wrong in looking at acquiring a large entity. This reasoning hints at the strategic reset underway in India's pharma boardrooms and sets the stage for more such moves.

But these decoupling/derisking strategies take time to fructify. In the near term, pharma companies remain vulnerable to news out of the US. Pharma shares took a beating on the day the additional 25 per cent tariffs set in, even though pharma imports remain exempted.

President Trump's diktat to pharma companies to slash prices on their own, and threats to "slash drug prices by as much as 1,400–1,500%" and impose higher levies on pharma imports, remains a hanging sword.

And let's not forget that there are slew of non-tariff barriers that could be deployed like increasing US FDA scrutiny etc. The tariffs could also derail India's plans to position itself as a key part of the China+1 strategy, as it makes other nations with lower tariffs more competitive.

India pharma might have to brace for a slow down on global FDI, and will find it harder to position itself. This could well be the right storm in the teacup moment to rediscover and reinvent India Pharma Inc from a volume to value play, moving from manufacturing to R&D services.

In fact, one of the trends highlighted in an April 2025 CBRE report, Global Life Sciences Atlas, is how pharma and biotech companies are on the lookout for high-quality lab clusters to support global collaboration, as they accelerate their R&D programmes.

As per the report, gross office leasing space by life sciences firms in India increased by -56% Y-o-Y to about 5.8 million sq. ft., witnessing the highest-ever leasing activity by the sector. While China currently exhibits the highest volume of ongoing laboratory construction worldwide, India is establishing itself as a hub for life sciences manufacturing.

India's pharma sector is rewriting its global playbook, pivoting to other markets like the EU, Africa and other geographies with new purpose and aggression

Hyderabad's Genome Valley is already home to over 200 biotech and pharma companies from 18 countries, including six of the world's top 10 research and development (R&D) companies . More than 20 life sciences and medical technology incubators are in Hyderabad, the highest concentration in India.

There is no doubt that India has a long way to go but the trends look promising. The CBRE report benchmarks emerging hubs like Hyderabad in the Asia-Pacific region (Beijing, Shanghai, Greater Tokyo), as well as the traditional hubs in Canada (Toronto, Montreal) and Europe (Cambridge, U.K., Paris) and Boston-Cambridge and the San Francisco Bay Area in the US. This benchmarking exercise also serves to show where the gaps are and how they can be plugged. India needs more Genome Valley-like clusters to make a true impact.

India's domestic market, thanks to demographics, remains attractive and we could see more investments here. Prime Minister's GST reforms and other policy easing are designed to soothe some of the tariff constraints. This spur for long overdue reforms might just turn out to be the silver lining in the tariff clouds.

Demographics is one major reason why India stands a good chance of weathering the 'who will blink first' tariff tiff. The sheer size of India's market remains a major draw. For instance, India's domestic market is already witnessing the battle of the weight loss majors Novo Nordisk and Eli Lilly. They will be joined next year by at least six of India's major companies when Novo Nordisk's semaglutide faces patent expiry.

As per a Reuters report, Novo Nordisk is already facing slowing global sales of Wegovy due to competition, leading to possible layoffs. Other Reuters reports detail the numerous lawsuits filed by Novo Nordisk against compounding pharmacies in the US for spinning off un-authorised Wegovy copies. Simultaneously, patients in the US are suing Novo Nordisk for not informing them and not creating enough awareness on serious side effects ranging from gastrointestinal issues, pancreatitis and vision loss.

Both Eli Lilly and Novo Nordisk, along with other global majors, have oral weight loss drug candidates making their way through clinical trials. In a country with India's climate and economic constraints, weight loss pills would make more sense than shots.

As tariffs wars play out, India's pharma sector forges its way ahead. India's patients and doctor communities too need to weigh the pros and cons of weight loss medications, as well as other launches, to safeguard their long term health.

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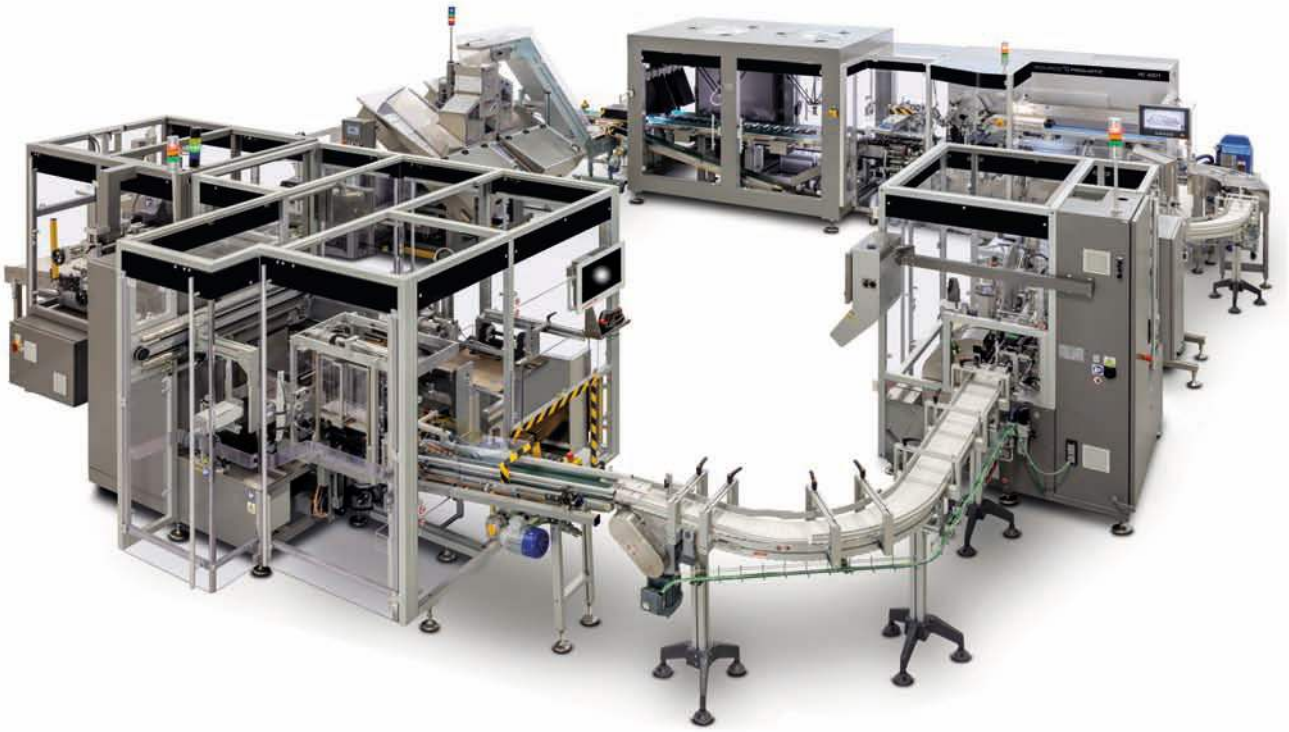

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Advanced bioprocessing capabilities form a core pillar of Syngene's growth strategy

Alex Del Priore, Senior Vice President – Manufacturing, Syngene explains how his company is positioning itself as a global CRDMO leader, leveraging integrated end-to-end capabilities, advanced biomanufacturing technologies, and strategic investments to support the evolving needs of biopharma companies, in an exclusive interaction with **Lakshmipriya Nair**

India is emerging as a biomanufacturing hub. So, how is Syngene positioning itself as a reliable and strategic partner in the global biopharma supply chain?

When you look at how pharma outsourcing has evolved, it was once largely limited to generics and API manufacturing, and India earned the reputation of being the "pharmacy of the world", supplying nearly 20 per cent of global generics and over 60 per cent of vaccines. But as drug discovery and development became more complex and expensive, pharma and biotech companies began seeking specialist partners to manage different parts of the value chain. This shift gave rise to Contract Research, Development, and Manufacturing Organisations (CRDMOs) like Syngene. Initially services such as medicinal chemistry and biology were outsourced to leverage India's strong scientific talent, especially in chemistry, where the country has long excelled. Over time, the scope of CRDMOs expanded significantly—from offering discrete services to managing full drug development programmes end to end. Today, CRDMOs mirror the operations of pharma companies themselves, working across modalities including biologics, ADCs, peptides, PROTACs, and cell and gene therapies.

India's CRDMO sector is currently valued at $3–3.5 billion and is growing at 15 per cent CAGR, nearly double the global average. This momentum is supported by several tailwinds. Global biopharma companies are rethinking their supply chains and increasingly looking beyond China, creating a $10 billion opportunity for Indian players. At the same time, the Indian government has provided policy and financial support, including the Production-Linked Incentive (PLI) scheme and dedicated funding for biomanufacturing infrastructure. This ecosystem has encouraged more global companies to place their trust in Indian partners and has spurred sustained investments in capacity and capability building.

> We operate on a twin-engine growth model, maintaining a strong and balanced focus on both our CRO and CDMO businesses. Over the last few years, we have invested close to $700 million in capital expenditure, with over half deployed in just the past five years

Syngene, with over three decades of experience, recognises the opportunity and has already taken steps to meet the evolving needs of its customers. We have evolved from offering standalone services to building integrated, end-to-end capabilities that cover the full drug development lifecycle—discovery to development to commercial manufacturing. Everything is available in one location, offering clients simplicity, speed, and scientific continuity. The acquisition of a biologics manufacturing facility in the US adds geographic flexibility and enhances capacity, demonstrating Syngene's commitment to a dual-shore model that helps clients de-risk their supply chains. These strategic moves are backed by significant investments in digitisation, automation, and talent development.

What sets Syngene apart is its scientific depth and breadth, combined with the ability to deliver value as a strategic, long-term partner. For instance, we have one of the largest PROTACs teams globally, with over 500 scientists dedicated to this area, reflecting the company's capability in supporting emerging therapeutic technologies. The company offers an end-to-end solution with the scale and resilience that global clients require in today's rapidly evolving biopharma landscape. With everything from discovery to commercial manufacturing available in one location—and supported by a dual-shore model, we are uniquely positioned to meet the needs of clients looking for integrated, flexible, and future-ready CRDMO solutions.

As per reports, Syngene is investing in advanced cell line development. Can you share more details about it? What are your considerations while making these decisions?

Cell line development is emerging as a cornerstone in the advancement of biologics, gene therapies, and vaccines, driven by the global rise in chronic conditions such as cancer and autoimmune diseases. Valued at $7.5 billion in 2024, the market is projected to surpass $19 billion by 2034, reflecting its growing relevance. To meet

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this demand, the industry is adopting high-yield, reliable platforms that can support large-scale production, with specialised contract manufacturers playing a key role in enhancing speed, consistency, and quality from early development to commercial delivery.

Against this backdrop, Syngene is reimagining cell line development (CLD) as a strategic enabler of speed, quality, and scalability in biologics development. With demand rising for flexible, high-performing cell lines, we have made targeted investments to help clients achieve faster timelines, higher yields, and seamless scale-up.

Central to this is SynWeave, our proprietary CLD platform that integrates transposon-based gene integration, high-throughput screening, and real-time analytics. This unified workflow enables the rapid selection of high-yielding, stable clones while enhancing predictability across scales and formats. It is particularly effective for complex biologics such as glycoproteins and bispecific antibodies, where conventional approaches often fall short.

Our CLD strategy is shaped by a forward-looking view of scientific progress and client needs. We actively invest in capabilities that support next-generation biologics, including complex protein formats and novel expression systems. Drawing on our broad experience, we design fit-for-purpose CLD programmes that align with clients' immediate objectives and long-term regulatory and manufacturing goals.

By embedding quality, speed, and scalability from the outset, Syngene helps clients de-risk development and ensure a smooth transition through clinical stages and into commercial production.

What differentiates Syngene's approach to biomanufacturing, particularly in complex categories like ADCs and nucleic acid-based therapeutics?

As complex modalities such as antibody-drug conjugates (ADCs) and nucleic acid-based therapeutics gain momentum, biopharma companies are looking for integrated partners with scientific depth, operational agility, and regulatory alignment. Syngene's biomanufacturing approach is designed to meet these needs by connecting all stages of development under one roof.

In ADC development, we support programmes from early discovery through to GMP manufacturing, including antibody engineering, linker and payload synthesis, conjugation, and bioanalytical support—within a unified workflow. With antibody production, linker-payload manufacturing, and conjugation co-located, we are able to reduce handovers, improve programme visibility, and shorten timelines. Our infrastructure is also equipped to handle emerging conjugate formats such as antibody-PROTACs, antibody-oligonucleotide conjugates, and peptide-drug conjugates.

Similarly, in the nucleic acid space, we offer comprehensive solutions that extend from construct design and functional validation to scalable GMP manufacturing. Our infrastructure is built to support both plasmid DNA and mRNA programmes, underpinned by advanced analytical platforms to ensure product quality and regulatory compliance.

While these are just two examples, the same integrated approach applies across a range of complex biologics. Our goal is to make the path from idea to clinic more predictable and efficient, regardless of modality.

Can you share how solutions such as transposon-based gene expression technologies and N-1 perfusion translate into strategic value for your global biopharma partners, from cost savings to faster commercialisation?

As biologics become more complex and timelines tighten, global biopharma companies are prioritising technologies that improve speed, scalability, and cost efficiency. At Syngene, transposon-based gene expression and N-1 perfusion have been integrated into our biomanufacturing workflows to deliver strategic value across the development-to-commercialisation continuum.

Transposon-based gene expression enables stable, efficient integration of therapeutic genes into host cells, significantly reducing the time required to develop high-yielding, production-ready cell lines. These cell lines are compatible with multiple manufacturing formats, offering flexibility as programmes advance from early development to commercial scale.

N-1 perfusion complements this by increasing viable cell density during the seed stage, enabling higher inoculation volumes and improved productivity in the main bioreactor—leading to greater yield without requiring major infrastructure changes or triggering additional regulatory complexities.

Together, these technologies contribute to faster development, higher yields, and more efficient scale-up. For our partners, this means reduced risk, tighter control over timelines, and more predictable cost structures as they move complex biologics through the pipeline.

From a business perspective, how will advanced bioprocessing capabilities contribute to Syngene's growth trajectory and value proposition?

Advanced bioprocessing capabilities form a core pillar of Syngene's growth strategy, equipping us to meet the rising global demand for complex biologics with speed, scale, and quality. Through investments in high-throughput development tools, perfusion systems, single-use technologies, and automated purification platforms, we are building a flexible, future-ready manufacturing model.

The acquisition of our biologics facility in Bayview, US with 30,000 liters of single-use capacity, expands our global footprint and strengthens proximity to international clients. Combined with our Unit 3 facility in Bangalore—designed to support both clinical and commercial supply—we now offer integrated development-to-manufacturing solutions across geographies.

At the same time, we are enhancing our chemistry capabilities to meet growing demand in small molecule programmes. This includes increased capacity for high-potency APIs, large-scale reactors, and cGMP manufacturing for complex molecules, enabling us to deliver end-to-end support across modalities.

Together, these strategic investments position Syngene as a trusted partner for global biopharma, enabling faster, more predictable outcomes across a broad and evolving pipeline landscape.

What are the biggest technology or capability investments Syngene is making in the next three to five years?

We operate on a twin-engine growth model, maintaining a strong and balanced focus on both our CRO and CDMO businesses. Over the last few years, we have invested close to $700 million in capital expenditure, with over half deployed in just the past five years. This reflects a clear commitment to scaling capabilities in strategically relevant areas.

