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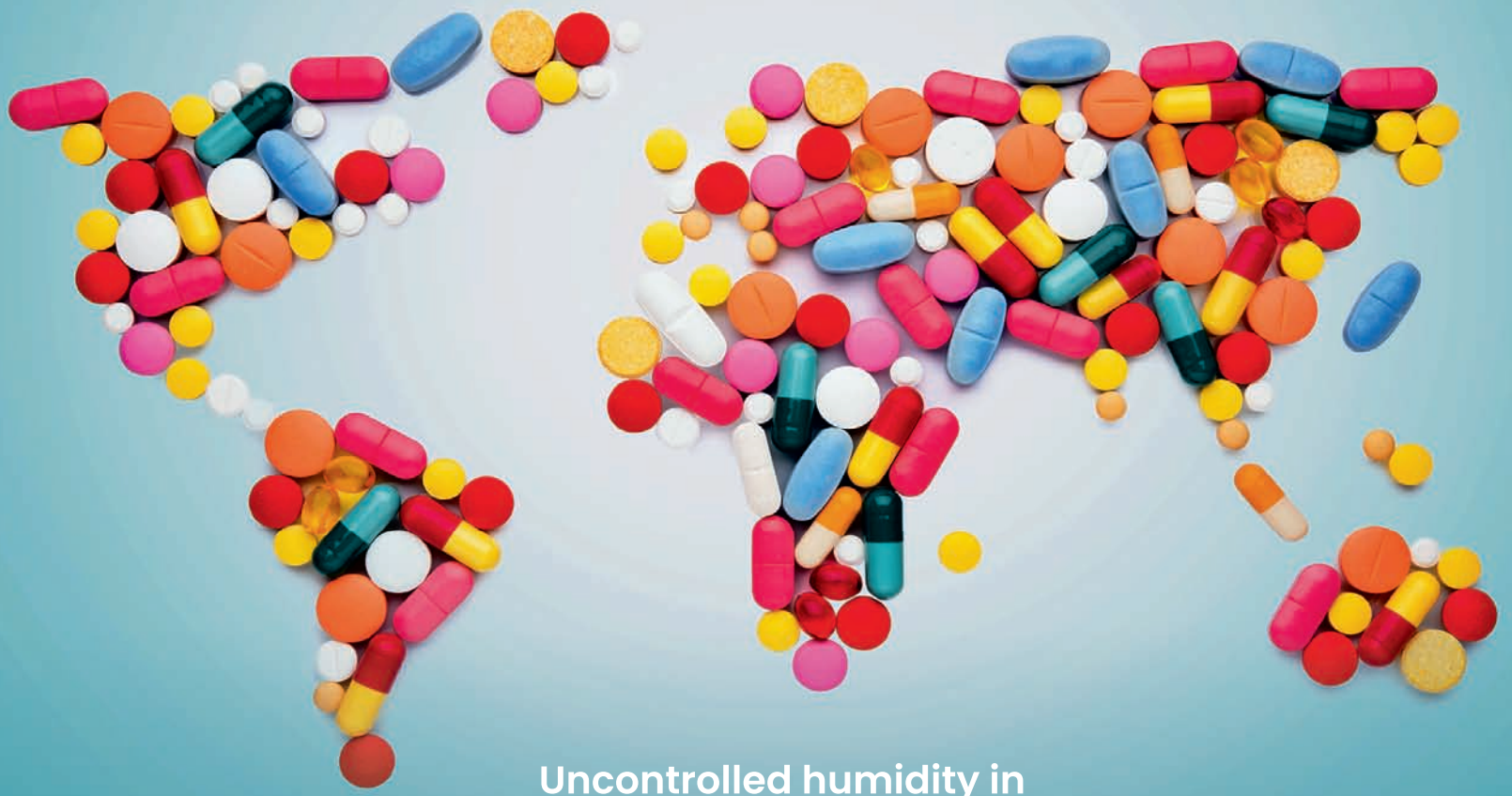

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Building India Pharma Inc's innovation muscle

India's biggest pharma voices reinforced that quality is the foundation of innovation and global trust at Indian Pharmaceutical Alliance's 11th Global Pharmaceutical Quality Summit (GPQS). This year's edition has sessions discussing how talent, technology, and trust were the pillars to reimagine pharma operations.

Setting the bar high in his recorded Keynote Address, Hon'ble Health Minister, Shri Jagat Prakash Nadda, said the Summit is a "reflection of India's commitment to move from being the 'Pharmacy of the World' to becoming the 'Innovator of the World.'

In the same vein, on a warning note, Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI), emphasised that the rigour of risk-based inspections, roll out of revised Schedule M and the weeding out of non-compliant cough syrup manufacturers in the country would continue. In his words, "Quality is not optional. Without quality, we cannot achieve innovation, export growth, or global trust. The journey from volume to value depends fundamentally on quality."

Borrowing from the title of Marshall Goldsmith's book, there was a general consensus that "what got us here (an affordable generics powerhouse) will not get us there (a leader in pharma innovation)."

In other words, how do we build muscle memory in pharma innovation? Some answers to that question came in the most awaited panel discussion of the two-day conference, featuring four titans of the industry.

Perhaps predictably, pharma gurus Dilip Shanghvi, Executive Chairman, Sun Pharma and Mohan Reddy, Whole-Time Director, Aurobindo Pharma tempered their optimism with caution, while Nilesh Gupta, Managing Director, Lupin and Sharvil Patel, Managing Director, Zydus Lifesciences and President, IPA, as second generation pharma leaders, were confident of running with the baton in the pharma innovation race. But they too are pragmatic, acknowledging that it's not a race but a marathon, with many stages to the final goal.

While Lupin's Gupta was proud that the four companies on the dais represented 25 per cent of the world's generics supply, he emphasised that this achievement doesn't automatically give them a seat at the innovation table. Which is why the industry is following global trends and has evolved over the last couple of years from generics to complex generics.

Zydus' Patel was confident that "just as India Pharma Inc built generics at scale, we can build innovation at scale." He clarified that innovation at scale doesn't mean we have to discover everything ourselves. "We can co-create, collaborate, license, partner, co-develop. And there are so many ways by which we can create in India through these ways, innovation at scale." He pointed out that while they built capabilities in-house in the initial part of Zydus' journey, as they didn't have the money to buy capabilities, they chose niche areas like rare diseases where they can create a much larger impact to all stakeholders, from regulators and patients to shareholders.

While we agree that "what got us here (an affordable generics powerhouse) will not get us there (a leader in pharma innovation)", how do we build muscle memory in pharma innovation?

Sounding a note of caution, Sun Pharma's Shanghvi pointed out that while the industry is making "tentative steps in focusing on innovation", and the same capabilities which made us a generic superpower will stand us in good stead, "we are not all in ... we are very tentative in terms of investment. All of us are CEOs from an age when we were generic and branded generic companies. Unless and until we recalibrate our thinking process and our process of taking investment decisions, it is going to be a challenge to recalibrate India to a new innovative world market." Emphasising that it is not only about innovation but innovating fast, and at scale, he is a strong believer that once a few Indian companies succeed, we will see a much higher level of confidence in other companies. "I am waiting for that positive cascade of innovation to happen."

Along the same lines, Lupin's Gupta recalled that two decades back, the big generic stories were in vaccines, which built the conviction of the entire industry and an increase in manufacturing quality on a global scale. He too echoed Shanghvi's opinion that the innovation part for India Pharma Inc has just started. While companies like Glenmark and Zydus have tasted success in innovation, Gupta believes that "we need a lot more stories, we need a lot more successes."

Aurobindo Pharma's Reddy too reminded the audience that we are today at the same place as we were two decades back, when we started doing generics. He pointed out that beginning with collaborations helped us gain access to knowledge and develop capabilities while putting us on the path to innovations. For him, the challenges that India Pharma Inc has to address are sustaining the global trust, building the right quality culture and keeping pace with global digital transformation initiatives.

The good news is that India Pharma Inc has self diagnosed its Achilles' heel. The bad news would be to allow black sheep, the quality defaulters, to undermine this hard-won reputation.

As Patel put it, "It's not only about cost, but how do we become a trusted source /supplier in difficult times, and make sure that we are able to be resilient supply chain partners." Sustaining as a generics superpower, while building innovation muscle is then the right prescription for India Pharma Inc. Which companies will stay the course and balance both plays?

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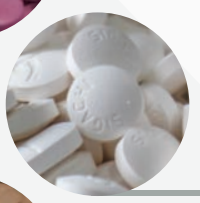

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India has the infrastructure to lead the global gene therapy market

Professor Philip J. Young, Director of Educational Analytics, School of Life Sciences, University of Warwick, outlines how AI is compressing drug discovery timelines, why affordability remains the real bottleneck in SMA care, and how India can lead the next phase of precision medicine, in an exclusive interview with **Neha Aathavale**

AI is often described as a game changer in drug discovery and manufacturing. Where do you see it making the biggest difference today, and where should expectations be more measured?

Regarding the biotech industry, AI has multiple impacts that are already revolutionising the sector, but the most obvious one is moving us closer to solving the protein structure issues that have dogged protein biochemistry for decades. Effectively, it is incredibly difficult (if not impossible) to predict how a protein folds from the amino acid sequence. Therefore, to develop drugs and small compounds that target / inhibit proteins (which is the bed rock of biological engineering) you need to perform structural analysis (crystallography / NMR). This can take many years and significantly impacts the time it takes to develop drugs. However, the introduction of AlphaFold2 (the Google DeepMind AI model that predicts protein structures with >90 per cent accuracy) has had a huge impact

For a direct comparison of the experimental approaches (crystallography) v AlphaFold2, scientists have been working for >20 years to solve the crystal structure of the Survival Motor Neuron (SMN) protein (mutations in SMN cause spinal muscular atrophy, SMA). In 2025, AlphaFold2 was used to solve the SMN structure- it took less than 10 minutes. To-date, AlphaFold2 has been used to predict the structure of >200 million proteins, for which Demis Hassabis and John Jumper were awarded the 2024 Nobel Prize in Chemistry.

> Rather than focusing on patent protection, it would benefit everyone if biotech companies were willing to 'franchise' drug production to India-based generic companies

What also excites me, but also has triggered concern, is the ability of AI to help introduce precision or truly personalised medicine. Drug discovery involves five different stages: 1) target identification; 2) structural analysis of the target protein; 3) biological engineering of small compounds that can target the protein of interest; 4) pre-clinical analysis (cell and animal-based work); and 5) clinical trials. In general, these five stages can take 10-15 years.

Ren et al, in 2023, used AI to optimise target discovery / validation and small compound screening/validation, meaning they were able to get a new therapy (TNIK) for Idiopathic Pulmonary Fibrosis (IPF) into clinical trials in around 24 months. This is incredibly exciting, but the rate limiting step (even with AI) is the preclinical (animal models) and clinical trial stages.

There is a growing belief that AI could ultimately be used to replace preclinical trails, reducing the reliance on animal models. However, before this can happen, we would need to be absolutely sure that AI can accurately predict off target effect, drug breakdown product toxicology, and (essential) be used to calculate NOAEL / DNEL and MABEL to ensure we can identify safe start doses for human clinical trials, and we are a long way off this being the case.

When a breakthrough therapy or technology shows promise, what is usually the biggest bottleneck in translating it into real-world healthcare impact?

Really good question, and there are several answers. The first is funding - it costs a lot of money to convert a promising academic discover into a marketable drug, and most interesting findings will never take the next step because academics cannot fund the research.

The second is the preclinical work (i.e. animal models). Drugs can show true promise in in vitro or in cell based assays but demonstrate unforeseen toxicological issues in animal models. For a drug to progress from preclinical to clinical trials, it needs to work (i.e. improve outcomes in animals), display minimal or tolerable side effects, and have a therapeutic dose that is considerably lower than the toxic dose. In many cases, this simply is not the case, meaning drugs work but the effective dose causes too many complications.

The third is clinical trial results, and this is probably the main bottleneck. Trials cost a lot of money, and there is no way of predicting if a drug that works well in mice or rats, will have the same beneficial effects in humans. Most drugs that enter trials will simply not work as well as hoped.

The final issue is financial and involves regulatory bodies. Even if a drug performs well in clinical trial, it does not directly mean it will make its way into clinical

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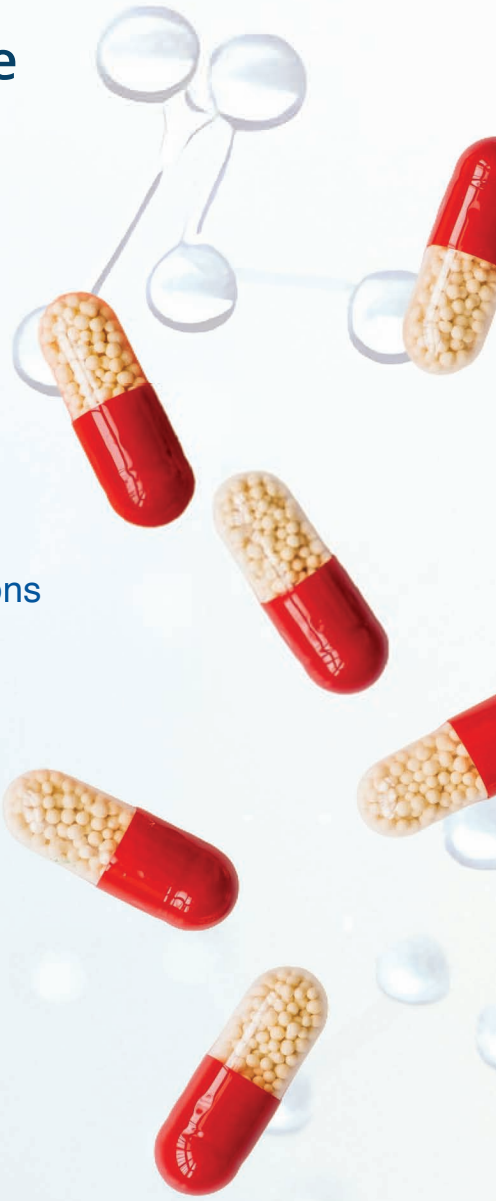

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practice. Regulatory bodies will assess whether the drug is cost effective, whether it produces marked improvement in patients' quality of life and whether it is better than existing drugs. Again, this step is more complicated than most people believe, and a high percentage of drugs will not be officially approved for clinical use, even when the clinical trials are positive.

In diseases like SMA, where timing is everything, how prepared are current healthcare systems in emerging markets to act quickly once a diagnosis is made?
The main two issues in emerging markets are manufacturing and costs. For SMA in particular there are three separate therapies - one novel chemical entity (NCE) and two biotechnological products (BTPs).