Our capital deployment will continue to focus on strengthening our position as an integrated, differentiated, and future-ready partner. This includes investments in both established and emerging technology platforms that support scientific excellence, drive innovation, and enhance overall efficiency. Whether through capacity expansion, technology infusion, or the addition of niche capabilities, our aim is to remain agile and responsive to the evolving needs of global pharma and biotech clients.

lakshmipriya.nair@expressindia.com
laxmipriyanair@gmail.com

Advanced bioprocessing capabilities form a core pillar of Syngene's growth strategy. Through investments in high-throughput development tools, perfusion systems, single-use technologies, and automated purification platforms, we are building a flexible, future-ready manufacturing model

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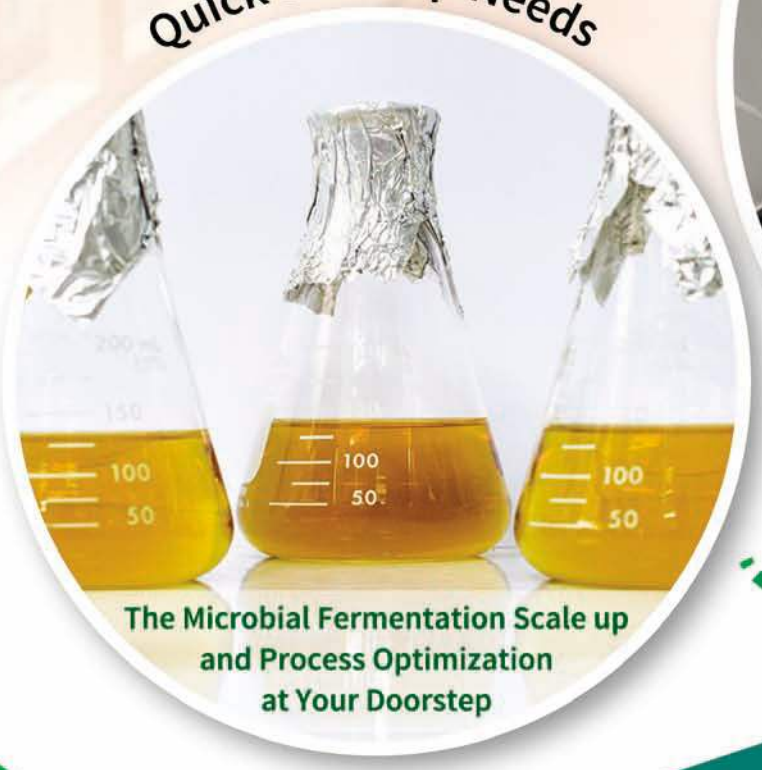

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A vigilant consumer is half the battle won

Manoj Kochar, President, Authentication Solution Providers' Association (ASPA), in a frank conversation with **Viveka Roychowdhury,** urges pharma companies to publicly acknowledge the problem of counterfeit medicine, and invest in multi-layered authentication solutions - overt and covert, physical and digital - to deter counterfeiters. Agreeing that QR codes, while useful for tracking, are not foolproof authentication tools and are easily cloned, he firmly believes that a vigilant consumer is half the battle won, and hopes that pharma companies can spur consumers to scan QR codes, search for anti-counterfeiting features like holograms etc. He hopes the Ministry of Consumer Affairs takes up ASPA's recommendation to have a medicine-focused Jago Grahak Jago campaign

What are the major findings of ASPA - CRISIL State of Counterfeiting in India Report 2022 on the state of counterfeiting in India with respect to the high-risk pharma sector?

The second edition of the new report on counterfeiting is still a work in progress. It is expected to be launched around September 11, 2025. . There were a lot of pretty startling findings in the first edition. Firstly, if you look at the problem of counterfeiting in an overall situation, the Indian pharma industry as per the fiscal 2023 estimates, was about Rs 3 trillion which is clearly one of the largest in the world. Most of it is meant for domestic consumption.

Coming specifically to the counterfeits, which includes spurious and substandard drugs, CDSCO did a survey in 2009 and they estimated that at that point in time, counterfeits or spurious and substandard drugs are about one per cent.

As per WHO, it was around 10 per cent. When we did the State of Counterfeiting in India 2022 report, 20 per cent of the consumers felt that there is counterfeit medicine in the market. The same study also discovered that 25 per cent of the people willingly purchase counterfeit medicines due to nonavailability of the original product and obviously lower cost. OECD did a report in 2020 where they said that India was the origin of 47 per cent in value terms of the total counterfeit value of the goods that was seized by EU custom authorities. This obviously suggests that India is a major hub.

> The pharma supply chain in India is kind of porous. A large part of the pharma business still happens in the unorganised sector. And that is where the counterfeiters find it easy to inject their spurious medicines into the supply chain

I'm not saying that all of these had their origin in India. Maybe some of them transited through India, we would never know that for a fact but at least 47 per cent that's nearly half the medicines found their route through India.

So the problem of counterfeiting in India is spread all over, not that there's certain pockets. The entire industry and the regulators in my opinion should come together to fight this menace.

What are the main reasons for the high incidence of counterfeits in India's pharma sector? Do you think that it's a fact that you know it's a very porous supply chain?

I agree that the pharma supply chain in India is kind of porous. A large part of the pharma business still happens in the unorganised sector. And that is where the counterfeiters find it easy to inject their spurious medicines into the supply chain. There is also the fact that there is a demand and supply gap. A lot of areas don't have the medicines that are typically prescribed by the doctor or needed by the patient. Counterfeiters see that as an opportunity and they are happy to push their products through the supply chain for their benefit.

As consumers I don't think we are very aware or vigilant enough to really be careful when we buy a medicine. One simple thing is when you buy a medicine, ask for a cash memo. The chemist will almost always write a batch number. Match that batch number written in the cash memo to what is actually printed on the medicine. That is a very simple check and if the retailer is indeed pushing fake medicines, he will not write that batch code on the cash memo.

So I think the consumer should perhaps take some simple steps, look for any obvious spelling mistakes or color mismatch. Just give a good look at what you're buying to be reasonably sure that what you're buying is indeed genuine.

I think that consumer awareness and vigilance is very important. Obviously rural areas are prone more because they perhaps are not as vigilant. So there I think the scope of pushing in spurious medicine is higher and that is what the counterfeiters are relying on and pushing a lot of products through the porous supply chain more into the rural areas than the urban.

The anti-counterfeiting measures in current use like track and trace technologies, QR codes that most pharma companies use are being replicated and being infiltrated more easily. It's always a game of catch up because anti-counterfeitors will always be able to break the code. What are the new more advanced measures of anti-counterfeiting

technologies?
Anti-counterfeiting or authentication technologies are all about staying ahead of the race as compared to the counterfeiter. Let's not underestimate the counterfeiters. They are people with a lot of resources and reasonably sized operations. All the anti-counterfeiting solution providers have to keep improving and upgrading their technology all the time because they need to stay ahead.

Having said that you mentioned QR codes. A QR code by itself is not an authentication technology. A QR code helps you conduct the track and trace. You can track where the medicine came from, trace the entire history. Yes, for that it's a great tool. It's a great technology.

But if you are looking at authentication features or anti-counterfeit features, then you have to rely on technologies like holograms, security printing or even nonclonable codes because QR codes per se can be cloned quite easily. I have also heard stories that people can counterfeit a code, print it on the medicine and create a fake website. So if you for instance bought a genuine medication, they would then create a fake site where that particular strip of medicine would be certified as genuine. So they even go to that extent.

So do not rely on QR codes per se as an authentication feature. Always look for security features such as a hologram, any security printing or any other feature that the brand has kind of created an awareness for.

It's so important to create awareness amongst the consumer. There are more technologies not currently found on Indian pharma products but there's always the cost angle. We understand that the pharma industry can spend only that much on these features. So as a result some of the newer technologies which might be far more expensive cannot be really factored into their current situation.

You mentioned that QR codes are not really the be all and end all of anti-counterfeit measures. There have been established cases of cyber theft of serial numbers of an anti-epileptic drug in multiple states. Serial numbers were then incorporated into QR codes and then applied on fake packs. What are the options for the regulator once they have proof of such large scale counterfeiting operations? Is a recall easy enough to enforce in India? You also talked about awareness campaigns at the consumer level. Do you feel the time has come for NGOs and patient activist organisations to take a new front seat on this because ultimately fake medicines are about patients' life at stake as well as reputational loss.
This is really more of a social crisis if I can use that word because the common people are getting affected for no fault of theirs. It's all right to expect them to carry out a certain bit of care and vigilance while they are buying a medicine but then it's equally the responsibility of the regulator and the brand to facilitate that authentication at the consumer end.

Like I said earlier, in the incident that you just mentioned where there was cyber theft and QR codes were stolen and then printed again on fake medicines. That's exactly the point I'm trying to make. QR code is not in itself an authentication technology. So it's important for the brands to look at the other technologies over and above the QR code.

I don't dispute the value of QR codes at all. But then is authentication one of its core propositions? In my opinion no. But this is exactly where you need to go into a physical space, where you have a physical technology like the hologram, the security printing and other elements that are there in the market and marry that with a QR code.

So visually you can check that yes this is indeed a

genuine product. I'm assuming that the consumer has been made aware of the physical security features and digital verification happens by the QR code where you can check the batch number or the expiry date or the origin or whatever.

So it's very important to merge the two technologies of physical and digital and that to me in the current situation seems like a more potent solution to fight this menace.

India's top 300 brands have the QR code, but what is the scan rate on those codes? To the best of my knowledge, not even 1 per cent. Again, awareness comes in. There may also be connectivity issues at times. So it's important to go the digital route. Of course, adopt the QR code, keep the QR code in place for the obvious benefits that brings in but do also look at the physical security features because then that makes the counterfeiter's task more difficult

The government has mandated certain anti-counterfeiting measures but we are still seeing such high levels of counterfeiting. What are the outcomes of these measures and is it time to have better regulation and implementation of these regulations? Any solutions on that and what is ASPA's role?

As far as the government mandate goes, they have only mandated the QR codes on the top 300 brands to the best of my knowledge. I don't think they really mandate the usage of authentication technologies as such. So yes, the regulator can of course start with saying that you must employ some authentication feature which the consumers need to be made aware of. That is extremely critical because you could use the world's best technology but if the consumer is not aware then it's not going to reap the full benefits that it should have. And so I think that awareness creation is important.

Technology is important because it is changing every day. So while the government may not want to specify the technology or the features they should use, which I think is fine. But they should at least encourage brands to use authentication features at least in some brands which are, let's say, beyond a certain value.

Let's say we said Rs 500 crores. So all brands that are more than Rs 500 crores or the popular ones should have some authentication feature and the consumer should be made aware of that feature. That is important because consumer awareness,coupled with technology and government regulation is going to be a very powerful mix to deal with the situation and counterfeit medicines.

Counterfeit wellness brands would impact consumers more than counterfeit medicines as wellness products are taken on a daily basis for a long term. What is the level of counterfeiting in the wellness sector?

The wellness sector is obviously a new sector that has come up and is gaining popularity as everybody wants to have supplements etc. They are also priced pretty handsomely in most cases.

They become a counterfeiter's darling because the counterfeiter has fatter margins to play with. Since this is an evolving sector, my advice to wellness brands would be that they should consider employing authentication features into their packaging and make consumers aware so that they stay in the game.

By the time counterfeiters catch up or try to counterfeit their brands, they find that this brand already has certain features which would be difficult to match. As they are a premium product I suspect wellness brands would be able to spend a little more on the technology and make their brand more secure.

It's also a known fact that once the counterfeiter sees that there are brand protection features on a certain pack or a certain brand, they tend to move away. You raise the bar with them on this brand, they look for another brand which is perhaps not as well protected or not protected at all and focus on that.That is a great deterrent. Keep raising the bar, you deter the counterfeiter, he'll move on. I am aware that my company has a few customers from this segment who are choosing solutions that are not only cost-driven, they're looking at the security that the solution brings to them and then adopting them.

To sum up, what three steps can companies take to prevent their products from being the target of counterfeiters?

The most important piece is that they should talk about it. I've been selling authentication solutions for 35 years now and a lot of brands don't want to accept in public that there is counterfeiting. They think that this will damage their brand perception.

I think brands need to talk openly about whether there is a problem in the market and the consumers should be aware. You need to create public awareness. I'd like to cite an example here.

The CEO of a very big pharma company in the country reached out to ASPA a year and a half back. He said, look there is counterfeiting in this space and I want to understand the entire ecosystem of what counterfeiting is, how in your knowledge or opinion they operate, what is the authentication spectrum like, how does that work. We had a one and a half or two hour call with him and we covered all aspects.

Ever since then the gentleman has been very vocal about the fact that there is counterfeit medicine in the market. His social media handles talk about it every week and they're encouraging people to be careful. They have created videos which they have released on public forums. They even collaborated with ASPA for those videos and we were happy to help them. A vigilant consumer is half the battle won. So create awareness.

First of all, acknowledge that there is a problem. There are counterfeits and we need to tackle it head on. We need to create that awareness around it. The consumers need to be aware that they need to look for a security feature that may be there. That is very important.

On the same note, if the brands adopted certain security features, they should advertise those features. Sometime time back, I saw a press advertisement of a major pharma company where they had actually mentioned this. They took a photo of the pack, saying look for this feature. This initiative is fabulous to keep the counterfeiters at bay.

I think that's a very important thing that a brand should do. What could happen is that the counterfeit is so good in terms of the look and fee that it's almost identical. When I say good you know the same kind of printing, the same colors, no spelling mistakes.I know personally that sometimes even brands struggle to identify by looking at the packaging whether this is original or not. So that is something which has been noticed as a problem.

So we advise the brands to go for a covert feature. A covert feature is a feature that is invisible to the naked eye.

For consumers, you have overt features that are visible to the naked eye, like security printing or a hologram. But a covert feature is something which is invisible. There are many technologies through which we can put a covert feature into the pack which only the brand knows and we know.

There could be a simple instrument to detect this feature with a hidden message or a green light or a beep, etc. This is a feature that we have already sold to a big pharma company and they have incorporated already.

Covert features will also help brands fight any product warranty claims or even regulatory action. We know counterfeit or substandard medicine could have lower API content. If a brand has 60 per cent API, the fake probably has 30 per cent or 20 per cent. So maybe it'll almost always be caught at the lab stage.

But if such a feature is introduced even at the packaging stage, then by conducting a thorough examination of the packaging, you can tell that this is not my medicine.

So creating that awareness is important. Advertise the features. Talk about the fact that there's a problem and I'm implementing a multi-layered security technology, which may be digital.

I'm not saying the QR code is bad. The QR code is there for a purpose but supplement it with physical technologies such as holograms and other robot features and also put in a covert feature, which is known only to the brand and the supplier knows.

So then it becomes a multi-layered protection against counterfeiters. As I mentioned earlier, the counterfeiter tends to shift to a brand that's not so well protected once you've raised the bar. That's a very good first step and you should be able to then secure your brand.

What is ASPA's role in increasing consumer awareness on counterfeiting?

We recently reached out to the Ministry of Consumer Affairs. You recall we had this brilliant campaign called *Jago Grahak Jago*? It's such a brilliant campaign and enabled the consumer in the sense that the consumer suddenly became of the rights as the consumer.

We approached the Consumer Affairs Minister to suggest that they do an extension to the Jago Grahak Jago movement, an initiative like this from the government will help fight the menace not only in the pharma sector but across all segments because every industry suffers from counterfeits.

viveka.r@expressindia.com
viveka.roy3@gmail.com

We plant to upscale our export business over the next three years

Nikkhil K Masurkar, CEO, ENTOD Pharmaceuticals in an interaction with **Kalyani Sharma** talks about his company's future plans, regulatory changes in the industry and more

Ophthalmology has been your focus. What kind of growth are you seeing in this segment, and how do you foresee the market evolving?
Ophthalmology remains the heart of our business, contributing about 65 per cent of our revenue. We've witnessed a 25 per cent growth in the last five years, while the Indian ophthalmic market has grown at around 13-15 per cent. But I believe the real boom in ophthalmology is still ahead. Increasing private equity funding into eye hospitals and greenfield projects will further fuel this growth. Many of these hospitals are looking for new ways to generate patient traffic, and pharma plays a vital role in this process.

We're also pushing innovation aggressively. For instance, our launch of Myatro XL, a myopia treatment eye drop, was a global first—introduced even before the US. We priced it at Rs 350, significantly lower than the Rs 1,500 it might have commanded if launched later with international licensing. That's how we ensure affordability and accessibility.

How do you maintain quality while relying on contract manufacturing? Why haven't you set up your own manufacturing plant?
We started as contract manufacturers, so our focus has always been on R&D, brand building, and innovation rather than owning manufacturing units. We develop formulations in-house, file patents, and do

tech transfers to our selected partners, ensuring they follow our stringent specifications.

Despite outsourcing, we have full control over the process from sourcing APIs to packaging. Every batch is tested by our own QA/QC teams before it reaches the market. We even retest products independently to maintain safety, especially because these are sterile ophthalmic formulations. That's why, in 48 years, we haven't had a single major quality complaint.

That said, we do plan to set up a USFDA-compliant plant within the next three years to support our global ambitions, particularly for regulated markets like the US and Europe.

What are your international expansion plans? Which markets are you focusing on?
We've already established a niche presence in Southeast Asia, the Caribbean, and parts of Africa. Now, we're expanding into East Africa, Latin America, and the GCC countries. Our aim is to significantly upscale our export business over the next three years, supported by our planned manufacturing capabilities.

We're particularly focused on offering Indian innovation at affordable prices in emerging markets, where accessibility is often a barrier. Many therapies used in India can be life-changing in these markets where alternatives are either unavailable or unaffordable.

You also entered the dermatology space recently. How is that progressing?
Derma has emerged as one of our fastest-growing verticals. Unlike many companies that enter with me-too formulations, we focused on innovation from day one. Our under-eye gel and Vasuki NT (a topical neurotoxin) are examples of products that stood out due to genuine innovation.

The Indian derma market is worth Rs 15,500 crore, but if you include D2C and OTC, it balloons to Rs 48,000 crore. It's a crowded space, but we've built our presence through quality and ethical promotion. We perform all necessary lab tests like skin patch and ocular irritation tests—even though they're not mandated. Our approach is always doctor-driven and evidence-based.

What other segments are you entering next?
We're expanding into respiratory, CNS, and mental health. The CNS segment, in particular, is expected to become the third-largest therapeutic area in the next five years, driven by a rise in mental health conditions. Our internal R&D team is also working on new insulin-based eye drops, among other innovations.

What's your take on recent regulatory changes—UCPMP, pharmacovigilance norms etc.?
We welcome these changes. Regulatory tightening—whether it's Schedule M, pharmacovigilance, or UCPMP brings more discipline to the industry. We've been advocating for ethical marketing and clean industry practices for over 15 years. These changes will separate genuine players from those who're in it just for a quick buck.

Cosmetics too, which have largely gone unregulated, are now under greater scrutiny. That's a welcome move, especially in a market flooded with influencers promoting questionable products without scientific backing. We've always maintained high standards in our cosmetic line with rigorous testing, even for non-prescription products.

With growing global demand, what are your thoughts on India's dependence on China for APIs and the US for exports?
Yes, India has historically been too reliant on both. Around 70 per cent of our APIs came from China earlier, though that number is now reducing thanks to the PLI scheme. At ENTOD, most of our ophthalmic APIs are now locally sourced.

Export-wise, it's dangerous for any country to rely too heavily on one market. For example, some companies get over 30 per cent of their revenue from the US alone. That's risky. We believe in diversifying to emerging markets to de-risk and ensure steady growth.

Kalyani.sharma@expressindia.com
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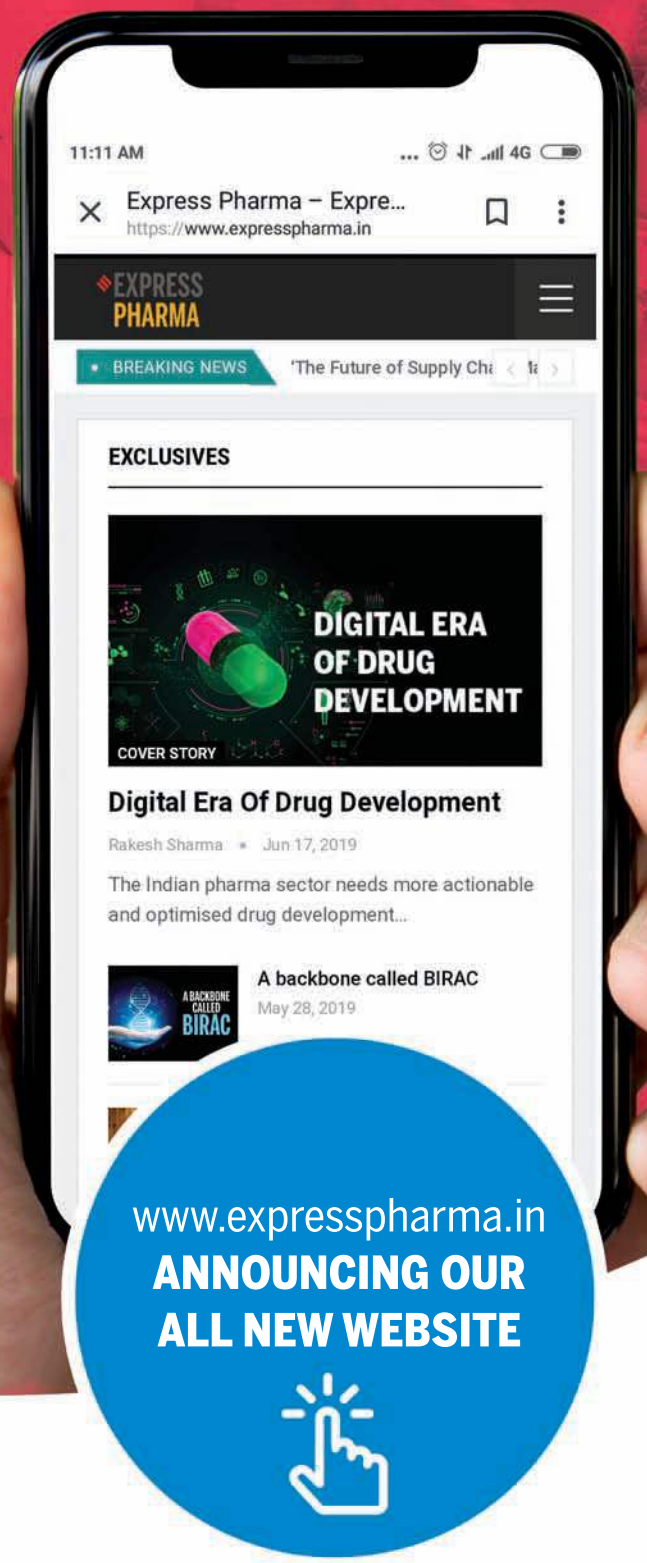

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From compliance to commitment: India Pharma Inc's safety reckoning

A spate of fatal incidents at pharma plants has exposed critical gaps in workplace safety. With growing ESG scrutiny and global expectations, industry leaders acknowledge that compliance alone isn't enough. A cultural reset—rooted in leadership, accountability, and systemic reform—is imperative to safeguard lives and sustain global pharma leadership, finds **Viveka Roychowdhury**

Recent incidents at pharmaceutical manufacturing plants point to glaring gaps in workplace safety standards. In the most recent one, four workers lost their lives on August 21, due to a gas leak at the Medley Pharmaceuticals plant located at Tarapur, Maharashtra. Two more workers were admitted to the ICU of a local hospital.

A few months back, on June 30, 46 people died at Sigachi Industries' Pashamylaram plant in Sangareddy district, Telangana. RPG Life Sciences' Navi Mumbai-based API manufacturing plant reported a fire in January this year.

And these are just the incidents that made the headlines as they are listed companies or the plants are located relatively close to urban India. There would be many more such incidents at MSME pharma plants in industrial parks, as I argue in a recent editorial. (*https://www.expresspharma.in/walking-the-talk-on-esg-workplace-safety/*)

The bigger companies have bounced back. RPG Life Sciences is reportedly on track to restore the plant with a completion target in Q2. Amit Raj Sinha, MD & CEO, Sigachi Industries commits to "bouncing back stronger", with the incident on June 30 acting as "a catalyst for a decisive transformation in how we approach safety, process integrity, and operational resilience."

But the ripples of such incidents reach far beyond a manufacturing plant's gates. After all, much more is expected from the 'pharmacy of the world.'

As a company pioneering a virtual model with multiple cGMP-compliant partners,

Hari Kiran Chereddi, MD & CEO, HRV Pharma and New Horizon Global Pharma perceives "workplace safety as not merely a legal and compliance obligation, but a shared

responsibility that defines the credibility of our industry in the future. Such accidents have once again indicated how vulnerable safety systems are, though India is one of the world's top producers of APIs and formulations."

At the heart of the problem is the scarcely hidden secret that the troika of Environment, Health, and Safety, or EHS, is an afterthought. And this needs to change, because as

Mehul Shah, Founder, Encube Ethicals and VP (Western Region), IDMA puts it, "Beyond compliance, a strong safety culture driven by leadership commitment and employee engagement is crucial."

Without EHS at the centre, India Pharma Inc's future is at stake because as Arpit Bhatia, Director, Laborate Pharmaceuticals warns, "Scaling high-volume pharma manufacturing safely requires embedding EHS as a hard production constraint, not a parallel function."

Regulatory labyrinth

So, why do pharma companies find it difficult to comply with EHS norms? Perhaps part of the answer is the myriad laws.

Pharma companies in India are governed by a mix of central and state government legislations, industry-specific regulations and international best practices. Shah puts them into four buckets:

1. Factories Act, 1948 and respective state Factory Rules (covering health, safety, welfare, working hours, accident reporting, etc.)

2. Environment Protection Act, 1986, Air & Water Acts, Hazardous and Other Wastes Rules, Biomedical Waste Management Rules – for environmental and waste management compliance

3. Fire & Explosives Safety norms as per Petroleum & Explosives Safety Organization (PESO)

4. International guidelines such as OSHA, ISO 45001, and WHO GMP to align with international best practices.

In addition, Chereddi points out that overseas guidelines including norms like US FDA, EMA, and WHO GMP also call for rigorous EHS systems.

Beyond compliance, a strong safety culture driven by leadership commitment and employee engagement is crucial

Mehul Shah
Founder, Encube Ethicals and Vice President (Western Region) at IDMA

The incident on June 30 has been a catalyst for a decisive transformation in how we approach safety, process integrity, and operational resilience

Amit Raj Sinha
MD & CEO,
Sigachi Industries

Workplace safety is not merely a legal and compliance obligation, but a shared responsibility that defines the credibility of our industry in the future

Hari Kiran Chereddi
Managing Director & CEO ,
HRV Pharma & New Horizon Global Pharma

Scaling high-volume pharma manufacturing safely requires embedding EHS as a hard production constraint, not a parallel function

Arpit Bhatia
Director,
Laborate Pharmaceuticals

Most norms are influenced by US Occupational Safety and Health Administration (OSHA) guidelines which include Risk assessment (especially for controlling solvents, inflammable chemicals, and biological agents) and even around hazard classification; stringent engineering controls like ventilation, fire-safety, and effluent treatment; training staff, SOPs, and PPE; and incident reports and documentation for accountability.

As Chereddi sums up, acquiring or renewing production licenses in India is often a time-consuming process, with different timelines for each agency, and delays are common. For SMEs, this regulatory labyrinth will leave projects pending for months, eroding competitiveness.

Shah suggests that renewals are generally smoother if a company maintains compliance records, statutory submissions, and audit readiness. However, he agrees that first-time approvals or expansions can take months due to sequential clearances.

Speaking from experience, Bhatia narrates that for a five-site company like Laborate Pharmaceuticals, compliance and renewals typically hinge on coordination across CDSCO/ State FDA licensing, environmental consents, fire NOCs, PESO, boiler/electrical inspectorates, and occasional foreign inspections (e.g., EU-GMP).

Pain points include asynchronous validity dates, interpretational differences between Schedule M and EU-GMP, and synchronising change control so one supplier or process change propagates consistently into each site's license and validation file.

But it's not impossible. As Bhatia reveals that what works is a central Regulatory Operations PMO with a master calendar, harmonised SOPs, and eCTD-ready QMS covering change, CAPA, training, and self-inspection mapped to ICH Q9/Q10 and WHO TRS. He also mentions having a "365-day audit readiness", evidenced through data integrity controls, validated cleaning hold times, and CAPA effectiveness checks.

In Bhatia's opinion, one needs to start by designing flow, facilities, and staffing around hazard profiles. For instance, Laborate Pharmaceuticals had segregated beta-lactam/cephalosporin/highly potent areas with dedicated HVAC pressure cascades, airlocks, and validated cleaning.

In addition, the company maintains single-direction movement and red-yellow-green zoning. For potent APIs, Laborate implemented closed transfers, contained charging, split-butterfly valves, single-use liners, and isolators.

Laborate also reduced musculoskeletal risk with lift-assists, height-adjustable jigs, and tool balancers at repetitive stations.

Importantly, Bhatia specifies that Laborate treats contractors like employees - gate induction, task-specific permits, colour-coded access, and strict hot-work controls. The company also conducts quarterly drills for fire, chemical release, medical response, and HVAC loss. They close actions via after-action reviews.

Sigachi's story so far: Bouncing back stronger

While the government-led investigation is still underway, Sinha of Sigachi Industries reveals that the company's preliminary internal review, supported by independent experts, points to a dust explosion originating in the dry section of the facility, specifically near the spray dryer chamber.

Key learnings include:

◆ Enhanced dust hazard analysis (aligned with NFPA 660 standards or Equivalent)

◆ Upgradation of Pressure Venting systems with installation of Rupture disc and interlock systems

◆ Stricter environmental controls in powder-handling areas

◆ Refined SOPs for preventive maintenance and inspection cycles

Sinha commits to "making our learnings publicly available, such that any powder manufacturing industry can benefit from them." Such transparency will go a long way towards workplace safety across the sector.

The final safety and design upgrades for the rebuilt Pashamylaram unit will be determined once the detailed government-led investigation report is received. This will ensure that every enhancement is rooted in evidence and addresses all identified risk factors. Sinha asserts that the rebuilt facility will incorporate global best practices in dust hazard management, process safety, benchmarked against leading international standards, with inputs from reputed equipment suppliers and safety experts.

While a final budget will be determined post design finalisation, Sinha anticipates safety system enhancements to require an additional Rs 1.5–2.0 crores over and above standard rebuild costs. These will be funded through a combination of insurance proceeds and internal accruals.

Giving an update on the time to reopen the Pashamylaram site, Sinha explains that as it has not yet been formally handed back to the company, officials are awaiting access to conduct detailed structural assessments of the remaining building systems and critical equipment inside the premises. Timelines for reopening will only be firmed up once these evaluations are complete. Additionally, the design and rebuild plan will depend on the recommendations of the expert investigation committee to ensure that the upgraded facility fully incorporates all learnings and improvements.

Back to business

From a business continuity point of view, in parallel with strengthening safety systems across all existing facilities, Sinha states that they have fast-tracked a 12,000 MTPA capacity expansion at the Dahej SEZ. Civil works are already underway, and this project will elevate Sigachi's total MCC capacity to 30,000 MTPA, reinforcing the company's ability to serve customers without disruption.

Sinha stresses that the Dahej expansion will feature the most advanced spray dryer systems available, procured in consultation with reputed suppliers and process safety experts, underlining that the company is "not only rebuilding what was lost but also raising the safety and operational benchmark for the entire industry."

Healing employee morale

But merely rebuilding and expanding infrastructure will not get Sigachi Industries or any other company back on track. Acknowledging this, Sinha says, "Our stakeholders — from customers and employees to investors and suppliers — have stood by us during this period. Their trust fuels our determination to emerge from this stronger, safer, and more competitive than ever."

Sinha reveals that since the incident on June 30, Sigachi has rolled out a multi-layered safety reinforcement programme across all operating sites to protect the workforce. Key measures include:

◆ **Comprehensive third-party safety audits:** Engaged independent safety experts to conduct detailed dust hazard

analyses, fire safety assessments, and equipment integrity inspections at all MCC units.

◆ **Immediate hazard mitigation:** Addressed identified dust accumulation risks, upgraded grounding and bonding systems, and recalibrated interlocks and emergency shutdown systems across facilities.

◆ **Refresher safety training for all staff:** Conducted 100 per cent retraining of operational and maintenance teams on dust handling protocols, hot work permit compliance, Lockout-Tagout (LOTO) procedures, and emergency evacuation drills.

◆ **Daily EHS checklists:** Instituted mandatory daily safety inspections signed off by plant heads, covering dryer systems, powder transfer lines, rotary valves, and dust collection equipment.

◆ **Safety committee formation:** Established an Expert Safety Committee combining internal leaders and external specialists to monitor and guide safety improvements across all MCC units.

◆ **Enhanced preventive maintenance:** Shortened maintenance cycles for critical equipment such as spray dryers, flash dryers, FBDs, and dust collectors; introduced predictive maintenance tools for early fault detection.

◆ **Employee engagement and whistleblower protection:** Launched open forums and a confidential reporting line for safety concerns, with strict non-retaliation assurance.

◆ **Job and income security commitment:** Ensured there are no layoffs, wage cuts, or benefit reductions — even at the Pashamylaram facility during its 90-day shutdown — with redeployment to training or administrative functions where required.

◆ **Psychological support:** Provided trauma counselling, wellness sessions, and ongoing check-ins for employees directly or indirectly affected by the incident.

Through these steps, Sinha reiterates that the company is "not only reinforcing safety systems but also building a culture where every employee feels responsible for, and confident in, the safety of their workplace."

One hopes that publicised cases like Sigachi Industries are a wake up call for the entire sector. The bad news is that this can't happen overnight, as it needs concerted action from industry as well as policymakers.

An insidious erosion

Chereddi cautions that while in comparison to sectors like mining or heavy engineering, pharma experienced fewer accidents, the risks are typically sneaky. "A chemical spill or exposure to high-concentration APIs may cause no immediate trauma but poses long-term occupational hazards. The challenge is cultural: pharma is a process-oriented sector, and hence safety often becomes a "checkbox" and not a holistic approach."

He also points out that globally, regulators have always held pharma plants to higher standards than, say, FMCG or textiles. But within India, enforcement varies —Tier-1 exporters follow stricter rules, while smaller facilities loosen under cost and other pressures.

Handling of inflammables and solvents tops Chereddi's list of the most common areas of non-conformities. He believes that employees far too often rely on "experience" at the cost of SOP rigor. Awareness classes supplemented by electronic checklists and real-time monitoring can cut risks considerably.

Secondly, insufficient training budgets lead small businesses to treat safety drills as one-off activities. Regular spending on refresher training is required.

Bureaucratic documentation errors is third on the common non-conformities list, as a majority of SMEs consider EHS records as inspector's forms instead of an active safety dashboard.