The two BTPs - Zolgensma (SMA gene therapy) and Spinraza (SMA antisense oligonucleotide therapy) - are incredibly expensive. While both have been approved for use in India, they are two of the most expensive drugs ever made and as neither are manufactured in India, their use is not covered by standard Indian insurance policies. This means families rely on alternative funding (i.e. crowd sourcing or international humanitarian programs) to gain access. This effectively introduces a two-tiered healthcare system for Indian SMA families, where families with the funds to cover costs can receive state of the art therapies quickly, while less affluent families must raise the funds to treat their children.

This is a major concern because as SMA is a progressive disease, with severe children unlikely to live beyond the age of 2 years if untreated, any delay in treatment can result in significant clinical complications.

The NCE (Risdiplam) is less expensive, due to simpler manufacturing processes. However, as with the BTPs, because it is not manufactured in India, there are issues with insurance policies covering costs. This means that because of cost and non-Indian manufacturing, the three therapies are not providing the benefit to Indian families that they should.

However, all this potentially changed in October 2025, when a Delhi High Court ruled that Natco Pharma was legally able to release a generic version of Risdiplam, called Natsmart. This is manufactured in India (as part of India's world leading generic pharmaceutical sector), meaning: 1) production costs are lower (it is effectively 97 per cent cheaper than Risdiplam); and 2) because Natsmart is manufactured in India, it's use will be covered by standard Indian insurance policies.

The ruling is a major boost for Indian families impacted by SMA, effectively putting Indian patient care and welfare above patent protection for international pharmaceutical companies. The company who manufactured Risdiplam are challenging the ruling in the Indian Supreme Court, but if the high court ruling is upheld, India will have one of the most affordable SMA therapeutic programs in the world.

There is growing discussion around developing affordable gene therapy alternatives for emerging markets. How realistic is this in the near future, and what role can countries like India play in making it possible?
India is incredibly well placed to not only be involved in the production of gene therapy alternatives, but to be the world leader in this market. Natsmart has shown India is capable of producing cost effective generic medicines. Importantly, India is also the global leader in biosimilar production, with >130 approved biosimilars manufactured by Indian companies already in clinical practice. This means that when the AveXis/Novatis patent and market exclusivity is no longer an issue, India has the biotech infrastructure to mass produce a Zolgensma biosimilar. However, if Natsmart is ruled to be legally acceptable by the Indian Supreme Court, the need for a biosimilar gene therapy is not as high.

From your experience, what is one assumption the global healthcare ecosystem still gets wrong when it comes to innovation in emerging markets like India?
I covered the main issue above - it is cost and place of manufacturing. Biopharma companies will predominantly produce drugs aimed at markets that can afford them, like Europe, Japan and the US. This produces a two tiered system in emerging markets, which is a major concern. While the biotech sector will have major concerns with the Natsmart High Court ruling, if up-held, I think it will have a significant impact on how emerging markets are treated.

I personally would like to see better collaboration between major biotech companies and Generic / Biosimilar manufacturers in emerging markets. Rather than focusing on patent protection, it would benefit everyone if biotech companies were willing to "franchise" drug production to India-based generic companies, like Natco Pharma. This would mean a version of brand named drugs could be produced in emerging markets, while maintaining the integrity of market exclusivity and patents, reducing costs of manufacturing, shipping and import duty on patent holder, while maintaining market share in India. It would also mean drugs were manufactured in India, allowing cheaper costs and insurance coverage.

From your experience across academia and industry, how can universities better bridge cutting-edge research with real-world healthcare impact, particularly through collaborations?
This is a really good question and one better people than me have struggled with for many years. The first, and basic approach, is to change the way we train academics and students. In general, university degrees are based around what departments can teach and tend to focus on the research interests of academics. However, this means we are not truly providing details skills that are needed to make real-world impacts. This means we need a paradigm shift in how we develop degrees.

To improve collaborations, you first need to make sure academics have core skills needed to work in industry, and this comes from changing degree structures. We need better communication between academics and industry, ensuring we produce tailored programs that produce graduates with core skills needed to make true impacts. This is what I am doing here in the UK at the University of Warwick, where I lead the educational arm of the STEM Connect program. We are identifying core real-world issues and building degrees that provide the core skills needed to address them. We are focusing on climate change, healthcare, manufacturing and scientific computing, with close involvement and input with the National Health Service (NHS) and industrial sector.

The second approach is focused on ensuring academic discoveries are ready for industrial scaling. This is a major flaw in the sector - and one that I have first hand experience with. When I worked for a biotech company, I had many meetings with academic researchers who were hoping to develop their concepts into marketable products. However, most of the time all the academics had was a basic idea and proof of concept data.

This means the route followed by most academics is to take their idea and use it to develop new start-up companies. However, academics in general are not prepared for this process, meaning 90 per cent of all biotech will eventually fail, and only 7-10 per cent will produce a treatment that makes it into clinical trials (if start-up companies do make it to trial, this is where large, more established companies will become involved).

So, what do we need to do (as a sector) is to improve the "start-up" part of this process? We need to improve support, provide better mentoring and help with patent production. Most universities will have teams that support this type of process, but one of the most impressive I have encountered is the Centre for Cellular and Molecular Platforms (C-CAMP), which is part of the National Centre for Biological Sciences (NCBS) based in Bengaluru.

C-CAMP provides an incredible link between basic / translational science and commercialisation. It acts as a major support hub for academics, providing mentoring and funding. What sets C-CAMP apart from other centres is they support many ventures from outside NCBS. Importantly, their core focus is development of real-world therapies that are affordable in emerging markets, meaning their efforts are impacting the whole of the Indian Biotech sector and patients alike. If any of your readers are considering developing a start-up company, I would strongly suggest they contact C-CAMP for support.

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Our approach is to combine localised production with global quality standards

Jean Charles Wirth, Global CEO of Merck Life Science, shares insights on the company's approach in a price conscious and quality focused market like India, the company's close alignment with the 'Make in India' vision and how Merck is fostering scientific talent to support customers in India, the Asia-Pacific region, and globally, in an interaction with **Viveka Roychowdhury**

What do you see as India's role in the evolving global life sciences and biopharma value chain over the next decade?
India is playing an increasingly strategic role in global life science innovation. Building on its strong manufacturing foundation, the country is advancing rapidly in biopharma R&D, supported by government incentives, modern research infrastructure, and exceptional scientific talent. These factors are driving India's emergence as a co-creator of advanced therapies and a cornerstone of the global innovation ecosystem.

How can India make the shift from a generics volume play to an R&D driven value play in the global Lifesciences and biopharma value chain?

India is well positioned to evolve from a value-driven manufacturer into an innovation hub for global life sciences. Programs such as the Promotion of Research and Innovation in Pharma MedTech (PRIP) scheme and the Anusandhan National Research Foundation (ANRF) are strengthening the research ecosystem and fostering collaboration between academia, startups, and industry. Combined with India's strong scientific talent base, expanding research infrastructure, and growing biomanufacturing capabilities, these efforts are enabling the country to advance discovery, accelerate technology development, and contribute more broadly to global scientific progress.

How important is the Indian market for Merck globally? What percentage of global revenue comes from India for Merck Life Sciences? How does the growth in the India business compare to other regions?
India has been integral to our growth for 57 years. Within our Life Science business, India plays a strategic role in our global operations. With more than 1,000 colleagues across three sites, the country plays a vital role in manufacturing, research, and development, as well as in fostering scientific talent that supports customers in India, the Asia-Pacific region, and globally. We continue to invest in infrastructure, partnerships, and skill-building initiatives that strengthen India's life science ecosystem.

While we do not disclose country-level financials, India plays a pivotal role across all areas of our Life Science business – from manufacturing and R&D to support customers globally. Our teams here are essential to how we deliver innovation and reliability to our customers worldwide.

What are the growth drivers for Merck Life Science in India? What are the challenges to grow in a price-sensitive market like India?
India represents an important growth market, driven by rising demand for high-quality research materials, local manufacturing capabilities, and deepening R&D partnerships. The expansion of our Peenya facility in Bengaluru strengthens our regional supply chain and allows us to serve customers faster and more efficiently. At the same time, innovation from India continues to expand. Our Jigani site, for example, is now a key export hub for deuterated compounds supporting the 'Make in India' vision.

In a price conscious and quality focused market, our approach is to combine localised production with global quality standards. By investing in process innovation and strategic partnerships, we ensure scientific excellence remains accessible while maintaining the reliability our customers expect worldwide.

On the policy front, how do India's Pharma and biopharma policies compare to those of other markets?
India has built a supportive policy environment for life sciences. Initiatives such as the Production Linked Incentive program and the Anusandhan National Research Foundation are driving long-term investment in research and innovation, while programs like Startup India strengthen industry–academia partnerships. Together, these efforts are positioning India alongside leading global innovation hubs and reinforcing its role in advancing science and economic growth.

What has been Merck's engagement with India's policy makers and support to policies like the Make in India vision and pharma R&D in India?
We've partnered closely with India's policymakers to advance the country's life science vision. Through our collaboration with the Department for Promotion of Industry and Internal Trade and Startup India, we share global expertise and technologies that help Indian biotech startups to succeed. Our partnerships with the Council of Scientific & Industrial Research and IMTech are building scientific skills and research capacity, while recent manufacturing investments in Bengaluru and Jigani reflect our strong commitment to the 'Make in India' vision and to India's role in the global life science ecosystem.

As the industry is evolving from pharma to biopharma, with new technologies requiring upskilling on the job, what is Merck's role in upgrading the skills of life sciences professionals in India?
Developing scientific talent is a priority for us in India and around the world. Through our Formulation & Technology Centre in Navi Mumbai, MLabTM Collaboration Center in Peenya, and MAT and Innovation Lab in Jigani, we provide hands-on training in advanced biomanufacturing, formulation, and analytical technologies. We have trained more than 15,000 scientists and engineers across these sites, helping equip the next generation with skills that support India's growing, innovation-driven life science ecosystem, while also strengthening the global biomanufacturing talent pipeline.

How has Merck engaged with biotech startups and incubators in India?
India's biotech startup ecosystem is growing rapidly, and we are proud to support this progress. Through our collaboration with the Ministry of Commerce & Industry, we provide mentorship, resources, and access to advanced laboratories and technical expertise to help startups innovate and scale. We are expanding collaborations with leading CDMOs and innovation hubs, including the Pune Startup Hub and incubation centers in Hyderabad, supporting startups such as Genext Genomics. These collaborations provide access to cutting-edge equipment and biomanufacturing capabilities, accelerating early-stage R&D and process development.

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I, Vaidehi Thakar, hereby declare that the particulars given above are true and to the best of my knowledge and belief.

sd/-
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In 2026, India serves as the reliable 'technical engine' for global research

Dr Seema Pai, President, Indian Society for Clinical Research outlines how India's clinical research landscape is evolving into a quality-driven, innovation-led ecosystem, supported by regulatory progress, digital adoption, and stronger patient-centric approaches positioning the country as a global research hub, in an interview with **Swati Rana**

How would you describe the current and evolving clinical research landscape in India, and what key shifts are shaping its future?
India's clinical research ecosystem has positively evolved over recent years. What was once viewed earlier as a low-cost destination for clinical research is now rapidly becoming a more science, quality, innovation and value driven R&D ecosystem. Recent initiatives like Biopharma SHAKTI signal a clear national commitment to high-end drug development and deeper scientific innovation, rather than just focusing on scale and volume. A few key changes are really driving the process. NDCT2019 rules

have helped the regulatory systems becoming more predictable than before which gives global sponsors greater confidence in working with India than pre-COVID. Technology is no longer an add-on but a part of how trials are designed, with data-led tools and hybrid models helping improve efficiency, patient access and operational quality. At the same time, stronger infrastructure through experienced sites and specialised institutions, investigator capability and expertise is making a real difference on the ground. Together, these developments are helping India evolve into a trusted, innovation-centric and globally integrated

clinical research destination.

How is digital innovation - particularly decentralised and virtual clinical trial models—transforming trial design, execution, and patient participation in India?
Digital innovation has fundamentally changed how clinical trials are designed and conducted in India. Instead of being limited to large urban hospitals, trials are increasingly using hybrid models where critical procedures happen at accredited centres, while routine follow-ups and monitoring can take place closer to a patient's home. Tools like electronic consent, mobile-based endpoint reporting, and digital health platforms such as ABHA are making participation and data gathering easier and real time. By reducing the need for frequent travel and using technology to stay connected, decentralised approaches are helping trials become more inclusive, practical, and patient-friendly, while still maintaining strong medical oversight and safety standards.

What recent policy and regulatory developments are most significant for clinical research, and how is India progressing towards global regulatory harmonisation?
Recent policy changes have made a noticeable difference in how clinical research operates in India. The updated NDCT Amendment Rules have simplified processes for certain low-risk studies and reduced approval timelines for others, making the system more predictable and efficient. This shift shows greater trust in sponsors while still maintaining regulatory oversight. At the same time, India is steadily aligning with global standards by strengthening data protection norms, formalising CRO registration, and harmonising pharmacopoeia standards. Initiatives like Biopharma SHAKTI have energised the Clinical research fraternity in the country by the emphasis on 1000+ clinical trial sites in the country and additional strengthening of the scientific review within the regulatory system in India which also reflect a clear intent to support advanced therapies and innovation. Overall, these developments show that India is serious about building a globally aligned, credible, and future-ready clinical research ecosystem.

Across core domains such as clinical operations, data management, medical writing, biostatistics, pharmacovigilance, and real-world evidence, where has India made the greatest progress and where are the key gaps?
In 2026, India serves as the reliable "technical engine" for global research, where our mastery in Data Management has evolved from simple outsourcing into a sophisticated, hub operations powerhouse. While we are world-class at managing the heavy lifting of data and regulatory writing, a human gap is still present in our specialised fields where we still lack clinical development professionals at scale who can develop indigenous protocols from India for global drug development keeping the scientific tenor at pace. We are incredibly efficient at processing safety reports in pharmacovigilance, yet we still need more veteran medical experts who can spot safety signals before they become problems and also efficiently work with the global data sets and triage them in India. Similarly, despite our massive digital health push, our Real-World Evidence is still finding its feet due to fragmented hospital records, and our capacity for Phase I trials remains limited to a few elite centers rather than being a nationwide reality. Our skilled manpower at sites is a strength where partnership with BIRAC, ICMR and all agencies working on the mission of 1000+ sites in India will be the opportunity for the upcoming years.

How are patient-centric and ethics-led research approaches being strengthened in Indian clinical trials today?
Truly patient-centric and ethics-led research at the site level in India means moving beyond compliance to genuine partnership with participants. Patients and their care givers are treated as informed partners, with consent explained in simple, local languages and supported by assisted digital tools where needed. Patient's are also ensured of flexible visit schedules, and remote monitoring where appropriate. The involvement of caregivers cannot be underscored as they are an important pillar of patient centricity. We also need involvement of the patient advocates to work to have patient voice incorporated in our protocols so that the designs are such that they promote practical usage close to clinical practice as much as possible depending on the disease under study. The ethics committees are also partners in making this as simple for the patient as possible. Ultimately, ethical research today is about trust, transparency, and making participation practical and respectful for every patient and their caregivers.