Lastly, structural shortcomings – fire alarms, PPE warehouses, and effluent systems are occasionally neglected due to a lack of funds.

Chereddi emphasises that these areas must have management commitment: safety must be part of boardroom KPIs, and not just floor level audits.

A time for reform?

With Prime Minister Modi's Independence Day address signalling reforms to nullify the coming tariffs regime, it is perhaps the best time for India Pharma Inc to ask for sweeping changes.

Chereddi's ask to essentially improve Ease of Doing Business lists three actions that are critical now:

1. Unified, single-window digital clearing system – Licensing, renewals, and safety clearances must be harmonised across agencies.

2. Proactive checks – Regulators need to shift from a "fault-finding" approach to a partnership approach, cautioning SMEs in advance.

3. Faster clearances for compliant units – ISO/GMP/EHS-certified units should have risk-based rapid clearances, freeing bandwidth to subject substandard units to stricter vigilance.

He believes that some of these changes would not only reduce accidents but bolster India's reputation as a safe, dependable global supplier.

Bhatia's recommendations on policy improvements to ease doing business include time-bound, risk-based pathways for post-approval changes, reliance on Stringent Regulatory Authority and WHO Prequalification decisions, and a single national portal consolidating permits with reusable master data and machine-readable submissions.

He also asks for predictable inspection calendars with standardised checklists and issue grading, digital acceptance of e-records/e-signatures and hybrid inspections, and coordinated joint visits for safety and environmental clearances.

On international harmonisation, Bhatia recommends aligning to ICH Q8–Q12 and adopting PIC/S inspection methodology to reduce duplicative expectations. Likewise, he suggests pursuing mutual recognition for GMP inspections and pharmacopoeial convergence, and accepting CEPs where suitable. He concludes that the outcome of these actions would be "safer plants, fewer administrative cycles, faster scale-up, and improved global market access."

And a cultural reset

In Shah's words, "Linking environmental sustainability with workplace safety is a must in the future pharma industry. Beyond compliance, a strong safety culture driven by leadership commitment and employee engagement is crucial."

While policy reforms would improve compliance culture and reduce delays, managements of pharma companies need to introspect and put in place additional workplace safety measures that go beyond mere laws.

Shah mentions periodic health surveillance, ergonomics, and mental health support as essential for employees in pharma plants.

Zooming out to the bigger picture of ESG and cultural change, Chereddi emphasises the long term and often hidden impact. "Accidents do not just cause physical damages but also impact the morale of

employees, confidence of investors, and faith of the local communities as well. Overseas customers now factor in ESG ratings when taking buying decisions. In order to have India continue as being the "pharmacy of the world", we must instill a safety culture—beginning from leadership commitment to shop-floor awareness.

He suggests that virtual manufacturing ecosystems like HRV's business model, can reduce this burden by working through existing licensed infrastructure. "By pooling resources, standardising SOPs, and sharing best practices across several partners, they can help with raising the safety baseline even for the smaller players," suggests Chereddi.

> Pharma managements cannot blame regulatory hurdles and wait for policy reform. Prevention is always better than damage control. Thus nurturing a safety culture should become the foundation stone for India Pharma Inc to be known as a safe, sustainable pharma manufacturing leader

He also points out that startups which lack such networks, face a lot of friction, discouraging innovation. For instance, HRV Global partners up only with cGMP-compliant & also cGMP capable units. Audits are conducted by HRV teams as well as third party safety firms from time to time. Co-sponsoring training modules for smaller partners and evaluating AI tools to predict compliance gaps before they turn into incidents also reduce risks of non-compliance.

As Chereddi highlights, workplace safety in the pharma and biopharma industry is no longer a compliance only discussion—it is a discussion of business continuity, ESG assurances, and public trust.

Comply or die

India Pharma Inc will have no choice but to comply with ESG norms and better workplace safety practices, if it wants to achieve its global aspirations.

As Chereddi reminds us, "Safety in the workplace for pharma is not a choice—it is a matter of existence. Some recent tragedies at other industries are reminders that one failure can negate years of achievement. Indian pharma has been built on quality and trust; to keep the leadership in this area, we have to shift from 'mere' compliance to 'strong' commitment."

Pharma managements cannot blame regulatory hurdles and wait for policy reform. Prevention is always better than damage control. Thus nurturing a safety culture should become the foundation stone for India Pharma Inc to be known as a safe, sustainable pharma manufacturing leader.

viveka.r@expressindia.com
viveka.roy3@gmail.com

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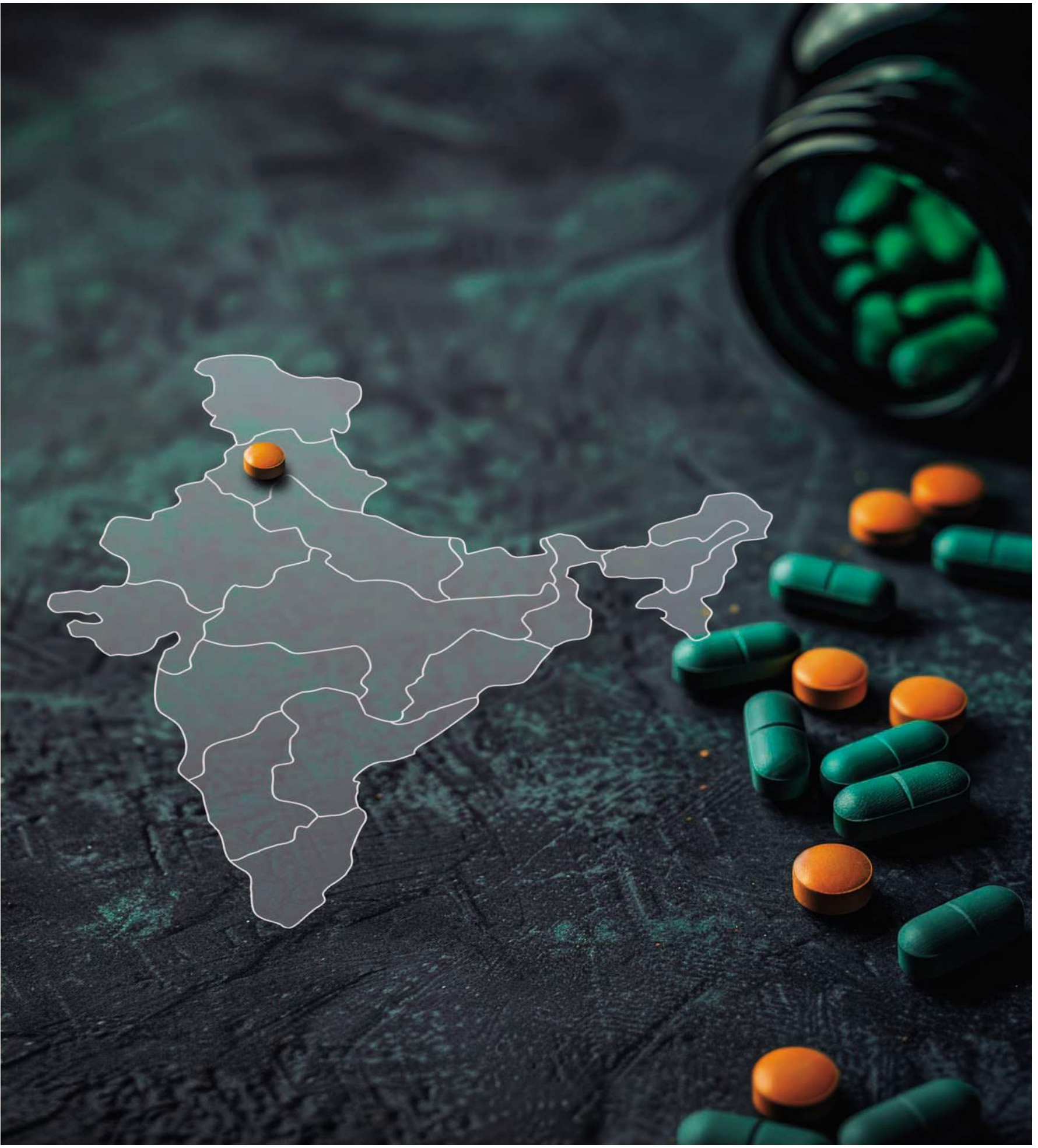
CHANDIGARH PHARMA SUMMIT 2025

FUELING INDIA PHARMA INC'S NEXT LEAP

Experts come together to highlight Chandigarh's rise as a high-value pharma hub, focusing on innovation, compliance, and talent and explore pathways for India Pharma’s growth and global excellence



Inaugural Session

Chandigarh Pharma Summit 2025 spotlighted the city's growing role as one of India's most dynamic pharma hubs.

This year's agenda included critical themes such as smart and green pharma manufacturing, elevating quality culture, biotech and biosimilars, academia–industry collaboration, and bridging skill gaps in the future pharma workforce. Key panel discussions, including "Building a high-value pharma destination: Making Chandigarh–Baddi investor-ready" and "Pharma 2030: Creating a future-ready, responsible, and resilient sector", underscored the region's role as a strategic pillar in India Pharma Inc's global ambitions.

L-R: Rajesh Bhatkal, GM-Express Pharma; Amit Duggal, Assistant Comissioner Drugs, Punjab FDA; Sumeet Sharma, Sales Director, Cilicant; Abhinav Vikash, GM, Sun Pharma; Gursharanjit Singh, Unit Head-Manufacturing Operations FTO-8, Dr Reddy's Laboratories; Rajeev Sharma, Sr GM -Supply Chain, Panacea Biotec

It kickstarted with a Welcome Address by Lakshmipriya Nair, Assistant Editor, Express Pharma, Express Healthcare & Express Nutra. She also highlighted Chandigarh's growing role as a high-value pharma hub blending manufacturing strength, compliance, and innovation.

The event began with a traditional lamp-lighting ceremony, symbolising knowledge and new beginnings.

The summit brought together industry leaders, policymakers, and innovators to discuss smart manufacturing, biosimilars, workforce skilling, and regulatory harmonisation, while also spotlighting Chandigarh–Baddi's investor potential.

The summit set the stage for shaping India's pharma growth story for the next decade.

Keynote Address: Enforcing revised Schedule M - A call for quality, compliance and patient safety

The Chandigarh Pharma Summit 2025 began with a thought-provoking key note session by Amit Duggal, Assistant Commissioner (Drugs), Punjab, on the theme 'Enforcing Revised Schedule M – A call for quality, compliance and patient safety.'

Duggal spoke on the journey of Good Manufacturing Practices (GMP), drug regulation in India, covering import, manufacture, sale, and distribution of drugs, cosmetics, and medical devices. Emphasising on patient safety and quality, Duggal informed that as India supplies medicines to not just to its own citizens but also to global markets, compliance to Schedule M (GMP) is not optional but mandatory.

He emphasised the importance of GMP in safeguarding public health. He pointed out that as every unit of a drug, whether a tablet, capsule, or vial, cannot be tested before release, quality must be inherently built into the product. He highlighted that non-standard quality (NSQ) drugs not only harm patients but also damage the reputation of companies and the country's standing.

Amit Duggal, Assistant Commissioner Drugs, FDA Punjab

The session also touched upon the principles of GMP, including prevention of mix-ups, contamination, and cross-contamination, ensuring consistent quality throughout the product's shelf life. Key challenges flagged were bioavailability and bioequivalence studies, fostering a quality culture across all organisational levels, continual training, and ensuring data integrity.

Dugal underlined the need for revising Schedule M, noting that GMP is dynamic and must align with global standards and technological advances. He stressed that harmonisation is critical for India to strengthen its positioning as the "Pharmacy of the world." As new therapies and formulations emerge, and as global regulators raise the bar, Indian pharma must match those expectations through stricter compliance, innovation, and continual improvement.

Specific technical aspects such as HVAC systems, pharma water quality, and stability studies were discussed as critical components for ensuring robust GMP adherence. Effective control of air, water, temperature, humidity, and packaging conditions are indispensable to product safety and stability, he noted.

The address reinforced the message that quality and compliance are not box-ticking exercises but the very foundation of patient safety and industry credibility.

Panel Discussion: Pharma 2030: Creating a future-ready, responsible and resilient sector

L-R: Lakshmipriya Nair, Assistant Editor, Express Pharma, The Indian Express (Moderator); Ravi Bhardwaj, VP-Quality, Ind-Swift; Gursharanjit Singh, Unit Head-Manufacturing Operations FTO-8, Dr Reddy's Laboratories; Abhinav Vikash, GM, Sun Pharma; and Rajeev Sharma, Sr GM -Supply Chain, Panacea Biotec

The Chandigarh Pharma Summit 2025 hosted a panel discussion on "Pharma 2030: Creating a future-ready, responsible and resilient sector." The session brought together industry leaders to examine the evolving dynamics of the pharma landscape and deliberate on how the sector can transform itself for the decade ahead.

The discussion was moderated by Lakshmipriya Nair, Assistant Editor, Express Pharma. It had an expert line up of panellists including Ravi Bhardwaj, VP–Quality, Ind-Swift; Abhinav Vikash, GM, Sun Pharma; Gursharanjit Singh, Unit Head – Manufacturing Operations FTO-8, Dr. Reddy's Laboratories; and Rajiv Sharma, Sr GM – Supply Chain, Panacea Biotec.

The conversation highlighted that quality will remain the bedrock of India's pharma sector. But, in a fast-changing ecosystem, quality cannot remain static, it must evolve continuously. Experts stressed the need to analyse operational gaps, anticipate future requirements, and drive improvements constantly. They emphasised that world-class quality standards will be a differentiator for Indian pharma companies.

The discussion also addressed thel transformation required within organisations such as adopting a growth mindset, breaking down silos, and fostering cross-functional collaboration. The industry cannot afford to operate in isolated units; instead, it must be agile, adaptable, and open to embracing change, stressed the panelists.

The panel agreed that pharma facilities of the future will demand foresight and integration of emerging technologies. Beyond bricks and mortar, the plants of 2030 will be defined by smart manufacturing practices, advanced automation, and sustainable design principles. This transition, however, is not only about infrastructure. It also calls for balancing machine capabilities with human intelligence and preparing the workforce to handle new technologies seamlessly.

Digitalisation as a pivotal driver of growth was also discussed. The experts highlighted that the ability to leverage data effectively, whether in R&D, manufacturing, quality, or supply chain, will be crucial to enhance efficiency, reduce risks, and enable predictive maintenance. The discussion spotlighted that digital adoption is an imperative to stay relevant in the global marketplace.

The panellists also noted that India Pharma Inc needs to identify newer geographies and untapped market segments for its next phase of growth. Companies must proactively explore international markets, diversify portfolios, and stay aligned with changing global healthcare demands.

Panelists were emphatic that innovation cannot be a distant goal. It must become integral to the industry's DNA and should be applied across processes, products, and business models. The discussion covered insights to build agile plants and upskill shopfloor talent for Industry 4.0.

Thus this discussion served as a timely reminder that the industry stands at an inflection point. By embracing innovation, digitalisation and future-ready strategies, India's pharmal sector can chart a resilient and competitive path toward 2030 and beyond.

KEY TAKEAWAYS

- As we move towards 2030, continuously analysing gaps and driving improvements is non-negotiable. Quality must evolve with the industry.
- Adopting a growth mindset, breaking down internal silos, and being open to new opportunities are essential for sustainable progress in pharma
- Building pharma facilities of the future requires foresight, agility and integration of emerging technologies.
- Data and digitalisation will be key growth drivers. Pharma players must effectively leverage them to retain global competitiveness.
- India Pharma Inc must identify and tap into newer geographies and lucrative market segments. What got us here won't take us forward.
- Innovation should not just be a goal—it must become a core part of the pharma sector's DNA, embedded throughout its journey.

Enhancing shelf life with innovative active packaging solutions

Ensuring product stability and shelf life is as critical as the formulation itself. Active packaging solutions are playing a pivotal role in safeguarding sensitive products against moisture, odour, and degradation throughout their lifecycle, informed Dhairy Sharma, Manager - Business Development (Healthcare Division), Cilicant. He showcased how Cilicant is enhancing shelf life with innovative active packaging solutions.

He detailed how Cilicant's Frexil stands out as a next-generation innovation in this space, offering a compressed canister format that combines efficiency with patient and manufacturer safety. Frexil is a dust-proof solution, eliminating the risk of particle contamination within the packaging. This not only maintains product integrity but also enhances compliance with stringent quality standards. Additionally, its advanced design actively controls odour, creating a more acceptable and consistent user experience.

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

He outlined that as the industry advances toward greater precision and reliability, active packaging solutions like Frexil highlight how innovation in packaging can play a decisive role in safeguarding product quality and patient trust.

> Frexil stands out as a next-gen innovation in this space, offering a compressed canister format that combines efficiency with patient and manufacturer safety

"You name it... we frame it, Customised polymer development

At the Chandigarh Pharma Summit 2025, S Mukharjee, GM-Marketing, Dhara Lifescience presented a session titled "You Name it! We Frame it – Customised Polymer Development," highlighting India's growing capabilities in excipients and coating technologies for the pharma sector.