What opportunities and challenges do you see in academia–industry collaboration, particularly in building a future-ready clinical research workforce?
Academia–industry collaboration offers a valuable opportunity to move from theoretical knowledge to practical, impact-driven innovation. India has strong academic talent, and when this is combined with industry's funding, infrastructure, and real-world exposure, it can help build a workforce that is prepared for emerging areas such as biologics, advanced analytics, and digital clinical trials. This is particularly important as clinical research becomes increasingly data-driven and technology-enabled. At the same time, there is a gap that needs attention. Academic institutions often operate on longer research timelines, while industry works with speed and commercial urgency. Bridging this difference will require deeper and more structured engagement through joint research programs, hands-on training, shared facilities, and real-world problem-solving initiatives. This will ensure that students enter the workforce not only with strong academic foundations but also with the practical skills and adaptability needed in a rapidly evolving clinical research ecosystem.

As India aspires to be a global clinical research hub, what skills, career pathways, and ecosystem enablers will be most critical in the coming years?
As India works toward becoming a global clinical research hub, the skills required are clearly changing. Professionals will need to combine strong medical knowledge with digital capabilities such as data analytics, AI tools, decentralised trial platforms, and a solid understanding of data privacy and regulations. The focus is shifting from routine execution to problem-solving and evidence generation. We are also seeing new roles emerge, including clinical data specialists, decentralised trial planners, and real-world evidence analysts. At the same time, stronger site networks, support for biologics research, better industry and academia collaboration, and faster, globally aligned regulatory systems will be key enablers. The future belongs to professionals who are adaptable, digitally fluent, and patient-focused.

On the occasion of Women's Day, what message would you like to share with women aspiring to build and lead impactful careers in clinical research?
Women have always played a vital role in shaping life, communities, and progress — and their contribution to science and healthcare is equally powerful. Clinical research is a field that requires empathy, integrity, attention to detail, and strong leadership. Many women bring these strengths naturally and their growing presence in this space continues to enrich the industry in meaningful ways. To those aspiring to build meaningful careers in clinical research, my message is simple: believe in your abilities, keep learning and step forward with confidence. Don't hesitate to take on leadership opportunities or make your voice heard. Our industry thrives on diverse perspectives and inclusive thinking, that is how we design research that is ethical, equitable, and truly patient-centered. Your contribution can shape not just studies, but lives. Stay confident, stay curious, and never underestimate the difference you can make. It is often observed that when men exhibit visionary and strategic leadership, credit is attributed to their personal capabilities. However, when women demonstrate similar leadership qualities, it may be perceived as dominance, with recognition frequently extended to the team instead. Regardless of how credit is assigned, it should not be regarded as the sole measure of success. Instead, focus on discovering your purpose and lead authentically according to your individual leadership style.

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Targeted incentives for innovation-driven research would further strengthen India's biotech ecosystem

Venkat Nelabhotla, Co-Founder, President and CEO of Vyome Holdings, shares how focused innovation, disciplined development and policy support can accelerate India's emergence as a global biotech innovation hub, in an interview with **Lakshmipriya Nair**

What unmet need are you fundamentally solving?
Vyome is focused on areas of significant unmet medical need within immuno-inflammatory disorders and supportive oncology. In several such conditions, available therapies may not fully address patient needs in terms of efficacy, safety, tolerability, or accessibility. In supportive oncology in particular, many patients experience complications that meaningfully affect quality of life during treatment. Our development efforts are directed toward scientifically grounded, differentiated approaches in these areas, with the objective of contributing to improved patient outcomes where current options remain limited or suboptimal with a very cost-effective development models.

What is the next phase of growth for Vyome — pipeline expansion, geographic expansion, or strategic partnerships?
Our current focus remains on advancing our existing development programs in alignment with applicable regulatory pathways and clinical milestones. As part of our broader strategy, we continuously evaluate opportunities for geographic expansion and strategic collaborations that align with our therapeutic focus and long-term objectives. Any such initiatives are undertaken in a measured manner, with attention to regulatory compliance, capital discipline, and sustainable growth.

Many biotech firms struggle to transition from R&D to commercial scale. How is Vyome preparing for that shift?
We recognise that the transition from research and development to commercial scale requires careful planning and execution. Our approach incorporates early consideration of regulatory

requirements, manufacturing scalability, quality systems, and intellectual property protection. By integrating commercial awareness into development-stage planning, we aim to reduce operational risks associated with later-stage progression. As with all development-stage companies, future commercialisation is subject to successful clinical development, regulatory approvals, and other factors beyond our control.

How is AI or data science influencing your pipeline strategy?
We view AI and data science as supportive tools that can enhance analytical capabilities across research and development activities. These technologies may assist in improving decision-making efficiency, data interpretation, and clinical trial optimisation where appropriate. However, scientific rigor, regulatory compliance, and validated clinical evidence remain the primary drivers of our development strategy. Our use of AI-related tools is pragmatic and aligned with established regulatory and scientific standards.

What policy shifts would most accelerate innovation-led biotech in India?
From an industry perspective, predictable regulatory timelines, alignment with global standards, and targeted incentives for innovation-driven research would further strengthen India's biotechnology ecosystem. Continued investment in clinical trial infrastructure, biologics manufacturing capabilities, sovereign biotech zone, global talent mobilisation, and Indian talent development can also enhance competitiveness. Policy clarity and consistency are particularly important for long-gestation biotech programs, where capital allocation decisions depend on regulatory and operational predictability.

How strategic is India in your long-term global ambitions — as a talent hub, clinical hub, or commercial market?
India remains strategically relevant across multiple dimensions, including scientific talent, development capabilities, and market potential. The country offers strong technical expertise and an evolving regulatory framework that increasingly aligns with global standards. As both a development environment and a growing healthcare market, India forms an important part of our broader strategic considerations. Future expansion decisions will continue to be guided by regulatory developments, clinical progress, and market conditions.

What is the single biggest strategic bet Vyome is making today?
Our core strategic focus is on advancing differentiated immuno-inflammatory science within carefully selected therapeutic areas. We believe that maintaining clarity of focus and scientific depth is essential in a capital-intensive and highly regulated industry. This strategy is subject to the inherent uncertainties of clinical development and regulatory review, and our efforts remain aligned with prudent risk management.

Where do you envision Vyome in the next decade?
As a development-stage biotechnology company, our long-term aspirations are to build a scientifically credible, globally compliant organisation with a defined therapeutic focus. Our progress over the coming decade will depend on clinical outcomes, regulatory approvals, capital availability, and market dynamics. We remain committed to disciplined execution, scientific integrity, cost effective development, capital discipline and delivering meaningful value to patients and stakeholders within the framework of regulatory compliance.

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Industrial and infrastructure sectors are undergoing rapid modernisation

In the pharma sector, precision is non-negotiable and compliance is constant. Attention often focuses on formulations and manufacturing processes; yet the foundation of operational excellence lies in infrastructure — the systems that quietly ensure safety, efficiency and regulatory adherence. **Jinali Gandhi,** Director at Gandhi Automations, represents a new generation of leaders shaping this critical dimension of the industry

How critical is infrastructure automation in pharma facilities?
Infrastructure is integral to maintaining controlled environments. In pharma manufacturing, environmental stability is directly linked to product quality and regulatory adherence. Access systems must support air pressure control, thermal insulation, contamination prevention, and secure material flow.

Automation strengthens this framework. Rapid-action doors reduce air exchange in classified zones, insulated closures help maintain stringent temperature parameters, and sealed loading bays protect sensitive products during dispatch. By minimising manual dependency and ensuring operational consistency, automated systems enhance reliability across the facility.

In pharma, infrastructure is not peripheral — it is a compliance enabler.

What differentiates pharma infrastructure from other industrial sectors?
Pharma facilities operate with an exceptional level of precision. In this industry, even small environmental shifts can have serious implications, which means infrastructure has to be designed with far greater attention to detail. Everything must align with cleanroom classifications, inspection requirements and international regulatory standards from the outset.

> Women leaders bring analytical decision-making, collaborative execution and long-term strategic thinking — qualities that align strongly with infrastructure planning and risk management

For us at Gandhi Automations, it's never just about supplying a door or dock solution. It's about understanding how that system supports the wider environmental strategy of the facility. We look at durability, traceability, integrated safety and consistent performance under demanding conditions — because in pharma, infrastructure has to deliver certainty, not just functionality.

As a young leader in automation, what has shaped your professional journey?
Curiosity and consistency have shaped my journey the most. I made it a priority to understand the technical side of the business — how the products work, the regulations that govern them, and the markets we operate in. In engineering-driven sectors, credibility comes from delivering results, not titles. Over time, staying informed, decisive and accountable naturally builds trust with teams and clients alike.

How is automation transforming pharma logistics?
Automation is reshaping pharma logistics by making access systems smarter and more responsive. High-speed doors, insulated cold room doors and advanced loading bay equipment are now integrated with facility monitoring platforms, allowing better visibility and predictive maintenance. This reduces unexpected downtime and supports more efficient operational planning.

At the logistics end, well-engineered dock systems and sealed loading systems improve vehicle turnaround while protecting temperature-sensitive products. The result is stronger supply chain continuity, improved energy efficiency and safer material handling — all critical in an industry where reliability directly impacts product integrity and regulatory compliance.

How do you see women contributing to the evolution of the industrial and infrastructure sectors?
Industrial and infrastructure sectors are undergoing rapid modernisation. Digital integration, sustainability objectives and global standardisation are redefining performance benchmarks. Diverse leadership plays an important role in navigating this transition.

Women leaders often bring analytical decision-making, collaborative execution and long-term strategic thinking — qualities that align strongly with infrastructure planning and risk management. As more women assume roles in engineering, manufacturing and international operations, the sector benefits from broader perspectives.

What truly differentiates Transchem is our technical-first approach

Sanjay Lanke, VP - Technical Business Development, Transchem Corporation Pharma, outlines its focus on innovation, strategic partnerships, and portfolio diversification to support complex formulations while expanding its presence across pharma, nutraceutical, and food ingredient markets, in an interview with **Lakshmipriya Nair**

What are Transchem's core focus areas today, and which segments are driving your growth?
Transchem's core focus today is on delivering high-quality, regulatory-compliant excipients and specialty raw materials that enhance formulation performance and manufacturing efficiency. Transchem is building its identity as a specialty excipient solutions company, not merely a sourcing organisation. Our growth is powered by high-performance excipients, regulatory-sensitive materials, and strategic collaborations with leading manufacturers across globe. As the pharmaceutical industry shifts toward complex generics and specialty formulations, demand for technically supported excipients continues to accelerate, directly contributing to our growth trajectory.

What differentiates Transchem in the technical services and specialty chemicals space?
What truly differentiates Transchem is our technical-first approach. We operate at the intersection of global quality and local agility. We specialise in excipients that require more than distribution — they require understanding. From solubility enhancement and bioavailability optimisation to controlled-release systems and process efficiency improvements, our team works closely with formulators to ensure functional alignment with product goals. Our strength lies in translating international manufacturing excellence into practical, formulation-ready solutions for our customers. This technical interface is a core differentiator and a direct contributor to repeat business and long-term partnerships.

What is your strategy for expanding market share, both domestically and internationally?
Our strategy is based on transformation rather than expansion alone and is focused on quality, diversification, and strategic partnerships.

We are expanding our excipient portfolio, strengthening supply chain reliability, and offering technical advisory support into our service model. Our focus is on deepening market presence by building strong, technically driven partnerships with formulation companies. We have moved from being a distributor to becoming a strategic supply partner.

Simultaneously, we plan to enter the food and nutraceutical segments in a calibrated manner. With increasing consumer demand for preventive healthcare and tightening compliance standards under regulators like the Food Safety and Standards Authority of India, we see a convergence between pharmaceutical-grade quality and nutritional applications. This convergence aligns perfectly with our strengths, and our compliance-driven foundation gives us a distinct

competitive advantage in this space.

Internationally, our strategy is to broaden our manufacturer base by adding reputed global producers to our portfolio. This will strengthen supply chain resilience, enhance product depth, and allow us to offer innovative and specialty ingredients to our customers. Over the next few years, we envision a balanced revenue mix across pharma, nutraceutical, and food ingredients — positioning us as a trusted global ingredient solutions provider."

How is Transchem positioning itself against global competitors?
We do not compete by scale alone — we compete by relevance. In an era where several Indian distributors have been acquired by multinational groups, Transchem has consciously remained independent and that is our strategic advantage.

Independence gives us agility, faster decision-making, and the flexibility to serve customers without global structural constraints. We combine deep local market understanding with international quality benchmarks. At the same time, we are expanding our global manufacturer portfolio to match multinational standards in compliance, innovation, and supply reliability. Our positioning is clear: globally aligned, independently driven, and strategically agile."

What role does innovation and technical capability play in your long-term growth plans?
Innovation is central to our long-term vision. In the excipient space, innovation does not always mean new molecules — it often means improved functionality, better processing efficiency, enhanced regulatory compliance, cost-effective alternatives without compromising quality.

We are continuously expanding our technical knowledge base and strengthening application support to align with evolving formulation challenges, including bioavailability enhancement, patient-centric dosage forms, and complex generics.

How are you building strategic partnerships while managing pricing pressures and protecting margins?
In today's environment, pricing pressure is a constant — but we do not compete on price alone. Our strategy is firmly value-led and margin-disciplined. We focus on partnerships that drive predictable volumes and shared growth rather than short-term deals. Diversified sourcing and portfolio optimisation help us stay competitive while protecting margins.

Where do you see Transchem in the next 3–5 years, and what investments will shape that journey?
The excipient industry is evolving rapidly. With formulation complexity rising and regulatory expectations intensifying, traditional supply models are no longer enough. The next chapter of specialty excipients will be defined by expertise, agility, and strategic partnerships. Transchem intends to lead that chapter. We envision Transchem evolving into a diversified, globally competitive ingredient solutions provider. We are expanding our portfolio by adding reputed new pharmaceutical excipient manufacturers and entering the high-growth food and nutraceutical segments. Strategic investments will focus on broadening our global sourcing network, introducing higher-value and specialty products, and strengthening supply chain capabilities. The goal is to deliver consistent quality, innovation, and commercial value to our customers while positioning Transchem as a trusted partner across pharma, nutrition, and functional food industries.

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Glass vs other pharma packaging materials: Safeguarding purity, enhancing trust

Rajesh Khosla, CEO, AGI Greenpac explains why glass stands out as a trusted material that continues to meet modern pharma's safety and sustainability demands

In the highly regulated world of pharmaceuticals, packaging is trusted to deliver efficacy, stability, and patient safety. As medicines evolve, the choice of packaging material has never been more critical. Among the many materials available today, glass continues to hold a special position, offering unmatched protection, purity, and sustainability.