The presentation gave an overview of the company and its polymer-based pharma solutions, exporting to the USA, CIS, MENA, SEA, South Asia, Africa, and South Korea. The company manufactures coating polymers under its brands Dharacoat (methacrylic acid co-polymers), Readycoat (ready-to-use film coating materials), and Ionex (taste-masking ion exchange resins).

Mukharjee showcased Dhara Lifesciemce's manufacturing facilities, which are EXCiPACT certified, US FDA registered, and compliant with GMP and ISO 9001:2015. He gave details about the company's cleanrooms, advanced processing and storage areas, and a well-equipped quality control department.

S Mukherjee, GM-Marketing, Dhara Lifescience

A major highlight of the session was the company's R&D capabilities. Mukherjee informed that the company creates polymers for protective, delayed, and sustained release applications, taste masking, dissolution enhancement, and controlled release formulations.

The presentation spotlighted Readycoat HS, a coating technology that reduces processing time by more than 50 per cent compared to conventional aqueous coatings. A case study on acetaminophen tablets demonstrated that Readycoat HS shortened the coating process from 240 minutes to 110 minutes, saving time, energy, and resources while improving swallowability and compatibility with moisture-sensitive actives.

Similarly, Dharacoat MAE 100 P and Readycoat EZE were introduced as faster, efficient solutions for enteric coatings.

Mukharjee also addressed the industry's need for alternative polymer sources, stressing that supplier evaluation, regulatory compliance, technical assessment, and product performance must all be considered.

In conclusion, the session positioned Dhara Lifescience as a reliable partner for global pharma companies.

One stop solution for oral solid dosage from Romaco Kilian

At the Chandigarh Pharma Summit 2025, Sunderraj Konar, GM – Sales Processing Division, Romaco India spotlighted his company's expertise in advanced tableting technologies through a detailed presentation.

He informed that the Romaco Group has built a global reputation for its innovations in granulation, coating, drying, blister and strip packaging, tablet presses, and filling lines. The session highlighted Romaco's experience in pharma engineering, particularly through its Kilian brand, which has been a pioneer in tableting technology.

The presentation traced Kilian's milestones, from the world's first rotary tablet press in 1918 to modern breakthroughs such as brake magnet technology, tab-in-tab machines, and the KTP X-Series presses that support mono-, bilayer, and effervescent tablets.

Sunderraj Subbiah Konar, GM Sales - Processing, Romaco India

The session introduced the E 710 Smart, described as an economical double-sided rotary press capable of producing up to 1.02 million tablets per hour. The machine offers proven features such as a changeable die table, patented bellow system to prevent contamination, and unique brake magnets for consistent output, informed Konar.

The presentation highlighted Romaco's value-added services, including retrofit and upgrade options, spare parts availability, operator training programs, and global service hubs. The Hyderabad-based Romaco Experience Centre was spotlighted as a hub for local demonstrations, training, and customer support, offering Indian manufacturers quick access to expertise and faster turnaround.

The session concluded with Konar reiterating Romaco's commitment to digitalisation, sustainable manufacturing, and customer-centric solutions.

Emergent technologies and systems in steam sterilisation and glassware washing

India's pharma landscape is evolving rapidly, and the allied sector has to match this pace with the help of emerging technologies and innovative solutions. So, Stinita Dsouza, Application Specialist, Equitron Medica, gave a presentation on the latest advancements in sterilisation and glassware washing and their impact on quality and safety standards.

Dsouza began by highlighting Equitron's offerings in steam sterilisation. She noted how Orbital welding and swept-piping designs play a crucial role in minimising dead-legs, reducing weld joints, and lowering the risk of corrosion. Combined with proper internal pipe finishing and rigorous pre- and post-treatment of welds, these practices enhance both reliability and hygiene. To ensure long-term integrity, hydraulic testing of pipes and strict adherence to welder qualification standards are essential.

Stinita Dsouza, Application Specialist, Equitron Medica

She also highlighted that Equitron offers both standard and GMP-compliant glassware washers, designed to meet the diverse needs of laboratory environments. These systems feature customisable shelves that can accommodate different sizes of glassware, along with compact loading accessories that optimise capacity and reduce the number of wash cycles required. The washers come with an intuitive cycle configuration and are equipped with a HEPA filter for efficient drying, ensuring both reliability and cleanliness. With this portfolio, Equitron addresses a wide range of applications, including microbiology quality control, organic chemistry research, pharmaceutical R&D, and healthcare pathology.

Equitron Medica is certified under the EU Pressure Equipment Directive (PED). It guarantees the highest standards in design, safety, and manufacturing. This rigorous certification sets a new benchmark in autoclave and pressure vessel performance.

Unlocking hidden capacity: Digitalisation of pharma manufacturing

Efficiency and precision are critical to pharma manufacturing, and digitalisation is emerging as a key driver of operational excellence, highlighted Kushagra Goyal, Lead – Digital, ACG Engineering. He also explained how ACG's Smart Connected solutions are transforming pharma manufacturing by uncovering hidden inefficiencies and optimising operations.

Goyal presented ACG's Smart Connected solutions and how it is transforming pharma manufacturing by providing real-time visibility into operations and uncovering hidden inefficiencies that often go unnoticed in complex production lines.

By leveraging continuous data monitoring, manufacturers can identify bottlenecks, reduce process variation, and take proactive corrective actions. Implementation of these solutions has shown measurable results, including an 11 per cent increase in Overall Equipment Effectiveness (OEE), a 54 per cent reduction in process variation, and a 20 per cent boost in machine speed, enhancing throughput, productivity, and consistent product quality. Beyond operational gains, the system supports predictive maintenance and regulatory compliance, demonstrating that digitalisation is not just a technological upgrade but a strategic enabler that unlocks untapped capacity and maximises the potential of existing pharma manufacturing assets.

Kushagra Goyal, Lead-Digital, ACG Engineering

Goyal emphasised that digitalisation is not merely a technology upgrade but a strategic enabler that unlocks untapped potential within existing assets. By embracing connected solutions, pharma manufacturers can achieve greater operational excellence, higher throughput, and improved compliance, positioning themselves to meet the growing demands of the global market efficiently and reliably.

Biotech and biosimilars: Chandigarh as a biopharma hub

With global demand for biologics and biosimilars steadily increasing, India is well-positioned to establish itself as a leading hub in this high-value segment. Dr Sandeep Arora, Professor & Dean, Faculty of Pharmaceutical Sciences, Amity University, highlighted how cities like Chandigarh are emerging as focal points for biopharma growth, leveraging domestic capabilities and proximity to academic and research institutions.

He started by explaining how biologics are transforming the therapeutic landscape by addressing unmet medical needs and paving the way for personalised medicine. Arora touched upon anti-sense technology, oncolytic vaccines, mABs, Aflibercept Indications, CAR-T cell therapy, CQAs for establishing biosimilarity, and CMC control parameters.

He explained how biologics—whether biosimilars, biosuperiors, or first-in-class—are complex, high-risk treatments requiring advanced technologies and manufacturing, with a high development cost. Despite these challenges, they offer targeted cancer therapies to improve patient outcomes.

Dr Sandeep Arora, Professor & Dean, Faculty of Pharmaceutical Sciences, Amity University

> With rising global demand and strong domestic capabilities, India is poised to become a major hub for biologics and biosimilars

He concluded that with rising global demand and strong domestic capabilities, India is poised to become a major hub for biologics and biosimilars. Strategic investments in R&D, regulatory alignment, and advanced manufacturing can help India tap into this high-value segment.

Future pharma workforce: Bridging skill gaps in R&D, digital and manufacturing

At the Chandigarh Pharma Summit 2025, Soumaya Dutt, Sr GM & Site Head, Glenmark Pharmaceuticals presented a session focused on the future of the pharma workforce, highlighting critical skill gaps across R&D, digital capabilities, and manufacturing, and outlining strategies to address them.

The session began with an overview of industry growth and associated workforce challenges. The pharma industry is projected to grow at a 6.3 per cent CAGR to $861.67 billion by 2028, yet faces talent shortages that threaten innovation and production. 80 per cent of manufacturers report skill mismatches, 83 per cent struggle to find skilled talent, and the shortage is expected to worsen in the next five years. Replacement costs per skilled worker range from $10,000-$40,000, adding financial strain.

Soumaya Dutt, Sr GM & Site Head, Glenmark Pharmaceuticals

Digital transformation was highlighted as a key disruptor. By 2025, 30 per cent of new drugs are expected to use AI, cutting development timelines by 25-50 per cent. Yet, while 83 per cent of supply chain leaders emphasise urgent upskilling needs, only 17 per cent of companies prioritise blended workforce models or HR reskilling investments. Digital fluency in AI, machine learning, data analytics, and cybersecurity has become indispensable.

The presentation further detailed skill gaps in R&D, including demand for data scientists in AI-driven drug discovery, shortages in bioinformatics expertise, and the growing need for digital research skills. In digital and manufacturing, advanced analytics, regulatory compliance knowledge, and cybersecurity were underscored, alongside specialised expertise in material handling and batch consistency.

Strategies proposed to bridge these gaps included reskilling existing employees, structured apprenticeships, emphasis on transferable skills, and skills-based hiring models. Workforce agility was also emphasised through hybrid work models, change management, and cross-sector mobility, while technology innovations such as AI-powered talent platforms and continuous learning were highlighted.

The session concluded with recommendations to act urgently, prioritise development, foster agility, and ensure leadership commitment to digital transformation.

Secure your pharma QC results by secondary standards

The session presented at Chandigarh Pharma Summit 2025 focused on how secondary standards can enhance the reliability of pharmaceutical quality control, offering laboratories greater efficiency, consistency, and regulatory confidence. Held on 6th August 2025 at Taj Chandigarh, the individual session was presented by Dr Shankar Varaganti, Commercial Marketing Manager, Merck.

The presentation began with an overview of the lengthy journey of drug development, from lead discovery through QC release, where reference materials play an essential role in analytical workflows. These include internal standards used in sample preparation, as well as calibrators and controls that support accurate detection, quantitation, and reporting. Such reference points enable both qualitative applications like screening and identification, and quantitative assessments such as potency, assays, and limit tests.

Dr Shankar Varaganti, Commercial Marketing Manager, Merck

The discussion then emphasised the importance of selecting the right grade of standard on a "fit-for-purpose" basis. Decisions depend on regulatory requirements, type of testing, availability, level of accuracy, and the sample matrix. Primary standards, produced by pharmacopoeias such as the European, US, and Indian Pharmacopeia, continue to serve as the official benchmark. In parallel, metrology-based primary standards provide measurement accuracy defined through internationally recognised procedures.

Against this backdrop, Merck's secondary standards were highlighted as fully traceable alternatives that complement primary references. With dual traceabilities—both to current primary standards and to SI units through a mass balance approach—they offer convenience, reliability, and time savings. Pre-qualified certified reference materials reduce the need for in-house preparation, while detailed certificates of analysis ensure transparency.

The session concluded with the importance of traceability, represented by the traceability pyramid, as well as Merck's expanding portfolio of compendial and non-compendial impurities. Together, these solutions strengthen pharmaceutical QC practices while supporting efficiency and compliance across the value chain.

Gangwal - Where formulation excellence meets operational efficiency

With manufacturing demands becoming more complex and quality standards rising, pharma companies are turning to smarter formulation strategies to stay ahead. At the Chandigarh Pharma Summit 2025, Dr Vijay Kumar Sharma, VP–Pharma Business (Portfolio, Sales & BD), Gangwal Healthcare, outlined how the company is delivering on this need through innovative excipients and advanced formulation approaches that enhance both productivity and consistency.

The presentation opened with an introduction to Gangwal Healthcare, a global partner to the pharmaceutical, nutraceutical, and personal care industries. With a workforce of over 320 employees, the company specialises in specialty excipients and high-performance PFIs, positioning itself as a trusted contributor to product innovation and process efficiency.

Dr Vijay Kumar Sharma, VP-Pharma Business (Portfolio, Sales & BD), Gangwal Healthcare

The session highlighted the company's focus on operational excellence through formulation intelligence. By advancing excipients and co-processed ingredients, Gangwal aims to improve productivity, enhance equipment utilisation, and ensure greater batch uniformity. Solutions such as wettable excipients, PFIs, micronised sweeteners, fillers, and co-processed systems were presented as enablers of better quality, faster processing, and cost efficiency.

Special emphasis was placed on ready-to-use formulation approaches like PFIs, which simplify manufacturing by offering scalable, GMP-compliant blends for direct use in processes like compression or filling. This approach streamlines production while supporting quality assurance and regulatory compliance.

The session closed with a broader outlook on how combining formulation expertise with operational efficiency can unlock new levels of manufacturing performance. By focusing on innovation in excipients and scalable formulation solutions, Gangwal Healthcare underlined its commitment to supporting the industry with reliable, high-quality technologies for the future of pharma development.

Elevating quality culture across pharma hubs

Quality has become the cornerstone of competitiveness in the pharma industry, and its integration across clusters is vital for long-term sustainability. This was the central theme of an individual session that explored the role of quality culture in shaping the future of pharma hubs, at the Chandigarh Pharma Summit 2025. The session was presented by Rajan Ramalingam, Senior Partner, InACE Pharma Consulting.

The presentation began with insights from the Survey of Pharma Clusters conducted by the Department of Pharmaceuticals in February 2023. The study mapped 118 clusters across 19 states and union territories, covering 7,673 pharma industries. Of these, 26 per cent were micro, 31 per cent small, 30 per cent medium, and 12 per cent large industries, with Baddi highlighted as a model cluster.

The session then explored the idea of quality culture, described as a collective responsibility that goes beyond regulatory compliance or SOPs. It reflects a mindset where quality is embedded in organisational values and employee behavior, extending from product development to distribution.

Rajan Ramalingam, Senior Partner, InACE Pharma Consulting

Key aspects identified included effective QMS, compliance, strong leadership, training and education, patient centricity, accountability, recognition of quality practices, and open communication. Strategies to build this culture emphasised technology adoption, continuous improvement, clear expectations, and investment in people.

Challenges were also acknowledged, such as ensuring consistency across supply chains, managing GMP-related costs, and balancing quality with commercial pressures.

The session concluded with the perspective that achieving a true quality culture requires embedding quality as a core value, ensuring it influences every decision and process across the pharma lifecycle.

Panel Discussion: Building a high-value pharma destination: Making Chandigarh-Baddi investor-ready

L-R: Dr Govind S Pandey, CEO & MD, Gamp Technologies (Moderator); Jawaid Imam, Sr VP, Aristo Pharmaceuticals; Shivaji Chakraborty, Head - Packaging Development, Fresenius Kabi Oncology; Suman Sharma, Head-Quality, Indchemie Health Specialities; Dr Saurabh Pandey, Cluster Head-R&D & Manufacturing, Sun Pharma; Sharad Bansode, GM, Nectar Lifesciences; Dr Sujeet Shrivastava, Head - GM-Analytical Research & Development, Synthimed Labs; and Dr Ashok Periannan, Plant Head, Welzo Research & Development

The Chandigarh Pharma Summit 2025 comprised a panel discussion that spotlighted the region's critical role in shaping the future of Indian pharma.

The distinguished panel was moderated by Dr Govind S Pandey, CEO & Managing Director, Gamp Technologies. Joining him were Jawaid Imam, Senior VP, Aristo Pharmaceuticals; Shivaji Chakraborty, Head – Packaging Development, Fresenius Kabi Oncology; Suman Sharma, Head – Quality, Indchemie Health Specialities; Dr Saurabh Pandey, Cluster Head – R&D & Manufacturing, Sun Pharma; Sharad Bansode, GM, Nectar Lifesciences; Dr Sujeet Shrivastava, GM & Head – Analytical Research & Development, Synthimed Labs; and Dr Ashok Periannan, Plant Head, Welzo Research & Development.

The panellists unanimously acknowledged the belt's robust manufacturing capacity as its strongest asset. With Baddi already contributing significantly to India's generics output, the next phase of growth, hinges on scaling up automation, digitalisation, and compliance with global regulatory standards. Such steps will not only enhance efficiency but also align the cluster with the expectations of international regulators, helping attract high-value global investments in the coming years.

Another major theme was the future of talent in pharma. With India's pharma sector expected to undergo rapid transformation, the need for continuous upskilling was flagged as critical. Panellists pointed out that stronger industry–academia collaboration, particularly with premier institutions such as the National Institute of Pharmaceutical Education and Research (NIPER), will be central to developing a workforce ready to meet evolving global demands.

The discussion also spotlighted India's growing leadership in biosimilars, one of the most promising global pharma segments. Experts noted that if the Chandigarh–Baddi belt invests strategically in specialised facilities, skilled talent, and regulatory know-how, it can evolve into a leading biopharma hub.