While the industry has innovated in terms of drug delivery and manufacturing, the packaging segment needs to balance modern convenience and uncompromised safety. In this balance, glass has consistently demonstrated that it remains at the gold standard.

One material, many benefits

At the core of pharma packaging lies the need for chemical stability. Medications must reach patients in their intended potency, free from contamination. Glass, being inert, does not interact with the drug it contains. This property ensures that the medication's composition remains unchanged from the moment it leaves the manufacturing line to the time it reaches the patient.

In contrast, some polymer-based containers can pose risks of. Even trace amounts of such contaminants can compromise product efficacy or trigger adverse reactions, particularly in sensitive formulations like vaccines or injectable medication.

This inertness gives glass an irreplaceable edge in critical applications such as vials, ampoules, and prefilled syringes - where purity is of prime importance.

Pharma products are often highly sensitive to environmental factors such as moisture, oxygen, and light. Glass provides a near-perfect barrier against all three. It does not allow gases or vapours to filter through, thereby maintaining the chemical integrity and shelf life of drugs.

Other alternatives, while lighter and less fragile, often require complex multi-layered coatings to achieve comparable protection - adding both cost and complexity to the packaging choice.

For light-sensitive formulations, amber glass serves as an effective shield, protecting drugs from photodegradation without the need for additional stabilisers that could otherwise compromise purity.

The pharma sector has very stringent standards of hygiene and sterility. Glass, being sterilisation friendly through methods such as autoclaving, gamma irradiation, and dry heat, meets these requirements perfectly.

> Modern glass packaging is a product of continuous innovation – that have seen the version of glass as we know of it today. These advancements have made glass packaging more robust, cost-efficient, and adaptable to high-speed filling lines

Some other materials may deform or degrade under high temperatures and can absorb sterilising agents, leading to potential contamination risks. The reusability of glass makes it ideal for repeated sterilisation cycles - particularly in hospital and laboratory environments.

Sustainability: Aligning health with environmental responsibility

Beyond functionality, the packaging industry now also needs to address concerns about its environmental footprint. In this regard, glass stands apart as a sustainable material that can be endlessly recycled without losing purity or performance. Every recycled glass container contributes to reducing raw material consumption, lowering energy use, and cutting carbon emissions.

While certain other lightweight materials have long been considered convenient, their environmental impact has raised significant concerns. The healthcare sector, with its vast consumption of single-use materials, is also under increasing pressure to adopt circular practices. Glass, with its infinite recyclability, offers a tangible path forward in building a greener pharmaceutical supply chain.

Innovation within tradition

It would be simplistic to view glass as a relic of the past. Modern glass packaging is a product of continuous innovation – that have seen the version of glass as we know of it today. These advancements have made glass packaging more robust, cost-efficient, and adaptable to high-speed filling lines.

Moreover, innovations in borosilicate and aluminosilicate glass compositions have further improved resistance to delamination and thermal shock. The result is a material that not only meets the demands of modern pharma manufacturing but is also future ready.

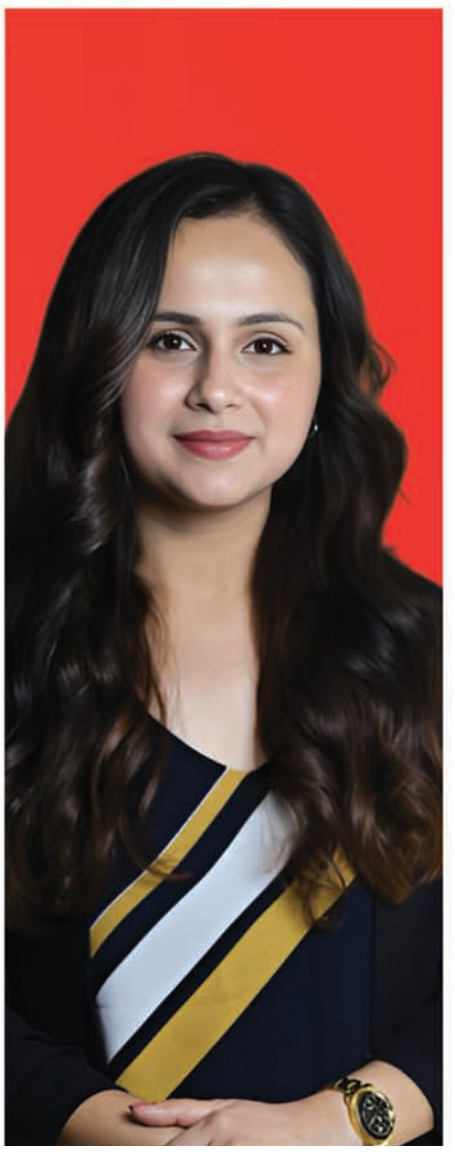
Balancing performance and practicality

It is undeniable that glass comes with its own set of challenges. But, when evaluated against its advantages, these limitations are often outweighed by the factor of product integrity.

In many cases, hybrid solutions are also emerging, combining the strength of polymer exteriors with the purity of glass interiors. These innovations point towards a future where performance and practicality coexist, ensuring that packaging never compromises patient safety.

Pharma packaging is ultimately about trust - trust that the medicine reaching the patient is safe and effective. In this pursuit, glass has maintained its standing as the most reliable and sustainable material available.

As the pharma landscape evolves to newer treatments and stricter environmental standards, glass remains not a material of the past, but a foundation for the future.



Women shaping pharma today share honest lessons and real-world leadership wisdom for the next generation of women who dare to lead

ADITI KARE ANANDIKAR

MD, Indoco Remedies

My dear Bhavani,

I refer to you as 'Bhavani', the form of goddess Durga who has eight hands and is revered for her creative power, her free spirit and looked upon as the universal mother. I call you Bhavani because that's what it's going to take. Like Bhavani's eight hands, you will endlessly juggle eight important priorities in your life; work, home, parents, spouse, children, siblings, friends and most importantly, YOU. You will do it all because, like me, you will soon realise that success at work will only come if you're happy and successful in all facets of your life. You will understand that these eight compartments will have differently proportioned significance, depending on where you are in the lifecycle. In my 33 years at Indoco and raising two kids, I have missed only one parent-teacher meeting. That's where the 'better' halves or your support system comes in. Never underestimate their significance and contribution to your success.

You have embarked on a very challenging and fulfilling journey of performance, growth and success. As you progress, there will be many highs, even more lows, many sleepless nights, even more days of exhilaration, but I promise you an unforgettable and interesting journey. You will do well if you capitalize on your inherent qualities as a woman, those of compassion, kindness and humility, they will be your enablers as you lead your teams towards success. We often self-restrict our own progress by imagining the perennial glass ceiling that restricts us from aiming higher. Remember, our competition is with ourself and no other. After all, statistics have shown that we live longer and healthier than the perceived 'stronger' sex. Strive not to be the 'best man for the job' but the best 'person' for it.

If I could speak to the younger version of myself, I would tell her that it is ok to feel unsure sometimes and that the leadership path is rarely straight. We need resilience to keep moving forward even when the path ahead is not fully visible.

Today, you are part of a vibrant and resilient industry that stands at crossroads of innovation and government policy. In this VUCA world, this is both surreal and an opportunity where one needs to have new skills and lead with agility. Success comes with hard work. Today, there are many opportunities and the environment is socially far more conducive for women.

Think Equal, Build Smart, Innovate for Change. Your journey may feel uncertain at times, but every challenge you take is shaping the leader you will become.

Happy Women's Day!

SUNEELA THATTE

VP & Head, Merck Healthcare R&D India

Dear Future Women Leaders,

As I reflect on my three decades of biopharma R&D, clinical research, and business leadership journey, I don't just see milestones- I see conviction, courageous choices, and the quiet resilience that helped me move forward. The safer path often felt tempting, yet growth rarely lives in comfort. Every challenge stretched me, and every risk opened doors I could not have imagined.

I have been privileged to lead highly talented teams, build successful organizations, drive sustainable growth across businesses and functions, and contribute to re-establishing and strengthening drug development and clinical research in India through stakeholder advocacy. Through this journey, one truth remained constant- consistent results are built on people, culture, and collaboration, and get reflected in business performance, employee engagement, and customer trust.

What sustained me most were people- mentors who challenged me, enriched my perspectives and encouraged me to raise my hand for accepting challenges head on, teams who believed in shared purpose, and collaborations that reinforced that innovation is never a solo pursuit. I would therefore advise you to seek mentors widely, even beyond pharma. Diverse perspectives sharpen judgment and deepen empathy. And as you grow, be mentors to others- as you will get valuable insights from your mentees that will further sharpen your leadership skills.

Engaging with industry forums has shown me the power of collective voices- when we come together, we shape balanced policies and drive meaningful progress. True leadership is not about standing alone; it is about building bridges, amplifying voices, and creating pathways that empower others.

We belong to the healthcare domain where I see leadership as a privilege- an opportunity for shaping progress with purpose. We are not merely building careers; we are advancing science that touches lives. So, stay curious, invest in learning, and actively build bridges across academia, research, and industry- where meaningful innovation truly accelerates.

Equally vital is the culture we nurture. The future of healthcare must be inclusive- where diversity of thought, background, and experience is actively valued, equity is championed, and every voice feels safe to contribute. Inclusive environments make innovation stronger and more human.

Finally, it is important to recognize that leadership is not sustained by professional success alone. Family, personal well-being, and a strong support system provide the grounding that enables long term effectiveness. Priorities will shift across life stages and balance is rarely perfect, but being intentional about what matters most will help you lead with clarity and resilience.

The path ahead needs your courage, compassion, and leadership. Therefore, embrace uncertainty. Speak up even when it is difficult. Take your seat at the table- and whenever possible, create more seats for others. In all this – do not forget to celebrate yourself and your teams and do nurture a hobby that will help you stay balanced.

All the best in shaping the future of healthcare!

SHWETA RAI

MD - India and Country Division Head - South Asia, Bayer's Pharmaceutical Division

Dear Future Women Leaders,

There is no substitute for hard work and no shortcuts to success. This is true not just for women but for everyone, including the next generation. With 25 years of industry experience, I learned that passion, resilience and determination are what ultimately shape our careers. Like many women, I had to balance my personal and professional spheres, overcome both, and unconscious bias, prove myself repeatedly and still steer ahead with confidence. What kept me steady was self-belief, a commitment to learning and excelling, and the support and guidance of my family and mentors.

The milestones I value most are the roles I chose to experiment with. I made a deliberate decision not to become comfortable, because growth rarely happens there. Each new assignment forced me to learn, adapt and perform beyond what I initially believed possible. Some of my most meaningful lessons came from challenging phases and even setbacks. There were also times when I shifted roles or chose to step back from certain opportunities to balance work, children and family priorities. I have always cherished that balance. Leadership is not diminished by a full personal life. Achievements feel richer when we have people with whom we can share our joy.

If you are keen to build a career in healthcare and pharmaceuticals, invest deeply in knowledge. This is a complex and technical field. Understanding the science, the relevance for patients and doctors and the environment in which they exist builds expertise.

Leadership is a marathon – you must be patient with your growth while celebrating others' successes as readily as your own. As we approach International Women's Day 2026, the theme of "Give to Gain" comes to mind. It reminds us that the progress we strive for is not just for women, but for everyone—men, women, and people of all ages. True progress is about recognising the individual strengths each person brings to the team and nurturing those skills. We all stand to gain when we foster an inclusive environment where diverse perspectives are valued and celebrated.

At the same time, we must acknowledge that women have entered professional spaces in larger numbers only in recent decades. Many still hesitate to highlight their achievements or voice their perspectives confidently. It is important to speak with clarity, to articulate your achievements with confidence and take measured risks. Focus on merit, integrity and what you can achieve together.

As more women step into leadership, we strengthen our journeys as well as the industry and country at large. Embrace opportunities and challenges, support those around you and collaborate with intent. A true measure of leadership lies in shaping systems that outlast you.

DR SALONI WAGH

MD, Supriya Lifescience

Dear Future Leader,

If you are reading this, you are probably standing at the beginning of something. A dream, a career, or perhaps a decision that feels bigger than you. I remember that feeling very clearly.

I grew up watching a business being built from the ground up. But inheriting a legacy and earning your place in it are two very different journeys. When I formally entered Supriya Lifescience, I quickly realised that respect is never inherited. It is built slowly, through work, consistency and integrity.

With a background in Analytical Chemistry, I decided that before I could lead, I needed to understand. I worked across functions, including marketing and business development in Southeast Asia, one of our key regions. I wanted to see how decisions affected teams, customers and numbers. Learning every layer of the organisation gave me confidence that no title alone could provide.

Even then, the journey was not simple. In rooms filled mostly with men, especially during technical and operational discussions, I often had to work harder to prove that I belonged there. There were moments of doubt. I questioned whether I was being heard because of my ideas or despite them. Over time, I realised that preparation is power. When you understand your subject deeply, your voice becomes steady, and your presence becomes stronger.

And you know, our IPO in 2021 tested that belief. Engaging with investors and guiding the company through new levels of accountability taught me that leadership is not about authority. It is about responsibility, discipline and staying calm when expectations rise.

At the same time, life does not pause for leadership roles. I became a mother while leading a listed company. There were days when I felt stretched between ambition and empathy, between boardrooms and home. I learnt that balance is not perfect. It is a conscious choice, made every day.

So if I can leave you with anything, it is this. Do not fear small failures. They shape resilience. Respect legacy, but bring your own thinking. Do not shrink yourself to fit into spaces. Prepare yourself so well that your presence becomes natural and necessary.

The future of pharma needs women who believe they belong there. Take the leap. Stay consistent. Your journey matters.

With belief in you

NEHA THAKORE

Director, Avik Pharmaceutical,
Committee Member - IDMA

Dear Future Leaders,

I grew up as the youngest of three sisters in a Gujarati business family—another girl, the "third one." Yet I was privileged in ways I understood only later. My parents never made me feel secondary. My mother was fiercely protective and ambitious for us, and my father—benevolent, tireless, and quietly progressive—never believed that gender defined potential. That belief became my earliest foundation.

I began life armed with idealism. I wanted to fix systems, believed deeply in socialism, and dreamed of joining the administrative services. Life, however, charted a different course. Family expectations, my own pull toward comfort, and the choice of my life partner led me into the family pharmaceutical business.

It was not a graceful entry. The business was struggling. I had to be part of the decision to shut down a manufacturing unit. There were no perfect exits or ideal compensation models—only the hard arithmetic of survival. Still, I showed up every morning.

Married into a joint family, I carried two full-time roles: managing a household and serving as a partner-director in a small pharma company. That was the unspoken reality for many women of my generation. I showed up every day, at 9 a.m. sharp. Discipline, I learned early, is the first tool of survival—and growth.

I tried my hand at sales and failed. I was uncomfortable asking, uneasy with negotiation, and drained by transactional conversations. But leadership has a way of circling back to the lessons we try to avoid. A mentor pushed me back into the market—not to sell harder, but to understand better. He nudged me toward a niche that aligned with my strengths: regulatory compliance. The work finally felt purposeful.

We sold 50 per cent stake in the business—not for valuation or gain, but as a lifeline. We revived our sole manufacturing facility. There was no money to take home—only continuity to protect.

During those years of closures and survival, I became a mother. It was a profound joy and a powerful temptation to step away from the fight. Once again, my own mother stepped in—this time as a mother to my daughter—while I learned how to grow. I came to understand that nurturing is not limited to motherhood. It is nurturing oneself, nurturing a business through uncertainty, and nurturing people into a team.

The hardest transformation was not external. It was internal. I had to confront my scarcity mindset, my risk aversion, and my desire to please. Coaching taught me a lasting truth: integrity is not moral perfection—it is alignment. Saying what you will do and doing what you say. Owning outcomes. Taking responsibility. Acknowledging those who walk with you. Gratitude became my quiet strength.

Today, I see a profitable company, a committed team, and the ability to give back meaningfully. I've journeyed from idealistic socialism to what I now call social capitalism.

If there is one thing I want you to remember: the biggest barrier is rarely the world. It is the limit we place on our own thinking.

Lead with honesty. Decide with data. Choose courage over comfort. Stay in integrity. Keep your commitments —with yourself first. The rest follows

ASAWARI SATHAYE

Director of Communications and Patient Advocacy, OPPI

Dear Future Leaders,

If I could speak to the young woman just stepping into the world of healthcare and policy, I would tell her this: leadership is rarely a straight line. It is built in quiet moments of doubt, in rooms where you are the only woman at the table, and in decisions that test your capabilities, conviction and your compassion.

Working in the pharmaceutical ecosystem has taught me that influence is not about volume, it is about clarity. Communications, especially in healthcare, sits at the intersection of science, policy, patients, and public trust. I have learned that credibility is your most valuable currency. Guard it fiercely. Speak only when you understand the nuance, and when you do speak, stand by your words. Always have data and relevant credible information backing your discussions and actions.

There will be moments when you question whether you belong in high-stakes conversations. In those moments, remember: you are not there by accident. Preparation builds confidence. Curiosity builds perspective. And empathy builds impact. The most effective leaders I have observed are those who listen deeply before they respond.

You will also encounter bias sometimes subtle, sometimes structural. Do not let it define your ambition. Instead, let it refine your resilience. Seek mentors, but also seek sponsors who will advocate for you in rooms you are not in. And when your turn comes, extend that ladder to others. Leadership is not a solo ascent; it is a collective climb.

Balancing ambition with empathy is not a contradiction, it is a strength. In healthcare, our work ultimately touches lives. Behind every policy debate or industry milestone is a patient waiting for access, innovation, and hope to lead a healthier life. Keeping that human lens will anchor you when the landscape feels complex or agenda driven.

Finally, allow yourself to evolve. Your voice will grow stronger with experience, but your values must remain steady. Lead with integrity, communicate with purpose, and never underestimate the power of thoughtful dialogue to shape change.

The future of pharma needs leaders who are informed, inclusive, and courageous. Stay curious, stay grounded, and stay authentic, you will not only find your place, but also create space for many more to lead.

URVEE GARG

Director, HAB Pharma

Dear Future Leaders,

In 2026, we are seeing more and more women stepping confidently into the corporate world. In life sciences especially—pharmaceuticals, medical devices, nutraceuticals—the numbers are encouraging. Women are thriving, contributing, building.

And yet, when I look at leadership tables, I still see a gap. When I look at the top 50 pharma companies in India, only five were led by women: Lupin Ltd (Vinita Gupta), Abbott India (Swati Dalal), Piramal (Nandini Piramal), Aarti Drugs (Aditi Kanakia), and Indoco Remedies (Aditi Panandikar).

Five out of fifty. Ten percent. Better than many industries—but still far from where we could be.I truly believe women are inherently strong leaders. We possess resilience, empathy, strategic thinking, and the ability to balance multiple dimensions at once. What we sometimes lack is not capability—but conviction. The belief that we deserve the seat at the table. The faith that we are eligible for it.

To the next generation, I want to say this: do not be afraid of starting at the grassroots. Many women hesitate to take up roles like being a medical representative because they seem tough, demanding, even uncomfortable. But that "gory" beginning is often the very foundation of deep industry understanding. Knowing what drives a doctor's prescription decision, understanding the realities of the field—this knowledge is powerful.Of course, there are many pathways—R&D, regulatory, marketing, strategy. But whatever you choose, think early. Think big. While you're still in college, ask yourself: Where do I want to be? Do I want to be the next CMO shaping the future of pharma? If yes, what steps today will take me there?Do not be afraid of hard things. Do not be afraid of bold moves.

Take the leap. Aim high.We absolutely belong there.

ARCHANA JATKAR

Associate Secretary General, IPA

Dear Future Trailblazer,

My professional journey began in the courtroom, practicing law, then moved into the analytical rigour of trade policy negotiations and eventually led me to the complex, human-centered world of pharmaceutical policy. Three distinct paths, each demanding a different lens, have shaped how I understand institutions, markets, and people.

My first court appearance was against a well-known Senior Counsel whose years of practice exceeded my age at the time. My senior chose to test me early. I was anxious, but I held on to one thought: I knew my case best. So I stepped forward. That decision to trust my preparation became my first lesson in courage. Often, courage is not dramatic. It simply begins with backing yourself.

Curiosity soon nudged me in a new direction. I left practice of law to pursue my master's in international Economic Law, driven by a desire to understand how international institutions shape national choices. I was drawn to organisations such as the World Trade Organization, World Intellectual Property Organization and to the larger question of how countries design and defend their trade and economic interests. That academic shift widened my lens - beyond individual cases to systems, beyond courtrooms to global frameworks of trading system.

From there, I moved into a trade policy think tank and later into pharmaceutical policy - a space where women are few. The opportunity to work towards welfare of patients and make a real difference in their lives renewed my sense of purpose. Confidence did not arrive fully formed, it grew gradually, each time I entered unfamiliar territory and chose to stay.

Over time, I came to understand that every decade brings change. Technology shifts—today it is AI and machine learning; tomorrow it will be something new. Geopolitics realigns, organisations restructure, roles evolve and once relevant skills fade quickly. In such times, resilience and continuous learning becomes essential for growth. Even when scrutiny & expectations are higher, especially for women, these transitions offer opportunity. For me, they reinforced the importance of staying adaptable, curious, and willing to keep growing.

At times, some seniors felt certain roles were "better done by men," and a few questioned whether empathy belonged in serious work. Over time, I understood that empathy is not weakness, it is a quiet strength, that comes naturally to a woman and manifests in her pragmatism. It helps bring balance, perspective, and better judgment to decisions. I was also fortunate to learn from mentors who led with integrity and kindness and who showed me that professionalism and character must always go hand in hand.

Looking back, my defining moments are not big milestones but steady discipline - understanding the ecosystem, anticipating change, and reinventing when needed. I was guided less by comparison, more by passion and commitment to the work: consistent effort, resilience, and decisiveness when it mattered.

One value never changed - respecting others while trusting my individuality. It anchored me when in doubt and grounded me in success.

If I have to leave you with one thought, it is this: understand your environment, keep learning, and allow yourself to evolve and be passionate for work in hand. Trust your instinct and guard your integrity. It is the strongest armour you will ever wear and to me it is the truest measure of dignity.

DR PRIYA KAPOOR G HINGORANI

MD, Miltenyi Biotec India
and VP APAC

Dear Future Leaders,

My time in the healthcare and biotechnology industry has taught me a few important things; most of all, that organisations are built on people, purpose and the courage to keep moving forward even when the path is not clear.

As I look at how the Indian biotech sector continues to evolve, I feel encouraged by the growing number of women shaping its future. They are leading clinical research, driving innovation, leading organizations and influencing major global business decisions that will define the next era of healthcare.

When I began my journey, leadership looked very different, largely male-dominated, with far fewer visible role models for women. Over the years, I have witnessed a meaningful shift, not only in who leads, but in how we lead.

Working in this field constantly reminds us that our work ultimately affects human lives. That awareness has anchored me through complex decisions, demanding roles and moments of uncertainty. There were times when I was the only woman in the room, when expectations felt unspoken but heavy and when balancing professional ambition with personal responsibilities required difficult trade-offs. Those experiences did not make the journey easy, but they made it purposeful.

What gives me confidence today is seeing women not waiting for opportunities but creating them. By bringing both competence and compassion to leadership. Progress may still be gradual, but it is real. With women representing a significant share of STEM graduates in India (over 40%–43%), the pipeline of talent is strong. The task ahead is to ensure that this talent finds pathways to leadership.

In my journey at Miltenyi Biotec, I've experienced how women can lead confidently across borders, bringing diverse teams together and turning scientific collaboration into real-world impact. I also see leadership through an entrepreneurial lens, i.e. building new pathways, fostering partnerships, and creating platforms where innovation can scale globally.

If you are starting out, know that you do not have to fit a predefined mould. Leadership does not require you to be the loudest voice in the room. Often, it is about asking the right questions, building trust and staying committed to the larger purpose.

The future of healthcare will depend on diverse perspectives and resilient leadership. I am hopeful that the next generation of women leaders will step forward with confidence, support one another and continue shaping a more inclusive and impactful ecosystem.

Tech, trust and traceability: Shaping India pharma's future

At the PPL Conclave 2026, hosted by **Express Pharma**, industry leaders explored how innovation, operational excellence and evolving regulations are positioning packaging as a strategic driver in India's pharma growth, reports **Neha Aathavale**

The eighth edition of the Pharma Packaging & Labelling Conclave, organised by *Express Pharma,* brought together packaging heads, regulatory leaders, material scientists and technology providers from across India Pharma Inc. The conversations were not about discovering something entirely new. Instead, they focused on examining what is already unfolding across plants, R&D centres and boardrooms, and analysing it through sharper operational and strategic lenses.

Over two days, the conclave revisited familiar industry pressure points while layering them with new realities around artificial intelligence, connected systems, global compliance shifts and advances in material science. Across sessions, a common understanding emerged. Packaging is no longer a downstream activity that begins after formulation finalisation. It increasingly influences development pathways, regulatory submissions, cost structures, lifecycle management and patient experience.

L-R: Dr K Anand Kumar, Indian Immunologicals; M Gopi Reddy, Sun Pharma; Atul Shastri, Eugia Pharma Specialities; and Viveka Roychowdhury, Express Pharma

L-R: Mr Avinash Kumar Talwar, Dr. Reddy's Laboratories; Manoj Kumar Pananchukunnath, Biocon; Dr Tathagata Dutta, Jodas Expoim; Sekhar Babu Puli, MSN Laboratories; Mahendra Kumar Sahu, Sun Pharmaceutical Industries

Leadership priorities redefining packaging

From the outset, discussions were anchored in practical leadership priorities. The opening leadership session, moderated by Viveka Roychowdhury, Editor, Express Pharma, brought together Dr K Anand Kumar, Managing Director, Indian Immunologicals; M Gopi Reddy, Vice President and Head – Corporate Quality, Sun Pharmaceutical Industries; and Atul Shastri, President – Global Operations, Eugia Pharma Specialities, to examine what pharma leaders must get right about packaging today.

The discussion highlighted four interlinked essentials: product protection, patient-centric usability, regulatory compliance and traceability. The panel emphasised that these are not parallel objectives but interconnected responsibilities. A weakness in one area can quickly create vulnerabilities in the others, particularly in tightly regulated and globally scrutinised markets.

Sustainability was presented not as a passing trend but as a responsibility linked to long-term industry viability. Measures such as reducing non-essential components, optimising pack configurations and evaluating material alternatives were discussed in relation to efficiency, cost control and regulatory preparedness. Counterfeiting was similarly examined as a systemic risk extending beyond supply-chain inconvenience to patient safety, brand credibility and regulatory standing.

Technology, the panel noted, must function as an enabler rather than a standalone solution. Robust design, careful material selection and cross-functional alignment remain essential for consistent packaging performance.

Packaging as strategic leverage

The same theme was explored in the keynote address on Day 2 of PPL Conclave 2026 by Chakravarthi AVPS, Chairman, Federation of Pharma Entrepreneurs (FOPE), Telangana and Andhra Pradesh. He positioned packaging not as operational support but as strategic leverage for India Pharma's global ambitions.

As the industry strengthens its international footprint, the transition from volume-driven growth to value creation becomes critical. Packaging, he emphasised, cannot be appended at the final stage of development but must evolve alongside the drug itself. For complex and specialty therapies, packaging becomes part of the treatment ecosystem, influencing adherence, safeguarding patient safety and shaping patient experience. Sensor-enabled and AI-supported packaging systems are already enabling a shift from reactive recalls toward proactive quality assurance. Environmental obligations, carbon footprint considerations and compliance-linked trade mechanisms are also emerging as competitive variables influencing global market access.

From strategy to execution

With leadership clarity setting direction, discussions at the PPL Conclave 2026 addressed execution realities within manufacturing environments. Tripti Nakhare, VP – Regulatory Affairs and Packaging Development at FDC, highlighted that serialisation is no longer an add-on compliance requirement. When integrated into core packaging operations, it strengthens stability, reduces line disruptions, improves throughput and enhances audit readiness.

Extending this operational perspective, Manjunath Nadella, AVP and Head – Packaging Development, Strides Pharma Science, stressed that sustainability must be engineered into packaging design from the outset. Right-sizing bottles and blister packs, simplifying closures and reducing polymer usage not only conserve materials but also improve logistics efficiency and warehousing performance.

What emerged was a systems-led view of packaging, where automation capability, material science and supply-chain strategy must align early in development. In such alignment, sustainability shifts from aspiration to measurable operational outcome.

Smart, digital, connected packaging systems

As operational discipline

L-R: Dr Sajeev Chandran, Lupin; Loganathan S, Onesource Biopharma; Dr Vaibhav Dubey, Kashiv Biosciences;

L-R: Mr Praveen Kumar Narlanka, Aurobindo Pharma; Tridip Mazumder, Dr.Reddy's Laboratories; Shivaji Chakraborty, Fresenius Kabi Oncology; Sailesh YHNB, Novo Nordisk; Dr Srikanth Reddy Sokkula, Jodas Expoim; Narendhar Kavide, Orbicular Pharmaceutical Technologies; Leena Padala, Eugia Pharma Research Centre; Nagendra Kumar Mall, Baxter Pharmaceuticals India

L-R: Ajay Bapat, Packaging Consultant; Prafull V Deshpande, Lupin; Satyanarayana Nandula, Laurus Labs; Munindra Roy, Gland Pharma; Amit Pathak, Inventia Healthcare; Hari Prasad, Jodas Expoim

Chakravarthi AVPS, Chairman, Federation of Pharma Entrepreneurs (FOPE), Telangana & AP

Hari Kiran Chereddi, MD & CEO, HRV Pharma

Tripti Nakhare, FDC

Manjunath Nadella, Strides Pharma Science

Jitesh Jadhav, Sun Pharma

strengthens, digital intelligence is increasingly shaping packaging performance at scale. The session steered by Avinash Kumar Talwar, VP and Head – Strategic Procurement (Packaging), Global Procurement, Dr. Reddy's Laboratories, brought together Manoj Kumar Pananchukunnath, Chief Scientific Officer, Biocon; Dr Tathagata Dutta, President, Jodas Expoim; Sekhar Babu Puli, AVP and Head – Packaging Development, MSN Laboratories; and Mahendra Kumar Sahu, GM, Sun Pharmaceutical Industries.