Geography, too, is playing to the cluster's advantage. With Nalagarh emerging as a key extension of the Chandigarh–Baddi belt, the region now offers additional cost-effective manufacturing space, easing the burden on Baddi. Its proximity to Chandigarh makes it especially attractive for small and mid-sized pharma companies looking for scalable operations with logistical convenience.

They pointed out that Chandigarh, with institutions like PGIMER and IISER alongside NIPER, is uniquely placed to provide a steady pipeline of pharma talent and research output. The speakers stressed that stronger linkages between academia and industry will address immediate workforce needs but drive innovation in next-generation therapies.

The panelists also addressed the urgent need for domestic manufacturing of APIs and intermediates. By setting up API and intermediate manufacturing units within the Chandigarh–Baddi belt, the region could contribute meaningfully to India's self-reliance goals under the Production Linked Incentive (PLI) scheme. This would make the cluster more attractive to global investors seeking integrated manufacturing destinations.

The discussion underscored that the Chandigarh–Baddi–Nalagarh belt is well-positioned to transition from being India's generics manufacturing hub to a global destination for high-value pharma and biopharma investments.

KEY TAKEAWAYS

- The Chandigarh–Baddi belt has robust manufacturing capacity. Scaling up with automation, digitalisation, and compliance with global regulatory standards will help attract high-value global investments
- Continuous upskilling and stronger industry-academia collaboration with institutes like NIPER can help meet evolving global pharma demands and build a strong talent pipeline
- India is poised to become a global leader in biosimilars. If the region invests in specialised facilities, skilled talent, and regulatory know-how, it can become a leading biopharma hub and lead in this high-growth segment
- Launch region-specific skill development programmes focused on GMP, regulatory affairs, QC/QA, and cleanroom operations to ensure practical, hands-on learning to make Chandigarh-Baddi for pharma of tomorrow
- Nalagarh is emerging as a key extension of the Chandigarh–Baddi pharma belt, offering cost-effective manufacturing space and easing the load on Baddi. Its proximity to Chandigarh adds strategic value, making it ideal for small and mid-sized pharma companies.
- Home to premier institutions like NIPER, PGIMER, and IISER, Chandigarh provides a strong pipeline of pharma talent and research output
- Setting up API and intermediate manufacturing units, reducing dependence on imports and strengthening India's self-reliance goals under the PLI scheme can make the cluster more investment-ready.

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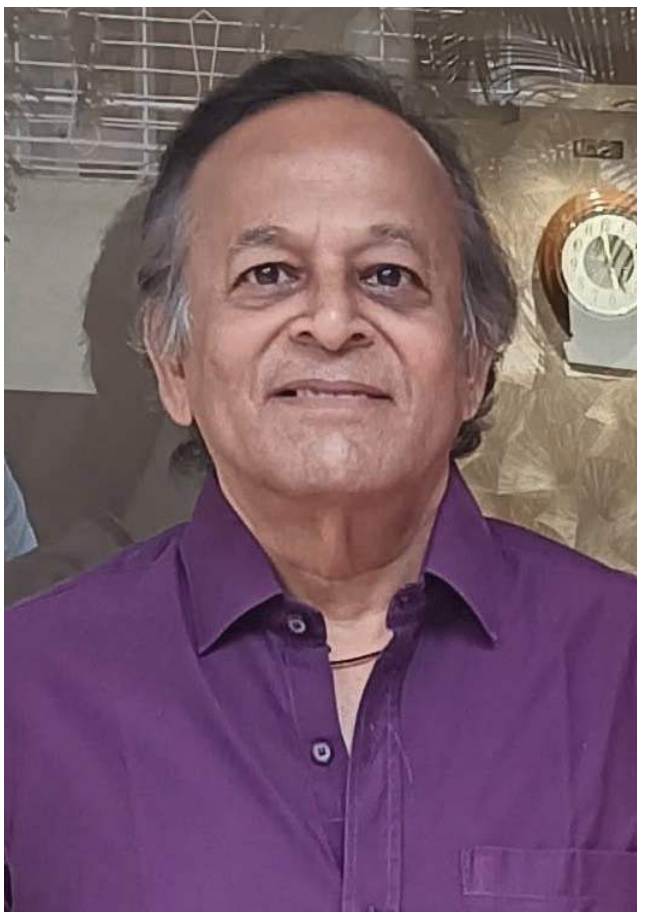
An orange book of India: The need of the hour

Milind Sathe, VP - IP and Tech, Themis Medicare explains why India's pharma sector urgently needs a transparent, publicly accessible database covering drug approvals, therapeutic equivalence, and patents, an Indian counterpart to the US FDA's Orange Book. He opines that this would enhance regulatory clarity, patient safety, and market competitiveness while supporting innovation and generic drug access

For a transparent, reliable, and public-oriented pharma regulatory system, every nation needs a database covering the full cycle—from application to approval, along with manufacturing permissions and biopharma regulatory details. This could take the form of two publicly accessible, mutually exclusive databases: one dedicated to regulatory application and submission management, and the other to drug approvals, therapeutic equivalence, and patent or exclusivity periods. The US FDA's Orange Book can serve as a reference point—with the aim of building an even better version.

India's Sugam portal serves as a reference database for the former category of database mentioned above. The differences between SUGAM and intended Saffron Book which is customised version of US Orange book are listed below.

India currently lacks an authoritative and comprehensive reference comparable to the US FDA's Orange Book. As the nation rapidly advances toward becoming a global leader in pharma, such a resource is urgently needed—for the benefit of the Indian public, the pharma industry, and the national regulatory framework i.e. Indian Food and Drug Administration (FDA). Such a resource would greatly assist the FDA by dramatically enhancing regulatory transparency, strengthening patient safety, and boosting market competitiveness in India. This article explores the necessity for such a resource, an Indian equivalent of the Orange Book, examining its potential benefits and far-reaching sector-wide impacts across the healthcare and pharma sectors.



What is the orange book and why is it important?

The Orange Book—formally known as Approved Drug Products with Therapeutic Equivalence Evaluations—is a freely accessible database published by the US FDA. It lists all pharma products approved for safety and efficacy. Its main functions include:

i) Identifying drugs approved after rigorous clinical trials.
ii) Providing therapeutic equivalence evaluations for generic drug substitution.
iii) Listing drug patent and exclusivity data.
iv) Supporting healthcare providers, patients, and industry stakeholders in evidence-based selection and substitution of medicines.

This compendium plays a vital role in facilitating generic drug approval, aiding competitive intelligence, fostering patent transparency, and ensuring ongoing public and professional trust in drug regulation.

Gaps in prevailing system

India is one of the world's leading pharma producers, known for its expertise in generics and active pharma ingredients. However, the absence of a single, authoritative, and continuously updated public reference for approved drugs, therapeutic equivalence, and patent data results in several persistent challenges:

i) Inconsistent drug information among regulators, prescribers, and manufacturers and public.
ii) Obstacles to efficient evaluation and approval of generics and biosimilars.
iii) Increased risk of medication errors due to confusion about substitutions.
iv) Limited transparency on drug patent status and exclusivity, affecting both innovation and generic entry.

If a central, comprehensive database is created, it would plug these gaps and benefit India in several ways.

Key benefits of an Indian Saffron Book

1. Enhanced regulatory transparency: A national Saffron Book would publicise up-to-date lists of all drugs approved by Indian regulators for safety and effectiveness. This supports:
a) Rapid verification of a drug's approval status.
b) Greater public trust in regulatory decisions.
c) Every stakeholder (healthcare providers, pharmacists, researchers, and patients i.e. member of the public) having access to the same, accurate information.

2. Facilitating safe and effective generic drug substitution: One of the defining features of the Orange Book is its system for evaluating therapeutic equivalence—confirming which generics can be confidently substituted for branded drugs at the pharmacy level.

For India, with its large market for affordable generics, such a framework would standardise substitution rules.

Reduces confusion and risk associated with switching between brands, reinforcing patient safety.

3. Promoting competition and lower drug costs: By listing generic equivalents and their approval status, the Orange Book enables fair market competition:
a) Encourages manufacturers to develop safe, bioequivalent generics.
b) Streamlines the drug approval process for generics, potentially lowering development costs.
c) Increases downward price pressure, making medicines more accessible to the Indian public.

4. Strengthening patent clarity and innovation
a) The US Orange Book lists patents and its type, expiry dates, and exclusivity details, supporting both originator and generic manufacturers to make informed decisions about market entry and IP strategy.
b) Indian innovators would benefit from clear public information on patent life and exclusivity, incentivising high-value R&D investments.
c) Generic makers could better plan launches, balancing patent respect with public demand for affordable drugs.

5. Boosting India's international standing: A rigorously maintained Orange Book-like repository would demonstrate India's commitment to global regulatory standards.
a) Facilitate international trust and acceptance of Indian drug approvals.
b) Support export ambitions, as international partners value reliable regulatory infrastructure.

Feature	SUGAM Portal (India) Administrative tool for regulatory processes	US FDA Orange Book "Approved Drug Products with Therapeutic Equivalence Evaluations."
Main Purpose	Regulatory application/ submission management	A public database listing all FDA-approved small molecule drugs (not biologics) and providing information about equivalence, patents.
Primary Users	CDSCO regulators, pharma companies seeking approval to manufacture, import, or sell drugs and biological products in India	Healthcare providers, pharma industry, legal professionals/experts, Physicians, pharmacists, and the public seeking to verify drug approvals, identify interchangeable generics, and check relevant patents.
Information Provided	Application status, licenses, NOCs, permissions	Drug approval and related documentation, therapeutic equivalence, patent/exclusivity periods
Drug Types	Both chemical and biological (for registration/approval)	Small molecule drugs (FDA-approved generics and brands)
Public Access	Limited (not a directory of approved drugs for public browsing)	Freely accessible, searchable database, with facility to export data indexed on different parameters.
Substitution Data	Not Provided.	Yes—therapeutic equivalence codes to support substitution
Scope	Focused on workflow management for regulatory applications; not as a comprehensive public reference on drug approvals or equivalence.	Central reference for drug safety, efficacy, patent and exclusivity details, and generic substitution in the US regulatory system, critical for clinical, legal, and commercial decision-making in the drug sector

c) Enable alignment with US and European systems, smoothing international collaboration and mutual recognition paths.

Practical features of an Indian Orange Book: Based on global best practices, a Saffron book i.e. Indian Orange Book should include:

a) A searchable list of all approved drugs, by active ingredient, trade name, manufacturer, and dosage form, provide access to related documentation such as CMC, Labels etc.

b) Clear marking of innovator and approved generic products.

c) Therapeutic equivalence ratings—showing which drugs can be safely substituted.

d) Patent and exclusivity database, including expiry dates and description of protection.

e) Real-time updates and open digital access for the public, medical professionals, researchers, and the industry.

Addressing potential concerns and implementation challenges

a) Data integrity: Requires rigorous vetting and regular updating and uploading CMC and other documents by an empowered executive giving identity, traceability of executives and time.

b) Patent disputes: Well-defined criteria and transparency in listing patents help reduce conflict and litigation. Need to create rules to govern the listing of patents and its types i.e. Product or process patent etc.

c) Integration with state regulations: Should coordinate with state-level authorities for nationwide applicability and uniform interpretation of Drugs and Cosmetic Act and Rule and provisions of other related legislations.

d) Industry participation: Continuous input from the pharma sector ensures accuracy and broad acceptance.

e) Inherent freedom and flexibility being a territorial regulatory endeavor: No global interference.

f) Brain teasing activity: It provides scope to creativity to boost national performance, healthy competition in pharma industry.

Building a comprehensive database based on existing model is straightforward. However, its design should actively involve input from industry, the public, healthcare professionals, and experts in legal, administrative, technical, and biopharma fields—ensuring it addresses the information they need to perform their duties and meet currently unmet needs. Above all, the database must be structured around user requirements, not solely the regulator's vision

Game changer for generic entry

It may prompt a provision like patent declaration or certification by generic applicant. As it would be publicly accessible, innovator would know it faster and seek appropriate remedies. On the other hand, generic manufacturer would first study patents protecting the product and inadvertent infringements would be eliminated.

Contents and verticals in proposed Saffron book

Building a comprehensive database based on existing model is straightforward. However, its design should actively involve input from industry, the public, healthcare professionals, and experts in legal, administrative, technical, and biopharma fields—ensuring it addresses the information they need to perform their duties and meet currently unmet needs. Above all, the database must be structured around user requirements, not solely the regulator's vision.

A call to action for Indian regulators and industry

India's pharma sector stands at a pivotal crossroads. The establishment of a Saffron book, an Orange Book-style reference is not just desirable—it is essential for:

1. Enabling sophisticated pharma market analysis, long-term pricing strategy, and smarter R&D allocation through transparency and real-time access.

2. Assisting in fulfilling Indian dream of becoming a global leader in both innovation and generics, while securing patient safety and promoting free-market competition.

3. Safeguarding patient welfare through reliable information and safe generic substitution.

4. Fostering innovation with clear patent and exclusivity data.

5. Enhancing trust, efficiency, and competitiveness in both domestic and global markets.

Regulatory policymakers, industry stakeholders, and public health advocates must work together to create, implement, and continuously update this vital resource. Only then will India realise its full potential as a pharma powerhouse—with benefits for its citizens and the world.

Pharma's next chapter: Smarter R&D, sharper regulation and hunt for rare talent

Shiv Nath Ghosh, Chief Commercial Officer, Professional Talent Solutions, Randstad India highlights that the new pharma playbook is being drafted at the intersection of science, technology, and talent. The companies that thrive will be those that recognise innovation is not just about molecules or markets, but about building the workforce and regulatory frameworks to sustain them

Pharma has always been an industry defined by complexity — the race against disease, the balance between science and safety, and the constant push to bring therapies faster to patients. But now, the traditional norms that once governed the industry are being modified. The laboratory bench is going digital, clinical trials are moving into virtual realms, and the science of molecules is increasingly intertwined with the language of algorithms. So, basically, the pharma world is stepping into an era where research and development (R&D), regulation, and talent are emerging as interdependent forces shaping its momentum.

At the core of this transformation lies the rise of tech-pharma, where drug discovery is no longer the exclusive domain. Artificial intelligence, machine learning, bioinformatics, and digital twins are reimagining how new therapies are conceived, tested, and delivered. This accelerated model promises speed and precision — lowering costs, reducing attrition rates, and opening doors to treatments that once seemed impossible.

Yet, with this leap comes an equally daunting challenge: finding the right talent. Scientists who can decode DNA are abundant; scientists who can decode DNA and train algorithms are rare. The search for this 'unicorn talent' thus sits at the heart of the industry's capability crisis.

This brings us to the workforce question. India's pharma industry — with its 3,000-plus companies and over 10,500 factories — is positioning itself as a global leader. But infrastructure alone will not propel India towards achieving its bold ambition of $400–500 billion by 2047, the workforce must evolve — faster, broader, and deeper. Roles like pharma analysts, genomics data specialists, and tele-consultants are entering the mainstream for the first time, signalling how far the sector has evolved. Production expertise will remain critical, but the new era demands hybrid professionals fluent in AI-driven analytics, health informatics, extended reality, and digital-first care platforms.

In short, the new pharma playbook is being drafted at the intersection of science, technology, and talent. The companies that thrive will be those that recognise innovation is not just about molecules or markets, but about building the workforce and regulatory frameworks to sustain them.

The rise of tech-pharma, R&D reimagined

Pharma R&D has always been resource-intensive, with a single drug often taking more than a decade and billions of dollars to reach the market. But the emergence of AI, machine learning, and advanced analytics is modifying that equation. Algorithms today can sift through vast molecular libraries in hours, identify potential leads, and even predict their interactions with human biology. Clinical trials — once rigid and linear — are being transformed through digital tools, real-world evidence, and patient-centric platforms that allow remote monitoring and adaptive designs.

However, this evolution has a direct consequence for talent. Traditional R&D relied heavily on chemists, biologists, and clinical researchers. While these roles remain critical, the industry now requires professionals who can bridge science with data. Bioinformaticians, computational biologists, and data scientists are as central to modern R&D as lab technicians. The challenge lies in finding individuals who combine deep scientific expertise with cutting-edge tech fluency. This unicorn talent — equally at home with molecular structures and machine-learning scripts — is in short supply, thus making talent development and cross-disciplinary skill training a strategic priority for pharma companies.

The regulatory puzzle: Compliance meets science

If innovation is the engine of pharma, regulation is the brake and steering system that keeps it safe and credible. The sector has always operated under stringent compliance regimes, but the shift towards precision medicine and AI-driven tools has added layers of complexity. Regulators now deal with not only the safety of chemical compounds but also the validity of datasets, the transparency of algorithms, and the ethical use of patient information.

This shift has created demand for a new kind of regulatory affairs professional. No longer confined to documentation and approvals, today's compliance leaders must navigate a world where law, science, and technology converge. They need to understand the molecular basis of personalised therapies, the data frameworks behind AI-led trials, and the global diversity of healthcare regulations.