A clear consensus emerged that packaging is no longer confined to containment. Technologies such as QR codes, NFC, RFID and serialisation now enable unit-level authentication and track-and-trace capability. Each pack can be authenticated, monitored and verified, strengthening transparency across supply chains while building regulator and patient confidence.

Importantly, connected packaging systems generate data that feeds back into R&D, manufacturing and quality operations. These insights are accelerating development timelines, enabling predictive interventions and strengthening lifecycle control.

AI in action

As the focus turned toward future-ready operations, in a presentation, Jitesh Jadhav, Manager – Packaging and Medical Devices, Sun Pharmaceutical Industries, highlighted how AI has moved from experimentation to practical application across packaging and device systems.

AI-powered vision systems now enable accurate tablet counting, real-time defect detection and smarter assembly processes, reducing variability while improving throughput and quality assurance. Digital tools are also accelerating development cycles through simulation-based validation and streamlined documentation workflows.

By analysing batch-level patterns, AI helps identify deviations early and supports root cause analysis, improving approval readiness and audit confidence. Across discussions, AI was consistently framed as an operational enabler embedded within existing systems rather than a replacement for human expertise.

Future-proofing packaging for advanced therapies

In parallel with intelligent and connected systems, the conclave also examined packaging challenges associated with biologics,

L-R: Dr Ravikumar N, MSN Laboratories; Prabir Das; Bhupesh Kumar Mittal, Bayer Consumer Healthcare; Avadhesh Sarawagi, Amneal Pharmaceuticals; Ramesh Punnam, Aurobindo Pharma; Pradip Som, Aculife Healthcare; Bhavesh A Shah, Intas Pharmaceuticals

L-R: Soumyanath Mishra, Mankind Research Centre; Chandi Prasad Ravipati, Aurobindo Pharma; Anahita Karande, Alkem Laboratories; Dr Pradeep Kumar Vishwakarma, Cipla; G V Srinivas, DifGen Pharmaceuticals; Anurag Chauhan, Amneal Pharmaceuticals; Dattatraya Batwal, Sandoz India

injectables and drug–device combination products. This session, moderated by Dr Sajeev Chandran, Vice President, OOD – Pharma R&D, Lupin, brought together Loganathan S, AVP, Onesource Biopharma; Dr Vaibhav Dubey, Senior General Manager, Kashiv Biosciences; Dhananjay M Chaudhari, DGM – Packaging Development (Formulations), Indoco Remedies; and M Naresh, Technical Lead – Packaging and Drug Device Combination Products, Dr. Reddy's Laboratories.

The discussion highlighted that innovation delivers value only when it addresses real patient needs. Packaging and device systems must reflect real-world patient and caregiver behaviour, with design choices directly influencing usability, adherence and therapeutic outcomes.

Investments in packaging material science and device engineering were identified as critical as India moves toward complex biologics and specialty therapies, where packaging performance directly affects stability and safety.

Regulations redefining accountability

As innovation expands possibilities, regulatory expectations continue to evolve. Hence, this formed another critical focus area at the event through a session moderated by Praveen Kumar Narlanka, AVP – Packaging Development at Aurobindo Pharma. It also brought together Tridip Mazumder, AVP – Strategic Sourcing, Packaging Material, Dr. Reddy's Laboratories; Shivaji Chakraborty, Head – Packaging Development, Fresenius Kabi Oncology; Sailesh YHNB, Associate Director, Novo Nordisk; Dr Srikanth Reddy Sokkula, Head – Regulatory Affairs, Jodas Expoim; Narendhar Kavide, AGM and Head – Packaging and Device Development, Orbicular Pharmaceutical Technologies; Leena Padala, Senior Scientist II and Head, Eugia Pharma Research Centre; and Nagendra Kumar Mall, Associate Manager, Global Pharma R&D at Baxter Pharmaceuticals India.

Speakers emphasised that packaging sits at the heart of patient safety, sustainability and compliance. Global mandates related to traceability, Extended Producer Responsibility and environmental risk assessments are embedding lifecycle accountability into packaging design.

Compliance gaps increasingly arise from interpretation challenges and insufficient scientific justification rather than absence of regulation. Evidence-based, risk-driven validation is emerging as the new benchmark for defensible packaging systems.

Building a cohesive packaging ecosystem

Beyond technology and regulation, industry leaders highlighted the need for stronger ecosystem alignment. In his special address, Hari Kiran Chereddi, MD and CEO, HRV Pharma, observed that India Pharma is steadily moving toward high-value segments such as complex formulations, biologics and specialty therapies. Future growth will depend on innovation, advanced manufacturing capability and coordinated collaboration across industry and government stakeholders.

This theme continued in the partner playbook session moderated by Ajay Bapat, Packaging Consultant. Prafull V Deshpande, Team Lead – Packaging Development (R&D), Lupin; Satyanarayana Nandula, AGM and Head – Packaging Development, Laurus Labs; Munindra Roy, AGM – Packaging Development, Gland Pharma; Amit Pathak, Group Manager, Inventia Healthcare; and Hari Prasad, Senior Manager – Packaging & Development, Jodas Expoim; were the other panelists in this session. They emphasised that India Pharma increasingly seeks long-term collaborators rather than transactional suppliers. Financial strength, technical capability, scalability and innovation readiness were identified as defining attributes of strategic partners.

Sustainability moves to the centre

While sustainability surfaced throughout the conclave, a dedicated session moderated by Dr Ravikumar N, President – Formulations R&D, MSN Laboratories, explored how eco-conscious packaging practices increasingly align environmental responsibility with business performance.

He was joined by Prabir Das, Mentor and Advisor – Packaging & Labelling; Bhupesh Kumar Mittal, Technical Packaging Program Lead, Bayer Consumer Healthcare; Avadhesh Sarawagi, DGM and Head – Packaging Development, Amneal Pharmaceuticals; Ramesh Punnam, DGM, Aurobindo Pharma; Pradip Som, Head – Packaging Development, Aculife Healthcare; and Bhavesh A Shah, AGM – Packaging Development, Intas Pharmaceuticals.

The panelists emphasised that lightweighting, recyclable materials and responsible sourcing improve margins while strengthening regulatory preparedness and supply-chain resilience.

Sustainable packaging, the panel agreed, is no longer peripheral. When integrated with design and operations, it becomes a measurable value-generating component benefiting business, patients and the planet.

Packaging 2035: Preparing for the next decade

Looking ahead, the session on Packaging 2035: Technologies, Trends and Transformations Ahead, moderated by Soumyanath Mishra, AVP and Head – Packaging Development, Mankind Research Centre, explored how packaging systems will evolve over the coming decade.

Industry leaders like Chandi Prasad Ravipati, Head – Packaging Development, Aurobindo Pharma; Anahita Karande, General Manager, Alkem Laboratories; Dr Pradeep Kumar Vishwakarma, Associate Director, MSTG – Respiratory, Cipla; GV Srinivas, Associate Director – Packaging R&D, DifGen Pharmaceuticals; Anurag Chauhan, Assistant GM – Digitalisation, Automation & Analytics, Amneal Pharmaceuticals; and Dattatraya Batwal, Head – Packaging Development, Sandoz were the panelists for this session.

The discussion projected a future defined by AI-driven inspection, predictive maintenance, flexible manufacturing systems and advanced anti-counterfeiting technologies. The experts emphasised that sustainability claims will increasingly require measurable and auditable metrics, while connected ecosystems integrating cloud platforms and smart devices will redefine packaging performance.

Shaping the next era of India Pharma Inc

Across sessions, one conclusion became increasingly evident. Packaging now sits at the intersection of technology, regulation, sustainability and patient experience. From operational rigour and AI-enabled intelligence to ecosystem collaboration and readiness for advanced therapies, packaging decisions are shaping how India Pharma competes globally.

For an industry transitioning toward innovation-led growth, integrating foresight, digital capability and purpose into packaging strategy will define the next era of leadership.

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Partners in Progress: PPL 2026

PPL 2026 brought together India's pharma packaging ecosystem to explore how collaboration, innovation, and technical expertise can strengthen patient safety, product stability, and operational efficiency. Across partner-led sessions, speakers discussed how structured systems, material science, regulatory alignment, and technology integration collectively elevate packaging from a support function to a strategic enabler.

Building on the importance of structured systems, the sessions began with combination products, where packaging directly influences therapeutic performance. Prabhaharan Sankaran, Manager – Technical Customer Services, India, West Pharmaceutical Services, highlighted that regulatory expectations for electronic drug delivery systems and integrated formats are steadily evolving. Submissions must now address all relevant performance criteria through a holistic, risk-based framework rather than isolated testing. In this complex landscape, specialised expertise and integrated capabilities are critical to streamline development, validation, and regulatory readiness.

From combination products, the discussion moved into chemical interfaces, particularly the challenge of nitrosamine control. Dr Vivek Jha, Head – R&D, Cilicant, and Dhairy Sharma, Manager – Business Development, Healthcare Division, explained that nitrosamine impurities can arise during manufacturing or form gradually during storage. Active packaging solutions combining scavenger matrices with reaction suppressors can significantly reduce these risks, transforming packaging into an active chemical control system that protects product stability throughout its lifecycle.

Chemical safety considerations extended to rubber stoppers, where Nitin Khaladkar, Head R&D – Rubber Stopper, Bharat Rubber Works, described how vulcanisation chemistry and accelerator choices can generate amines contributing to nitrosamine formation. Laminated stopper technologies and risk-based extractables studies aligned with ICH M7 provide practical mitigation pathways, reinforcing that risk management begins at the design and material selection stage.

Even seemingly peripheral components, such as printing inks, carry critical implications for product safety. Jatin Takkar, Head – Product Safety and Regulatory, Siegwerk India, highlighted how migration risks through diffusion, set-off, or gas-phase transfer can compromise product integrity. Ensuring safety requires cross-functional alignment, clear verification protocols, and proactive collaboration between brand owners, ink suppliers, and regulatory teams.

The conversation then shifted to innovation and technology solutions. Anil Mittal, MD, Alutech Packaging, introduced ActivePac™, a system that actively controls moisture and oxygen to protect sensitive formulations. By reducing blister failures, odor issues, and overages while maintaining low headspace humidity, it extends shelf life by two to five times. Building on this, Vijaya Kumar K, Regional Manager – South, Sun Teknovation, showcased AI-driven inspection and Track & Trace solutions designed to handle real-world manufacturing variability. These systems streamline aggregation, reduce scan times, and integrate anti-tamper mechanisms seamlessly. Shivashankar Nagarajan, Director, Sandilyam Automation Systems, highlighted the importance of continuous barcode verification from design to production to safeguard traceability, audit readiness, and regulatory compliance.

Taken together, these sessions formed a cohesive narrative. Serialisation discipline, combination product validation, nitrosamine mitigation, stopper chemistry, sustainable materials, and AI-driven traceability are interconnected layers within a complex packaging ecosystem. Speakers emphasised that emerging risks, regulatory evolution, and practical mitigation strategies must be addressed through stronger design choices, better validation, and tighter cross-functional alignment.

PPL 2026 underscored how partnerships, technical expertise, and proactive innovation are essential to building robust, compliant, and future-ready packaging systems that deliver tangible value to patients and the pharma industry.

Prabhaharan Sankaran, Manager-Technical Customer Services (TCS), India, West Pharmaceutical Services

Jatin Takkar, Head – Product Safety & Regulatory, Siegwerk Indi

Dr Vivek Jha, Head - R&D, Cilicant

Vijaya Kumar K, Regional Manager – South, Sun Teknovatio

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

Shivashankar Nagarajan, Director, Sandilyam Automation Systems

Nitin R Khaladkar, Head R&D - Rubber Stopper, Bharat Rubber Works

Anil H Mittal, MD, Alutech Packaging

PPL Awards 2026 honours packaging leaders and innovators

Highlight advancements shaping the future of pharma packaging and labelling

Express Pharma honoured industry leaders, innovators and emerging professionals at the PPL Awards 2026, celebrating excellence in pharma packaging and labelling.

Held alongside the PPL Conclave, the awards brought together key stakeholders from across India's pharma packaging ecosystem.

Organised by Express Pharma, presented by West Pharmaceutical Services, and powered by Cilicant, the awards recognised individuals and organisations advancing packaging innovation, quality and patient safety.

The evening began with a welcome address by Viveka Roychowdhury, Editor, Express Pharma and Express Healthcare.

She highlighted the objective of the PPL Awards is to recognise contributions that are strengthening pharma packaging and labelling.

Prabir Das, Advisor & Mentor – Packaging & Labelling and Jury Member, PPL Awards 2026, explained the award evaluation methodology. He outlined the structured and transparent selection process followed by the jury.

The audience also witnessed a special video address by Chakravarthy AVPS, Chairman, Federation of Pharma Entrepreneurs (FOPE), Telangana & AP, who encouraged industry professionals to continue showcasing their achievements through platforms such as the PPL Awards.

Next, the presentation of the PPL Leadership Awards and PPL Innovation Awards followed.

The PPL Leadership Awards 2026 recognised professionals driving progress in pharma packaging functions. Awards were presented in alphabetical order. Winners shared brief remarks after receiving their honours.

● **Rising Stars:** This category recognised emerging professionals showing strong potential and innovation-led contributions.

Winners of PPL Leadership Awards 2026

Winners of PPL Innovation Awards 2026

The winners in this category were:

- **Bangarayya M**
- **Rushikesh Kurade**
- **Srinivasa Nerati**
- **Sushant Tatkare**

Achievers: The Achievers category honoured professionals delivering measurable impact through execution and innovation. The winners in this category were:

- Avadhesh Sarawagi
- Bhupesh Kumar Mittal
- Leena Padala
- Prafull Deshpande
- Satyanarayana Nandula
- Veeranjaneyulu Yelavarthi

● **Leaders:** This category recognised experienced professionals driving strategic transformation in pharma packaging.The winners were:

- Subrajit Bhowmik
- Tridip Mazumder

PPL Innovation A wards spotlight next-genpackaging

The PPL Innovation Awards 2026 recognised organisations developing advanced and future-ready packaging solutions under three categories. The winners are as follows:

1) Sustainable Packaging: Packaging solutions that minimise environmental impact through material innovation, recyclability and resource efficiency.

- **Aurobindo Pharma**
- **Amneal Pharma**

2) Patient-centric Packaging: Packaging designs that improve patient safety, usability, adherence and overall treatment experience

- **MSN Laboratories**
- **Mankind Pharma**

3) Intelligent Packaging: Technology-enabled packaging solutions that enhance traceability, authentication, monitoring and supply chain visibility

- **Aurobindo Pharma**
- **MSN Laboratories**

Viveka Roychowdhury also felicitated the jury members with Certificates of Appreciation for their contribution to the selection process.

Driving packaging excellence

The PPL Awards 2026 highlighted the growing importance of innovation, collaboration and leadership in pharma packaging. The event concluded with closing remarks congratulating the winners and encouraging continued industry progress.

The evening ended with cocktails and dinner, offering attendees an opportunity to network and celebrate achievements.

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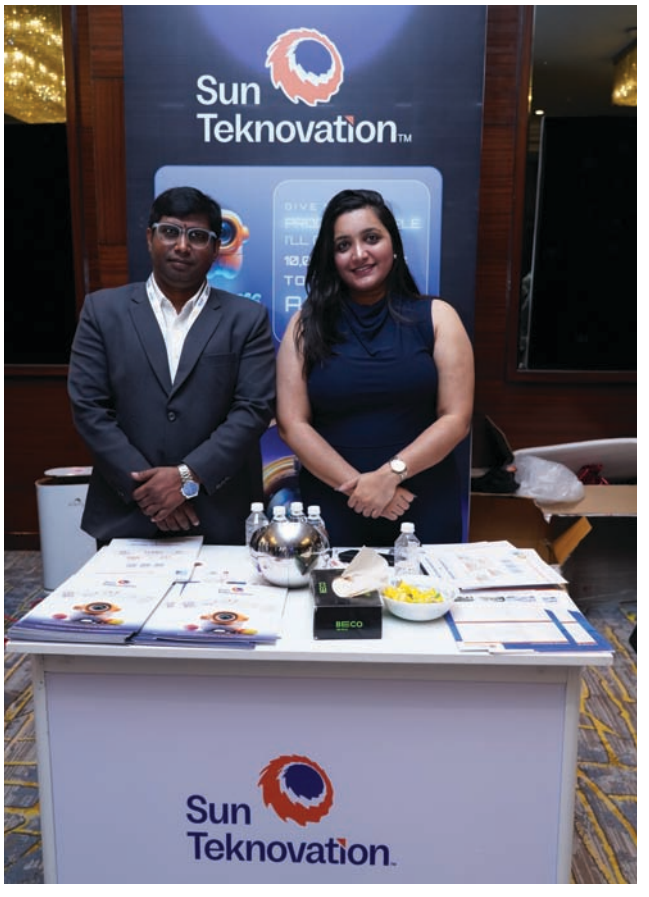

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India's pharma industry trails behind: The digital validation technology gap

Stephen Ferrell, Chief Product Officer, Valkit and Chair, GAMP Americas Community of Practice; and **Arjun Guha Thakurta,** Director-Consulting Operations, Life Science Consulting, a Convalgroup Company explore why AI-native digital validation is critical for strengthening compliance, agility, and global competitiveness

Stephen Ferrell, Chief Product Officer, Valkit and Chair, GAMP Americas Community of Practice

Arjun Guha Thakurta, Director-Consulting Operations, Life Science Consulting

India's pharmaceutical industry will not lose its edge because it forgets how to manufacture; it will lose it because it insists on validating 2030 facilities with 1990s tools. Digital validation is the clearest window into this gap. At one extreme, some organisations still run critical GxP validation on pen, paper, and spreadsheets—impact assessments written in Word, test evidence buried in file shares, traceability held together by human memory and ad-hoc cross-checks. This feels familiar and "under control," but it collapses under modern expectations for data integrity, real-time transparency, and network-level risk management. When every reasonable question from QA, auditors, or global partners requires days of hunting through binders and folders, validation stops being a quality enabler and becomes an expensive drag on responsiveness.

A larger portion of the market has "digitised" without truly transforming. Their validation platforms are essentially paper-on-glass: Word and Excel templates re-created in a browser, wrapped with workflow, e-signature, PDF output, and forms-based assessments that still behave like stand-alone documents. These systems address obvious pain—lost documents, version chaos, manual signature chasing—but they leave the underlying model unchanged: each protocol is still a bespoke document bundle, data is largely unstructured text, and critical logic remains trapped in people's heads rather than in reusable objects. Reporting is limited to surface-level metrics such as counts, cycle times, and status pies because the platform does not "understand" controls, risks, or test coverage as first-class structured entities. In effect, organisations have paid dearly to move their paper problem into a browser, while the fundamental economics of validation—re-authoring, re-execution, and re-review—remain stubbornly manual.

Into this landscape, vendors are now sprinkling "AI" as a cosmetic upgrade—auto-generated paragraphs, suggested requirement phrasing, chatbot overlays, or simplistic risk-ranking widgets. These features can look impressive in a demo, but on top of a document-centric, siloed platform, the AI has very little of substance to learn from. It cannot see patterns in control failures across products, cannot reliably reuse test logic, and cannot perform genuine impact analysis across interconnected systems and sites because the underlying data model is still document-first rather than object- and relationship-first. The result is parlour-trick AI: occasionally helpful, visually engaging, but fundamentally disconnected from the core questions that matter to plants and IT—how much effort validation consumes, how effectively it mitigates risk, and how quickly it can adapt to change. Leadership teams who stop here will have "AI" on their slide decks but no meaningful change in throughput, right-first-time rates, or audit posture.

The AI-native alternative

The alternative is an AI-native validation architecture, built from the ground up around structured, reusable building blocks. In this model, user requirements, risks, controls, test cases, and evidence are discrete objects linked in a graph, not static paragraphs embedded in documents. Changes to a system, configuration, or process propagate through this graph, allowing the platform to automatically identify what must be re-assessed, which tests can be confidently reused, and where new testing is truly required. When this structured validation layer is integrated with change control, GxP system inventories, MES, LIMS, and infrastructure monitoring, AI can move beyond word games to answer the questions operations actually care about.

- What is the true impact of this change across products, sites, and integrations.
- Which tests have historically found defects and should be prioritised.
- Where are we over-testing, adding effort without appreciable risk reduction.
- Which validation packages and systems are at highest risk of audit findings.

For plant leadership, the benefits are concrete and measurable. A structured, AI-native platform can drastically reduce copy-paste authoring, simplify evidence collection, and apply machine-driven checks to the evidence itself—automatically surfacing gaps, inconsistencies, and outliers so QA can focus on true exceptions rather than line-by-line review. It becomes possible to reuse prior qualification work with confidence—through package-level cloning, standardised libraries, and golden baselines—instead of re-inventing protocols for every minor change, shortening project timelines and freeing scarce SME and QA capacity for higher-value

activities. Operations teams gain real-time visibility into validation bottlenecks, enabling better scheduling and avoiding the all-too-familiar scenario where equipment or functionality sits idle because validation paperwork is lagging plant needs. Because test evidence is captured digitally and analysed in real time, unusual patterns—such as inconsistent screenshots, unexpected system states, or repeated tester errors—are flagged early, reducing errant deviations and strengthening data integrity. Over time, this changes the lived experience of validation on the shop floor—from "the thing that always slows us down" to "the system that shows us where we can safely go faster."

For IT, an AI-native validation layer becomes the connective tissue between the change pipeline and the GxP risk landscape. When system inventories, configuration baselines, and integration maps are linked to validation objects, IT can see which changes present the greatest validation, business, and regulatory impact before they are executed. This supports smarter release planning, more realistic timelines, and a shift away from the adversarial "IT versus QA" dynamic toward a joint risk-management model in which both functions share a single, transparent view of impact and evidence. It also lays the groundwork for continuous validation approaches aligned with emerging digital-validation and data-integrity guidance—ongoing evidence and monitoring instead of rigid, document-heavy cycles that treat every change the same.

Three traps holding Indian pharma back

Escaping the current stagnation means recognising three traps that hold Indian pharma back. The first is the pen-and-paper trap, where validation is entirely manual and inherently opaque, consuming huge amounts of hidden labor in rework, reconciliation, and audit preparation. The second is the paper-on-glass trap, where organisations invest heavily in platforms that digitise forms but keep data unstructured and brittle, limiting any meaningful automation, analytics, or AI beyond basic dashboards. The third is the AI-bolt-on trap, where leadership believes they have "done AI" because the platform can autocomplete sentences, chat about SOPs, or suggest risk scores, while the underlying validation model—and its cost profile—remains unchanged. None of these positions are compatible with the level of agility, traceability, and predictive control that regulators and global partners will expect over the next decade.

A pragmatic roadmap for leadership

Plant and IT leaders who want to move beyond these traps can follow a pragmatic sequence.

1. Map the current validation landscape across sites: What proportion of effort is still paper-based, semi-digital, paper-on-glass, or genuinely data-driven, and where are the biggest pockets of rework, re-authoring, and audit pain.

2. Target high-value use cases: Where structured validation and AI can show quick, defensible impact—automatic change impact analysis for a critical platform, standardised test libraries and golden packages for widely used systems, or systematic reuse of prior protocols for recurring changes.

3. Evaluate platform investments rigorously: Not by how slick the UI or "AI demo" appears, but by whether they expose validation as structured data objects, support robust APIs and integrations, and fit cleanly into the broader digital thread of the plant and enterprise.

4. Integrate with the broader enterprise: Connect digital validation to change control, system inventories, MES, LIMS, and infrastructure monitoring so that impact, risk, and evidence flow automatically rather than being re-keyed into multiple systems.

5. Build governance around data and reuse: Establish clear ownership, stewardship, and quality standards for validation objects and libraries so they become trusted, reusable assets rather than one-off artifacts.

6. Invest in workforce capability: Train plant, QA, and IT teams not just in tool usage, but in risk-based thinking, data literacy, and the principles of continuous, AI-enabled validation.

Two futures: Which will Indian pharma choose

Over the next several years, the sector will likely split into two camps. One will keep validation in a largely document-centric, manual or quasi-digital state, occasionally enhanced by AI gadgets that never touch core process design. The other will treat digital validation as the backbone of its digital plant strategy—turning validation content into a reusable, analysable asset that improves with every project through structured models, integrated data flows, and AI that is genuinely validation-aware. The first group will continue to experience validation as overhead and constraint; the second will use it to accelerate technology adoption, respond faster to regulatory change, and credibly claim AI-enabled quality as a competitive differentiator in global markets.

For Indian pharma, the stakes could not be higher. Cost advantage and manufacturing scale are well established, but global customers and regulators are increasingly selecting partners not only on price and capacity, but on digital maturity, data integrity, and the ability to adapt quickly to new modalities and expectations. Plants that modernise validation only superficially—paper on glass plus parlor-trick AI—risk finding themselves technically compliant but strategically sidelined. Those that embrace AI-native digital validation platforms, integrated into the broader enterprise architecture and built on AI-ready data models, will be positioned to lead: moving faster, learning faster, and demonstrating with evidence—not marketing slides—that their quality systems are as advanced as their manufacturing lines.

The choice is clear. Indian pharma can continue to pay the hidden tax of manual and document-centric validation, or it can seize the opportunity to make digital validation a competitive advantage with platforms explicitly engineered for reuse, intelligence, and connected risk management. The technology exists today; the question is whether leadership will act decisively before the gap becomes too wide to close.

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The algorithmic inversion of pharma

Drug discovery is becoming a compute problem. As AI models begin designing molecules faster and cheaper than any laboratory, the trillion-dollar question is no longer whether technology will reshape pharma — it's who will own the system that designs the next generation of medicines, and what that means for every nation on earth, informs **Dr Rajpushpa Labh,** Consultant Physician, Health-tech entrepreneur, AI researcher & Published Author

The century-old model is cracking

For more than a hundred years, pharma innovation followed a reassuringly stable pattern. A chemist had a hunch, a lab tested it, a molecule emerged after years of trial and error, and a company spent billions navigating it through clinical trials and regulatory approvals. Intellectual property sat squarely with whoever discovered the molecule. Manufacturing, distribution, and commercialisation were tightly bundled around that core act of discovery.

That model is now under pressure from an unlikely direction: Silicon Valley. The same forces that upended media, retail, and transportation — artificial intelligence, platform economics, and data network effects — are now converging on the most complex and consequential industry of all.

Artificial intelligence — spanning protein structure prediction, generative chemistry, reinforcement learning, and biological simulation — is rewriting the economics of drug discovery. When the equation becomes data + models + compute = molecules, the centre of gravity shifts toward whoever controls the computational infrastructure. And that terrain belongs overwhelmingly to technology companies.

Think of what happened in consumer electronics. Apple captures the lion's share of smartphone value through design, software, and ecosystem control. Foxconn builds the devices but keeps thinner margins. In apparel, leading brands own the design and the brand; contract factories do the stitching. The value migrated upstream, toward whoever controlled the intellectual blueprint, while the physical making of things became interchangeable. Could pharma be heading down the same path — with tech companies owning the molecular 'design' and pharma firms reduced to manufacturing contractors? The industry is already more modular than most people realise: clinical trials are outsourced to contract research organisations, manufacturing to CDMOs, even regulatory writing to specialist agencies. If discovery itself becomes modular, the last bastion of pharma's differentiation falls.

The entity that trains the model that invents the molecule has a powerful claim to the intellectual property. That's a tectonic shift from a century of pharma practice

The AlphaFold moment — and what came after

The shift from theoretical possibility to tangible reality has a name: AlphaFold.

In 2020, Google DeepMind's AlphaFold 2 cracked the protein structure prediction problem — a grand challenge that had stumped biologists for half a century. Since then, more than three million researchers have used the tool, and it has been cited in over forty thousand academic papers. Demis Hassabis and John Jumper won the 2024 Nobel Prize in Chemistry for the work.

But AlphaFold 2 was just the opening act. Its successor, AlphaFold 3, launched in May 2024, goes further: it predicts not just protein shapes but the full molecular dance between proteins, DNA, RNA, drug-like ligands, and ions — outperforming the best physics-based methods on standard benchmarks. In February 2026, DeepMind's drug-focused spinoff, Isomorphic Labs, unveiled an even more powerful proprietary engine called IsoDDE. The company has been described as building 'an AlphaFold 4' in all but name, and it comes backed by partnerships with Eli Lilly and Novartis worth a combined three billion dollars. Isomorphic is preparing its first AI-designed oncology drugs for human clinical trials.