Talent insights: Building a future-ready workforce

The talent narrative in pharma is increasingly data-driven and specialised. Ensuring quality, economies of scale, and cost competitiveness is critical to maintaining India's edge as a manufacturing powerhouse. Parallely, the skill portfolio is rapidly expanding. The demand for pharmacovigilance analysts — specialists who monitor drug safety after market launch — is rising sharply, reflecting the sector's increasing emphasis on end-to-end patient safety.

Furthermore, pharma companies are showing a diverse and sustained demand for specialty doctors, research analysts and healthcare management professionals at all levels. Next in line, a hotbed of talent opportunities lies with API, healthcare management and specialty doctors featuring among some of the top PHL skills in demand.

Looking ahead, the skills shaping the sector will extend far beyond today's portfolio. AI-driven analytics, health informatics, advanced cybersecurity, cloud computing, extended reality (XR), and digital-first telemedicine platforms are already on the horizon. What is encouraging is the positive intent among employers: a healthy hiring trend across senior professionals and junior talent alike, signalling that companies are not only filling immediate gaps but also investing in long-term capability pipelines.

India levels up in solving complex drug formulation challenges

Chetan Shah, Director and COO, Senores Pharma highlights India's shift from APIs and generics to becoming a global leader in complex drug formulations. With strong talent, infrastructure, and regulatory expertise, the industry is driving advanced therapies and patient-centric innovations

India's pharma industry has undergone a remarkable transformation over the last few decades. Once known primarily for active pharmaceutical ingredients (API) and bulk drug production, it has steadily moved up the value chain to become a global hub for complex finished dosage forms. Today, Indian manufacturers are producing biosimilars, vaccines, new chemical entities (NCEs), and new biological entities (NBEs), showcasing technical maturity and readiness to meet evolving global healthcare needs.

The shift from high-volume generics to high-value, high-barrier products is redefining India's position in the global pharma supply chain. Cost advantage is no longer the only differentiator — expertise in development, manufacturing, and compliance is equally important

Complexity as the new norm

Advances in medical technology have extended life expectancy and improved patient outcomes, but they have also reshaped disease patterns and placed greater demands on drug development. Lifestyle disorders, chronic conditions, and the push for targeted therapies require medicines with greater formulation sophistication.

Developing complex drugs involves more than combining active ingredients. It means ensuring stability under varied storage conditions, improving bioavailability for poorly soluble drugs, achieving precise release profiles, and creating patient-friendly dosage formats to encourage adherence. These attributes make complex drug formulations a growing focus of innovation.

India's strategic advantages

India is uniquely positioned to lead in this space. As the world's largest supplier of medicines by volume, it hosts one of the highest numbers of USFDA-approved manufacturing facilities and benefits from a strong base of scientists, engineers, and pharma specialists.

This combination of talent and regulatory familiarity allows Indian companies to integrate research, development, and manufacturing to deliver high-quality, complex products at scale.

Complex drug development and its challenges

Complex drugs — such as peptides, liposomes, topical extended-release products, injectables, inhalers, biosimilars, and other advanced delivery systems — come with significant technical and regulatory challenges. These range from sophisticated particle engineering and maintaining sterility to device integration and advanced analytical testing. The high barriers to entry make them strategically valuable for companies seeking long-term competitive advantage.

R&D and regulatory integration

The industry's move into complex formulations is driven by strong R&D capabilities. State-of-the-art development centres staffed by multidisciplinary teams are working on stability enhancement, solubility improvement, extended-release technologies, and targeted delivery systems. These efforts are not only about improving existing drugs but also about addressing unmet medical needs with innovative solutions.

Equally important is integrating regulatory strategy from the start of development. Complex generics and biosimilars face greater scrutiny than traditional generics, requiring detailed characterisation, stability data, bioequivalence or clinical studies, and adherence to global Good Manufacturing Practices. Early regulatory involvement reduces approval risks and speeds time-to-market.

Strengthening global positioning

The shift from high-volume generics to high-value, high-barrier products is redefining India's position in the global pharma supply chain. Cost advantage is no longer the only differentiator — expertise in development, manufacturing, and compliance is equally important.

Innovation hubs in cities such as Hyderabad, Bengaluru and Pune are enabling faster product development through close collaboration between R&D, manufacturing, and regulatory teams.

Policy support and the road ahead

Government policies supporting R&D funding, skill development, and technology transfer are accelerating progress in complex drug development. With sustained investment, India's pharmaceutical sector can expand its capabilities in novel delivery systems, biopharmaceuticals, and sustainable manufacturing.

The next growth phase will focus on:

- Sustained-release and targeted delivery technologies
- Biosimilars and biologics meeting stringent quality standards
- Patient-centric dosage formats
- Environmentally responsible manufacturing practices

Conclusion

India's evolution from bulk API manufacturing to complex drug formulation is more than an industrial shift — it reflects growing scientific and technical strength. As healthcare challenges become more complex, the ability to develop advanced therapies will be essential.

With its talent pool, infrastructure, and regulatory expertise, India is positioned to be not just the largest supplier by volume but a valued innovation partner in the global pharma landscape.

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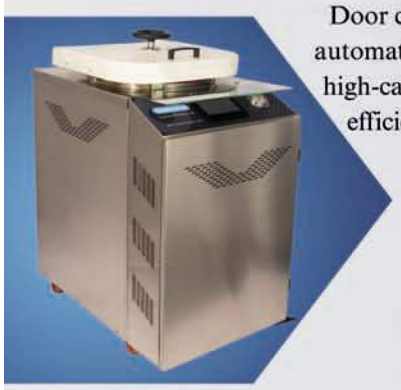

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Pressure Resolution	1 PSI

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CONTACT US

Osworld Scientific Equipments Pvt. Ltd.

B-44, New Empire Industrial Premises Kondivita, J.B. Nagar, Andheri (East) Mumbai-400 059

info@osworldindia.com

www.osworldindia.com

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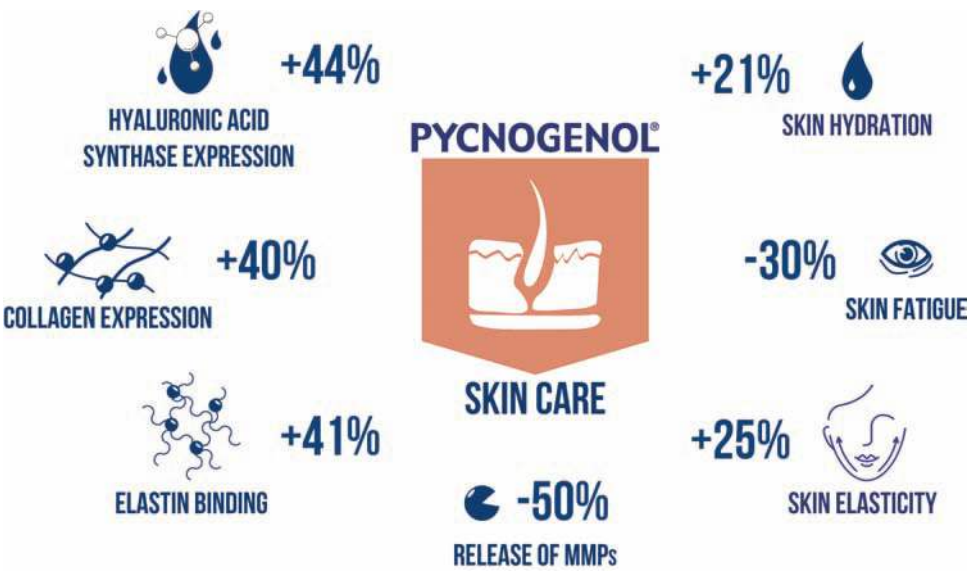
Pycnogenol® - The Skin's Matrix Activator (Collagen, Elastin, Hyaluronic Acid)

Healthy skin is well hydrated and shows a high level of elasticity to be able to better deal with external stress such as sun radiation, heat, humidity, changes in temperature or air pollution. To achieve that, skin consists of different components, such as collagens that make up over 30% of the extracellular matrix, acting as supportive tissue material and bringing stability and elasticity [1]. Elastin, which together with fibrillin microfibrils make up elastic fibers, is crucial for elasticity and extensibility of various tissues, including the skin [1]. Another important component of the extracellular matrix is hyaluronic acid, which contributes to water retention in tissues and to their structural integrity [1].

Pycnogenol® French maritime pine bark extract has shown significant benefits for skin health and beauty and tissue support. Clinical investigations of Pycnogenol® supplementation for 3 months in healthy female volunteers, aged 55 to 68 years revealed significantly increased expression of hyaluronic acid synthase within the skin by 44%, leading to improved skin hydration and improved tissue architecture support [2]. Hyaluronic acid synthase is the natural source of water-binding hyaluronic acid in the dermis, which moisturizes the skin and keeps it taut and smooth. Additionally, Pycnogenol® was shown to stimulate the synthesis of new collagen - skin´s connective tissue – by increasing its expression in average by 40% [2]. Furthermore, Pycnogenol® was shown to prevent the release and activity of destructive enzymes *(metalloproteinases 1, 2 and 9)*, which break down dermal tissue proteins, like collagen or elastin [3, 4]. The reduced activity of these lytic enzymes saves the connective tissues from degradation, representing the basis for maintaining an elastic and youthful-looking skin.



Pycnogenol® improves skin hydration and elasticity

Skin care extends well beyond beauty as it plays a key role in our overall health. Oral skin care offers additional benefits as it reaches the dermis – the inner layer of the skin – of the entire body. By increasing hyaluronic acid and collagen production within the body and protecting elastin and collagen from being degraded, Pycnogenol® was shown to increase skin elasticity and skin hydration [2-5].

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

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

Another finding that supported Pycnogenol®'s positive effects on skin barrier function, was an increased expression of genes involved in keratinocyte differentiation and barrier formation including loricrin, indicating that Pycnogenol® supplementation was associated with an improved formation of cornified envelopes and thus preserve skin hydration by reducing trans-epithelial water loss [10].

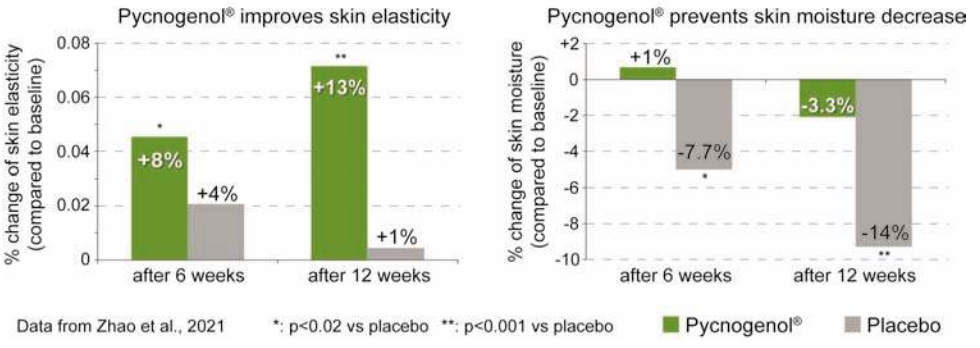
Pycnogenol® reduces melasma development and limits photo-ageing

In addition to its effects on skin hydration and elasticity, Pycnogenol® was shown to provide potent photo-protective and melasma-reducing effects from the inside out, contributing to an even skin tone [5-11]. Melasma is a common form of hyperpigmentation and may be caused by UV exposure, female hormones or by predisposed genetic background [12]. In clinical studies, Pycnogenol® reduced the area and intensity of melasma and led to a more regular and even skin complexion [5-7]. It was shown that Pycnogenol® suppresses tyrosinase activity, an enzyme that activates the production of melanin - the pigments, responsible for melasma [8, 9]. These findings of Pycnogenol®'s ability to counteract skin hyperpigmentation were clinically validated in a study, in which Pycnogenol® was shown to significantly lower UV-induced expression of enzymes that are linked to long-lasting pigmentation [10]. Pycnogenol® was further shown to increase the resistance of participant's skin to solar UV exposure, needed to trigger skin redness [11]. The results from these studies suggest that Pycnogenol® has photo-protective and melasma-alleviating efficacies.

Beneficial effects on wound healing, eye health and joint function

As part of the extracellular matrix, collagen, elastin and hyaluronic acid are actively involved in the process of wound healing [13-15]. With all of Pycnogenol®'s beneficial effects on molecules in the extracellular matrix [2-4], this helps to explain why Pycnogenol® has demonstrated efficient wound healing effects [16-19].

Hyaluronic acid is also a natural part of the tear film,



stabilizing and thickening the ocular lubricant [20]. Pycnogenol® increasing hyaluronic acid production within the body [2] explains the beneficial effects of Pycnogenol® on dry eyes shown in several studies [19, 21, 22].

Collagen, elastin and hyaluronic acid are important components of articular cartilage, the shock absorber of the joint [13, 23, 24]. Four clinical studies confirmed Pycnogenol®'s beneficial effects on joint health, showing reduced discomfort and stiffness and improved physical function as well as reduced need for analgesic medication in patients with osteoarthritis [25-28]. Pycnogenol®'s abilities to increase the synthesis of hyaluronic acid and collagen and to protect elastin and collagen from being degraded [2-4] are backed up by the finding of a strong increase of the concentration of Pycnogenol®'s anti-inflammatory metabolites in the synovial fluid of osteoarthritis patients [29, 30].

Pycnogenol® French maritime pine bark extract has shown very interesting effects on components of the extracellular matrix. By stimulating new collagen synthesis, increasing hyaluronic acid generation and inhibiting the activity of destructive enzymes, Pycnogenol® was shown to enhance skin elasticity and skin hydration. Additionally, Pycnogenol® provides photo-protection and reduces melasma, contributing to an even and healthy skin tone. In addition to skin care benefits – and based on similar mechanisms of action – Pycnogenol® has been shown to help with wound healing, eye health and joint function – naturally and from within.

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

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Powder Bags

Introduction:

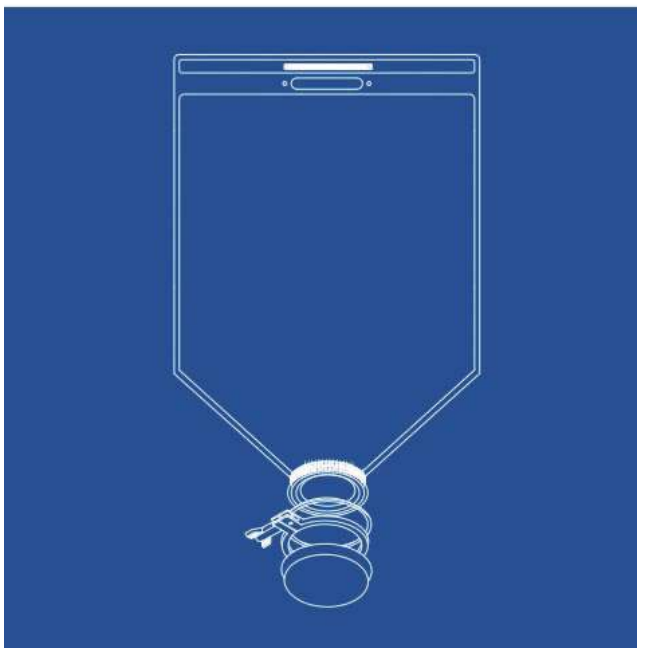
In the biopharmaceutical industry, every detail matters. Each gram of material is critical – the less wasted, the better the quality, safety, and cost efficiency of the final drug product. One often overlooked yet crucial component in this workflow is the antistatic powder bag.

What is an Antistatic Powder Bag?

An antistatic powder bag is a specialized bag made from antistatic film – a plastic material engineered to prevent static electricity build-up. These bags are widely used in biopharma for weighing, transferring, and transporting powders into mixer bags or processing units.

Because of the antistatic property, powder does not stick to the walls of the bag, which improves transfer efficiency and minimizes waste.

Static electricity can cause powders to cling to surfaces, leading to measurement inaccuracies and material loss. Antistatic bags eliminate this issue, ensuring unobstructed movement of powders between



process stations in manufacturing workflows.

Applications in Biopharma

Antistatic powder bags are most commonly used with mixer bags, which blend multiple ingredients during drug formulation. The generic workflow includes:

Weighing, Transfer, Dispensing.

Weighing: Exact quantities of powder ingredients are weighed directly into the antistatic bag.
Transfer: The bag is sealed and moved to the blending or processing area.
Dispensing: Powders are transferred into mixer bags or reactors with minimal to no residue, ensuring accurate formulation.

Controlled Environment Handling.

Key Benefits

Accuracy: Enables precise transfer of exact weights without loss from sticking.
Efficiency: Reduces cleaning time and handling challenges.
Product Safety: Minimizes contamination risks, critical for sterile and high-potency formulations.
Cost Savings: Reduces wastage of expensive active ingredients, contributing to overall cost efficiency.

Other Benefiting Industries

While biopharma is the primary user, antistatic powder bags also find utility in:

- ◆ Food processing
- ◆ Specialty chemicals
- ◆ High-purity industrial powder handling
- ◆ Regulatory Compliance

Certifications:
FDA 21 CFR 177.2600
USP Class VI, USP 85, USP 788, USP 661, USP 381
ISO 10993, ISO <11737-1>
European Pharmacopeia <3.1> & <3.1.9>
TSE/BSE freeBPOG extractable studies

Conclusion :

As the industry continues to demand higher precision and sterility, simple innovations like antistatic powder bags make a profound difference. They minimize waste, ensure formulation accuracy, and maintain stringent regulatory standards, ultimately advancing healthcare quality worldwide.

Written by: Manoj Kumar
Sales Executive - Pharma Division
Ami Polymer Private Limited
Manoj.y@amipolymer.com
Contact No - 917700908412

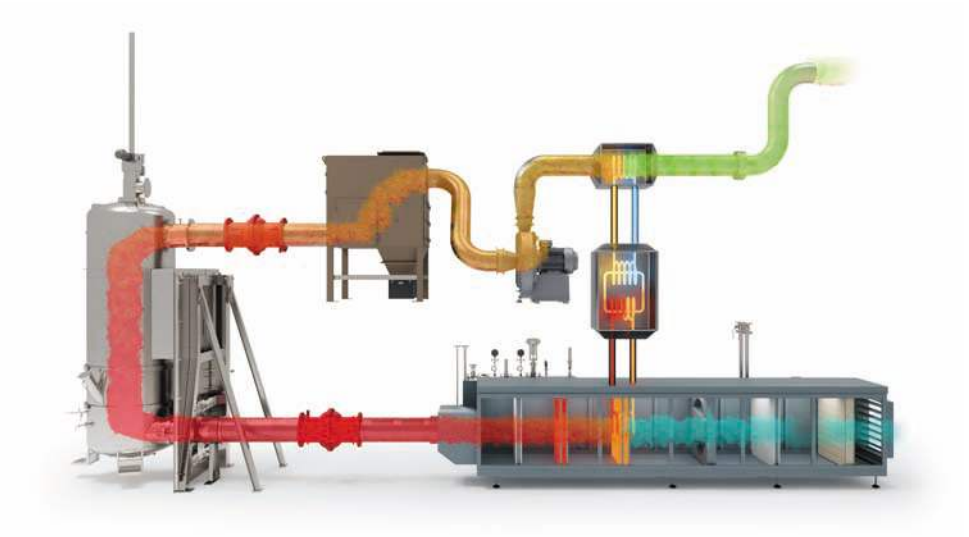
Heat recovery in fluid bed processes Up to 60% energy saving

Romaco Innojet is implementing a high-temperature heat pump in the fluid bed process for the very first time, enabling heat from the outlet air to be efficiently recovered. The thermal energy recovered in this way is fed directly into the process, cutting energy consumption by around 60 percent. Frictional heat from the outlet air fan is also used.

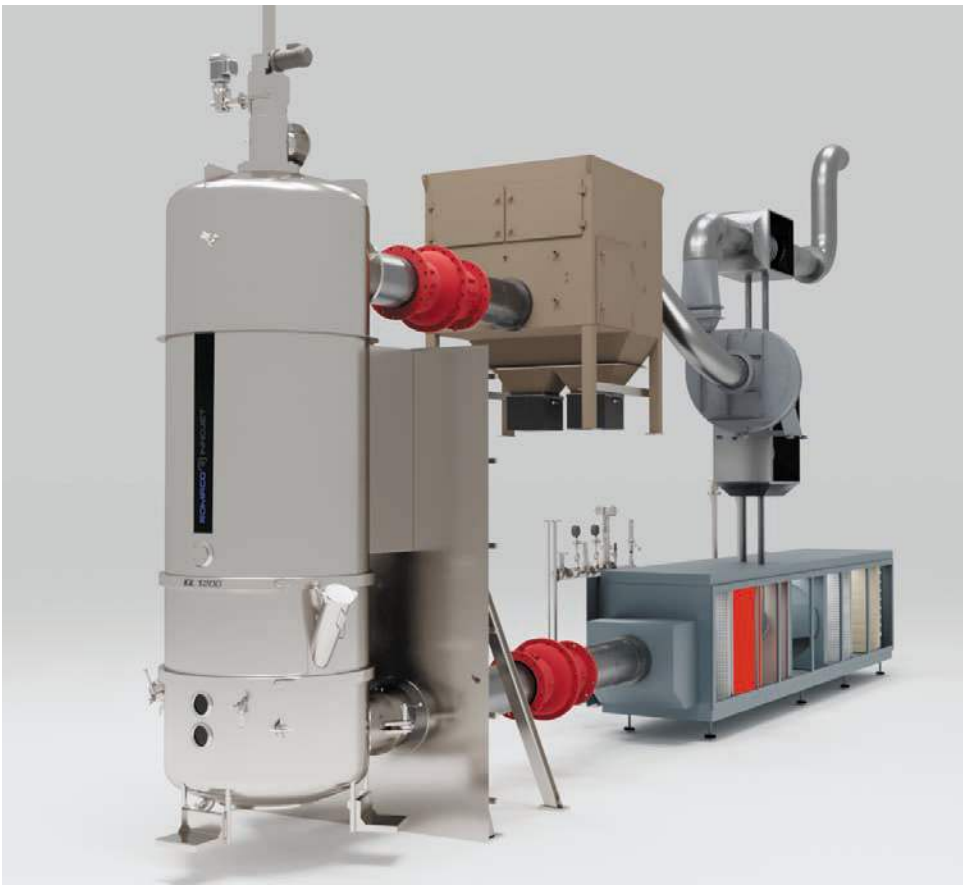
It is a well-known fact that the fluid bed process is extremely energy intensive. Huge amounts of energy are needed for the drying process during the production and coating of granulates and pellets for the pharmaceutical, food and chemical industries. The Heat Recovery System (HRS) developed by Romaco Innojet for its VENTILUS® product family aims to sustainably reduce this enormous energy consumption. The innovative technology is very easy to implement in the fluid bed process and enables energy savings equivalent to up to 60 percent of the heat output.

The heart of the Romaco Innojet Heat Recovery System is an industrial heat pump rated for a flow temperature of up to 100°C. It responds flexibly to the outlet air conditions of the different processes running on the machine. The parameters dictated by the production process, such as air and spray flow rates or the required heating temperature, result in variable outlet air conditions and the heat pump adjusts its operation accordingly. The setpoints for the temperatures of the cold and hot water streams are set on the HMI panel or in the fluid bed processor's automated process recipe system, which is also where users specify the process step in which the heat recovery system should be activated. The fluid bed process runs independent whether or not heat recovery is active.

The following pictures are enclosed with the press release



The HRS Heat Recovery System from Romaco Innojet enables energy savings equivalent to up to 60 percent of the heat output



The HRS Heat Recovery System from Romaco Innojet can be easily integrated into any fluid bed processor in the VENTILUS® product family and IGL series

Efficient energy cycle

The water-to-water heat pump that is used for this purpose is no different from a standard commercial heat pump in terms of the way it works. The relatively low temperature level of the outlet air is sufficient to boil the refrigerant in the heat pump and transform it into a gaseous state. This gas is then compressed to high pressure, so that it heats up to a very high temperature and emits the heat to the processing machine's inlet air via a water circuit. The energy transfer causes the refrigerant to cool down again, so that it condenses and flows through an expansion valve in a liquid state. It then expands due to the pressure drop and returns to its original temperature, whereupon the heat pump cycle begins anew.

In Romaco Innojet's HRS Heat Recovery System, the heat pump is divided into two water circuits – one for the inlet air and one for the outlet air. The energy transfer is controlled using four heat exchangers. The thermal energy that is recovered from the outlet air is fed directly into the inlet air of the process and utilized solely to heat the process air stream. There is no longer any need for complex intermediate storage or secondary usage scenarios for the recovered energy.

Innovative use of outlet air heat

The frictional heat from the outlet air fan is also used by the recovery system in addition to the thermal energy from the process outlet air. The high-pressure fan, which pulls the process air through the fluid bed system, is situated in the outlet air handling unit upstream from the recovery module. It heats up the air by approximately 5 to 15°C. Thanks to the HRS, this energy can be fed directly into the heat pump and recovered rather than simply escaping into the atmosphere unused together with the outlet air. Romaco Innojet has registered intellectual property rights regarding the development of the circular heat recovery system.

The heat pump achieves a COP of 3.5 on average – in other words, 3.5 times more energy is recovered than is used electrically. In relation to the fluid bed process, this means heating energy savings of up to 60 percent – equivalent to up to 50 tons fewer carbon dioxide emissions per year, depending on the size of the machine.

The Innojet fluid bed processors ship with an energy

monitor that is integrated in the HMI to enable precise calculations of energy efficiency. This tool measures the exact consumption of both the system as a whole and its individual components. All energy streams, including recuperative heat recovery streams, are recorded over the machine's entire service life. These values can be displayed in megawatt hours, carbon dioxide or carbon equivalents and are stored in the system. Robust data can be obtained in this way for sustainability reporting, which is mandatory for a growing number of companies worldwide.

Easy to implement

The HRS Heat Recovery System is very easy to implement in all new machines belonging to the Romaco Innojet VENTILUS® product family and IGL series. The system can also be retrofitted. At the InnoTech laboratory in Steinen, Germany, a V 150 featuring an integrated heat recovery system is available for product trials. A pharmaceutical manufacturer from southern Germany is the first to use the technology in practice – in a VENTILUS® processor with a maximum batch volume of 900 liters.

The Romaco Innojet HRS Heat Recovery system is particularly efficient when it comes to granulating and drying wet granules – in short, in all processes with high spray rates and high air consumption. The enormous energy saving potential where fluid bed processes are concerned represents an important step towards more sustainable production of pharmaceutical, food and chemical products. In 2024, Romaco was awarded its first-ever gold medal in the EcoVadis sustainability ratings for its commitment to climate protection.

Romaco Group

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

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

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

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

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Company contact
Susanne Silva
Market Communications
Romaco Group
Am Heegwald 11
76227 Karlsruhe
Germany
T: +49 (0)721 4804 0
E: susanne.silva@romaco.com

Press contact
Micha L. Harris
Senior PR Consultant
Carta GmbH
Iggelheimer Str. 26
67346 Speyer
Germany
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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:

Gandhi Automations Pvt Ltd-
Chawda Commercial
CentreLink Road, Malad (W),
Mumbai-400064, India.
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Compactrol: A new age diluent

COMPACTROL®

COMPACTROL® is calcium sulfate dihydrate, an inorganic material, which is naturally derived. It is roller compacted and size classified to obtain a median particle size and size distribution ideal for pharmaceutical and nutraceutical applications.

COMPACTROL® - Calcium Sulfate as a diluent has an advantages of possessing low concentration of unbound moisture as well as having a low affinity for atmospheric moisture. These are required features for any excipient material to be combined with a water sensitive drug. The bound water of calcium sulfate is not released until a temperature of approximately 80°C is reached. Such bound water is usually unavailable for chemical reaction. Such excipients containing tightly bound water and having a low remaining moisture demand may be vastly superior to an anhydrous diluent, which has moderate to high moisture demand[1][4].

Types of calcium Sulfate [3]

There are three types of calcium sulfate -

A) Calcium sulfate Dihydrate is used in the formulation of tablets and capsules. In granular form, it has good compaction properties and moderate disintegration properties.

B) Calcium sulfate hemihydrate is used in the preparation of plaster of Paris bandage, which is used for the immobilization of limbs and fractures; it should not be used in the formulation of tablets or capsules.

C) Anhydrous calcium sulfate is hygroscopic and is used as a desiccant. Uptake of water can cause the tablets to become very hard and to fail to disintegrate on storage. Therefore, anhydrous calcium sulfate is not recommended for the formulation of tablets, capsules, or powders for oral administration. Therapeutically, calcium sulfate is used in dental and craniofacial surgical procedures.

COMPACTROL® is 23.3% calcium and can be used in dietary supplements as a calcium source [2]

Table 2. Physical properties of COMPACTROL®	
Bulk density	Max 1.1 g/ml
Median particle size	120 µm

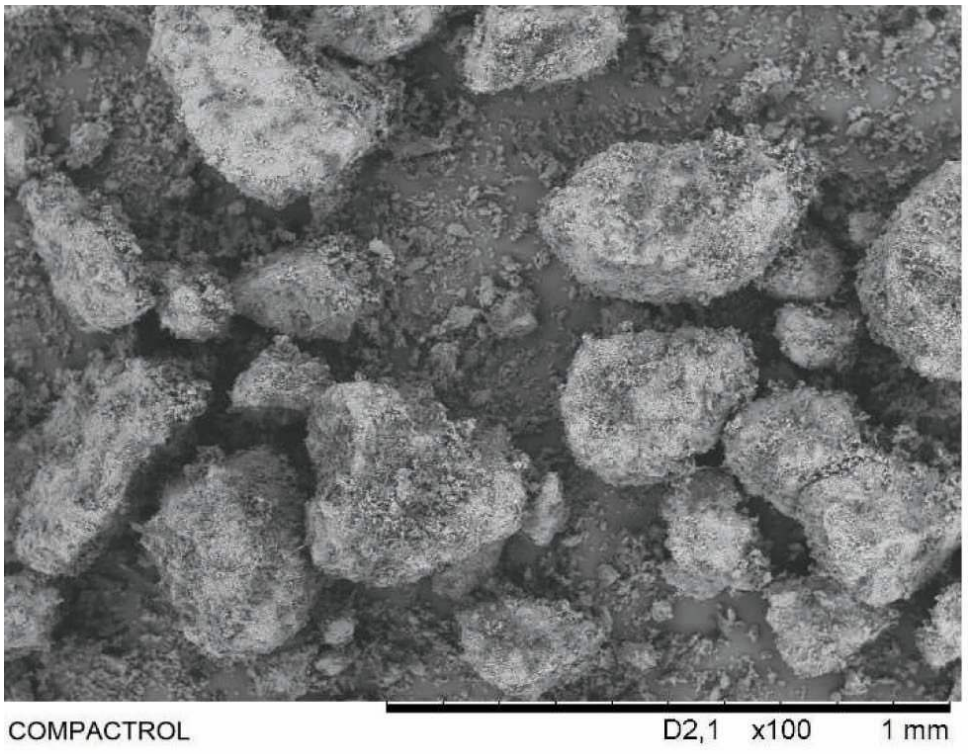

Figure 1. SEM Image of COMPACTROL®

Table 1. Solubility of COMPACTROL®	
Solvent	Solubility at 20°C Unless otherwise stated
Ethanol (95%)Water	Practically insoluble 375 mg/l 485 g/l at 100°C

Benefits of COMPACTROL® [2]

Wet granulation

COMPACTROL® is a calcium sulfate dihydrate material meeting Ph.Eur., NF and FCC monograph requirements. It is mainly used in wet granulation to improve the binding properties of classical granulation bases such as starch or powdered cellulose. When COMPACTROL® is wetted during the granulation process and dried afterwards, it acts like a glue in powder mixtures.

Direct compression

COMPACTROL®, specially processed calcium sulfate dihydrate powder, is also suitable as a filler in tablets manufactured by direct compression. It is also an effective diluent for two-piece hard capsule filling application.

It is a non-hygroscopic and free-flowing powder which is relatively inert offering excellent long-term stability and provides required flow characteristics necessary for high-speed compaction and capsule filling.

API, ARBOCEL® and COMPACTROL® were wet granulated in a fluid bed processor. After drying and sieving, the granules were compressed using a mixture of VIVAPUR® 102, VIVASTAR®P and magnesium stearate.

Incompatibilities [3]

In the presence of moisture, calcium salts may be incompatible with amines, amino acids, peptides, and proteins, which may form complexes. Calcium salts will interfere with the bioavailability of tetracycline antibiotics. It is also anticipated that calcium sulfate would be incompatible with indomethacin, aspirin, aspartame, ampicillin, cephalexin, and erythromycin since these materials are incompatible with other calcium salts. Calcium sulfate may react violently, at high temperatures, with phosphorus and aluminum powder; it can react violently with diazomethane.

TABLE 3. Formulation Example	
API	10.0%
ARBOCEL® (Powdered cellulose)	70.0%
COMPACTROL®	20.0%
Water	q.s.

Applications:

- As a binder in wet granulation.
- Filler & Diluent for tablets.
- High Bulk density filler suitable for capsule filling.
- For water sensitive drugs as it absorbs very less moisture.

References:

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Author:
Mr Prashant Bhangdiya
Technical Manager-Pharma
Rettenmaier India Pvt Ltd
Prashant.bhangdiya@jrsindia.com

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