And DeepMind is far from alone. An open-source model called Boltz-2, built by MIT researchers and Recursion Pharmaceuticals, can predict how tightly potential drugs bind to their protein targets. EvolutionaryScale's ESM3 generates entirely novel proteins that don't exist in nature. Baidu and ByteDance have launched comparable platforms from China. The race to build a 'foundation model for biology' is well and truly on.

What makes this particularly potent is the compounding nature of the advantage. Each clinical outcome feeds back into the model, improving the next prediction. Each patient dataset enriches the training corpus. Each failed molecule teaches the system what to avoid. These data network effects — the same flywheel dynamics that made Google and Meta so dominant in their markets — create self-reinforcing moats that late entrants will struggle to replicate. The companies that build these loops earliest will be hardest to catch.

The rise of the dark lab

If AI is the brain of the new drug discovery, robotic laboratories are its hands.

A new breed of 'dark labs' — fully automated facilities that operate around the clock with minimal human intervention — is emerging as a critical piece of the puzzle. Recursion Pharmaceuticals runs one of the most advanced: a platform that combines robotics, high-content cellular imaging, and a staggering sixty-five-petabyte proprietary dataset in a continuous design–make–test–learn loop. When Recursion merged with Exscientia in 2024, it created an end-to-end system linking AI-driven molecular design with automated precision chemistry.

Insilico Medicine has gone a step further, deploying a humanoid robot in its AI-powered laboratory — designed to observe human scientists, learn their techniques, and eventually replicate them autonomously. Meanwhile, XtalPi, founded by quantum physicists at MIT, operates automated labs in Shenzhen, Shanghai, and Cambridge, Massachusetts, linking physics-based simulation with machine learning and robotic wet-lab work in a single closed loop.

These are early prototypes of what the industry calls 'self-driving laboratories': systems that autonomously propose molecules, synthesise them, test them, and feed the results straight back into the generative model. The human scientist doesn't disappear — but their role shifts from bench worker to systems architect. A 2025 industry review noted that while these autonomous platforms have dramatically accelerated the design–make–test–learn cycle, none has yet independently discovered a validated drug candidate. The technology is proven for acceleration; the question of whether it can improve clinical success rates remains the defining test for the field.

Enter Quantum: The next computational frontier

If AI is already disrupting drug discovery, quantum computing could supercharge it.

Here's the core insight: drug-target interactions are fundamentally quantum-mechanical phenomena. When a drug molecule approaches a protein pocket, the electrons in both systems interact through quantum effects — superposition, tunnelling, entanglement — that govern whether the drug binds effectively. Classical computers can only approximate these interactions, and those approximations introduce errors, particularly for complex cases like metalloenzymes and chemical transition states. Quantum computers, by representing molecular states natively using qubits, can in principle simulate these interactions with far greater fidelity. In essence, you'd be using quantum mechanics to simulate quantum mechanics — an idea first articulated by the physicist Richard Feynman in the early 1980s.

McKinsey estimates that quantum computing could unlock between two hundred billion and five hundred billion dollars of value in life sciences by 2035. The world's biggest pharma and technology companies are already placing bets. AstraZeneca is working with IonQ and NVIDIA on quantum-accelerated workflows for small-molecule drug synthesis. Merck and Amgen are collaborating with QuEra to predict the biological activity of drug candidates. Pasqal and Qubit Pharmaceuticals are applying neutral-atom quantum computing to model how drugs bind to proteins.

Fault-tolerant quantum hardware is still years away, but hybrid quantum-classical pipelines are already producing useful results for specific chemistry problems. Researchers have demonstrated quantum workflows for covalent bond simulation and free energy calculations in prodrug activation — real pharma problems, not just academic exercises. When the hardware catches up, quantum simulation will likely become the foundational layer of the entire TechBio stack — feeding high-fidelity molecular data into the AI models that sit above it. Nations that lead in both AI and quantum computing will hold the keys to the next generation of medicines.

> If a single entity controls the 'operating system' layer of this stack, it exerts gravitational pull over the entire ecosystem — just as iOS and Android do in smartphones.

Mapping the TechBio stack

Taken together, these developments are assembling into a coherent architecture — what we might call the TechBio stack. Think of it as the pharma equivalent of a modern tech platform, organised in layers, each reinforcing the ones above and below it. Whoever controls the critical middle layers controls the value.

At the base sits compute infrastructure: hyperscale cloud, GPU clusters, and emerging quantum accelerators. Above that, a biological data layer — population-scale genomics, proteomics, wearable telemetry, longitudinal health records — creates a powerful data moat. The foundation model layer is where molecules are actually generated: protein folding predictors like AlphaFold 3, small molecule designers, and antibody engineering systems. A digital twin and simulation layer compresses timelines by testing candidates in silico before they enter a lab. A clinical platform layer optimises trial design through AI, wearable monitoring, and decentralised recruitment. And at the top, a patient ecosystem closes the loop — continuous monitoring feeds real-world outcomes back into the models, making the whole system self-improving.

An important milestone: in 2025, the first drug with both its target and molecule designed entirely by AI completed Phase IIa clinical trials. No AI-discovered drug has yet received FDA approval, but the pipeline is maturing fast. The World Economic Forum projects that by 2025, thirty per cent of drugs in early development will have AI involvement. The gap between 'AI-assisted' and 'AI-native' drug discovery is narrowing with each quarterly earnings call from the major TechBio companies.

Who owns the molecule?

This brings us to perhaps the most consequential question of all: where does the intellectual property sit?

Traditionally, pharma patents protect specific chemical entities, synthesis methods, and therapeutic uses. In a computational world, the real source of competitive advantage may shift to the model architectures trained on proprietary datasets, the algorithmic design pathways, and the synthetic data pipelines that simulate efficacy. The shift is subtle but momentous: you don't just own a drug — you own the machine that can generate an infinite number of optimised variants. And that machine gets better with every molecule it designs, every trial it observes, every patient outcome it ingests.

Can the generative capacity of an AI model be patented? Does algorithmic design count as inventorship? Who owns a molecule that a model designed autonomously from globally aggregated data? These aren't abstract thought experiments. They are live questions that will reshape patent law and international IP treaties in the coming decade.

The geopolitics of molecular sovereignty

If you think this is purely an industry story, think again. The geopolitical implications are enormous.

Historically, pharma power was shaped by who had the labs, the regulatory expertise, and the manufacturing plants. In a compute-driven world, power shifts to whoever controls advanced semiconductors, hyperscale cloud, population-scale biological datasets, and AI talent. Biological sovereignty becomes inseparable from digital sovereignty.

The US leads in AI infrastructure, venture capital, and semiconductor design. Its tech giants have the scale to integrate computing, health data, and platform ecosystems into a unified stack. NVIDIA's BioNeMo platform, Microsoft's protein design tools, and Google's AlphaFold ecosystem are already assembling the pieces. China offers a different model: state coordination, massive population data, and vertically integrated AI ambitions that could produce sovereign biological foundation models insulated from Western systems. Baidu, ByteDance, and Chinese research institutions have already launched protein prediction platforms of their own. The world may bifurcate into parallel biological model ecosystems — Western and Chinese — with limited interoperability, much like rival internet ecosystems today.

Europe retains regulatory muscle through the EMA and data protection frameworks, potentially shaping global norms on algorithmic transparency and AI governance in medicine. But without competitive compute infrastructure, it risks becoming a rule-writer without innovation ownership.

India occupies a unique position. It is the 'pharmacy of the world' in generics, has massive population dataset potential, and deep IT talent — but currently lacks hyperscale compute and foundation model leadership. The strategic choice is stark: remain the manufacturing backbone of global therapeutics, or climb the stack into algorithmic drug design leadership. The decision will shape India's position in the global health architecture for decades.

The big-picture question is whether we're heading toward consolidation or fragmentation. In one future, a small number of tech firms own the biological foundation models and license drug designs globally — efficient, but dangerously centralised. In another, multiple sovereign AI-biology ecosystems emerge, each protecting domestic data and compute — more equitable, but potentially slower. History suggests a messy middle: partial consolidation with strategic fragmentation at critical chokepoints, much like today's semiconductor supply chains.

Pharma is not dead yet

Before declaring the triumph of TechBio, it's worth acknowledging what pharma companies still bring to the table.

Regulatory expertise is a genuine moat. Navigating FDA and EMA approvals requires decades of institutional knowledge, safety infrastructure, and pharmacovigilance systems that no tech company has built overnight. The sheer

complexity of running a global Phase III clinical trial — with thousands of patients across dozens of countries, each with different regulatory requirements — remains a capability that takes years to acquire. Manufacturing is another barrier: biologics production, cell therapy scaling, and cold chain logistics are capital-intensive, process-sensitive operations that resist easy commoditisation. And commercial infrastructure — physician networks, insurance negotiations, market access — remains firmly in pharma's hands.

The most likely near-term future is co-evolution, not outright replacement. Three models will probably coexist. First, tech discovers and licenses molecules to pharma for commercialisation — already happening today. Second, joint ventures with shared IP and pooled risk, which is likely to be the dominant model in the near term. Third, and further out, fully integrated TechBio companies that handle everything from discovery through to patient delivery. In January 2025, the US FDA issued its first draft guidance on AI in regulatory decision-making for drug products — a signal that the regulatory ecosystem is beginning to adapt to a world it didn't build.

The equity question

There's a darker possibility embedded in this transformation. If foundation models are trained primarily on Western population data, the therapies they design may carry systematic biases — working well for some demographics and poorly for others. If access to personalised AI-designed medicine is gated behind platform subscriptions, new forms of health inequality could emerge. The concentration of biological IP within a handful of corporations raises hard questions about who benefits from the algorithmic future of medicine — and who gets left behind.

On the other hand, AI could dramatically reduce R&D costs and direct attention toward neglected tropical diseases and rare conditions that have long been commercially unattractive. AlphaFold-powered research has already been used to identify existing drugs that could be repurposed to treat Chagas disease, a tropical parasitic illness that infects up to seven million people annually. The outcome will depend on governance: whether public AI infrastructure — think government-funded biological foundation models trained on public datasets — emerges as a counterweight to corporate concentration, and whether regulators mandate dataset diversity, transparency, and equitable access.

The Endgame: Therapy as software

The most radical scenario looks like this: AI designs a molecule personalised to your genome. It's synthesised on demand at a hospital-based automated unit. Your response data feeds back into the model. The therapy is updated like a software patch. The IP sits in the algorithm, not the molecule. The drug isn't a product — it's a service.

Speculative? Yes. But early precursors already exist in mRNA platforms and gene-editing pipelines, where the therapeutic modality is already programmable. Moderna's mRNA platform, which designed a COVID vaccine in just two days from the viral sequence, is a glimpse of this future. And when quantum computing matures enough to simulate molecular interactions without classical approximations, generative AI could design compounds invisible to today's methods. The convergence of quantum simulation and generative AI may be the ultimate compute substrate for programmable biology. That's not science fiction — it's engineering with a timeline.

The decisive question

The platform inversion of pharma is not inevitable. But it is structurally plausible — and the signposts are multiplying.

As drug discovery becomes computational, intellectual property migrates upstream toward whoever controls the models and the data. Platform economics could reshape health innovation as profoundly as they reshaped retail, media, and communications. The geopolitical stakes are immense: control of biological generative systems — and the quantum and classical computing infrastructure underlying them — could determine national resilience, economic competitiveness, and public health autonomy for the rest of this century.

The question is no longer whether AI will design drugs. It is who will own the systems that design them — and on what terms. Will the molecular blueprints of future medicines be open or proprietary? Distributed or concentrated? Governed for public health or optimised for shareholder return? In those answers lies the future balance of power in global health. The time to shape it is now.

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Ensuring clean room integrity with Prime Clean Reset high-speed doors: Minimising air permeability and leakages

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

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

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

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

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

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

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

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

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

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

- **Low air permeability**: Designed to maintain low air permeability in pressurised rooms with both positive and negative air pressure.
- **Compact design**: The doors are designed to fit inside the columns, with a self-supporting construction that minimises air leakage.
- **Customisable transparency**: They can be equipped with transparent PVC horizontal sections or vision windows for visibility.
- **Specialised side guides:** The special side guides ensure a tight integration of the curtain, providing high leak tightness.
- **Efficient operation**: The doors offer high efficiency and low permeability values, compliant with EN 12426 and EN 12427 standards, ensuring < 12 m^3/m^2 h ? 50 PA.
- **Durable control device enclosure**: The control device enclosure is made of Stainless-Steel SS 316, ensuring durability and resistance to corrosion.

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

For further information about high-speed doors, contact:

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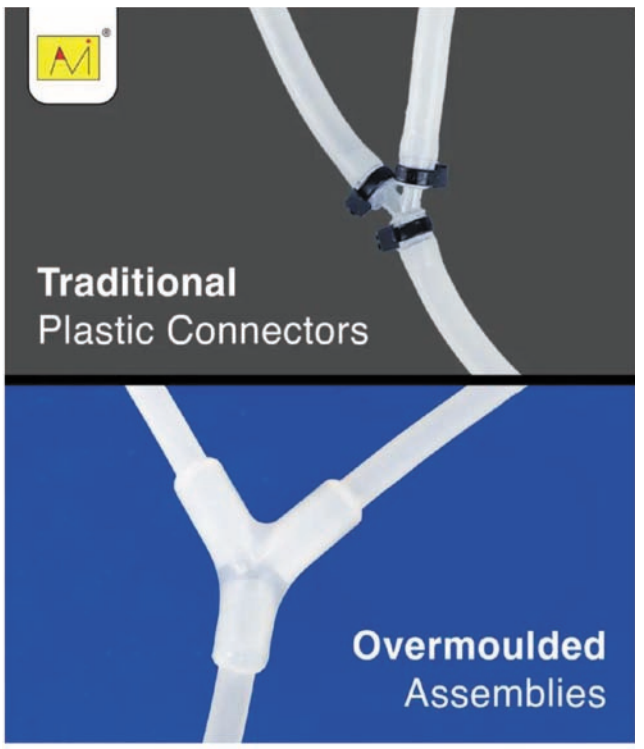
ImaLINK™ overmoulded assemblies: Raising the bar for sterile fluid handling in pharma and biopharma

In the world of pharmaceutical and biopharmaceutical manufacturing, sterility is everything. Single-use technologies (SUTs) have already changed the game helping companies cut down contamination risks, speed up processes, and make validation less of a headache.

However, here is the catch: traditional assemblies made up of tubing, connectors, and ports still leave room for trouble. Think leaks, dead volume, or even assembly errors. That is where ImaLINK™ overmoulded assemblies from AMI Polymer step in. By fusing multiple fluid-handling components into one seamless structure, they eliminate weak points and bring reliability to critical operations like sterile fluid transfer, sampling, and filter integrity testing (PUPSIT).



Seamless by design

The magic lies in overmoulding a process that permanently bonds tubing, connectors, and housings into a single, unified interface. No adhesives. No threaded fittings. No mechanical joints. Just one smooth fluid path.

Why it matters

- No dead legs → less risk of contamination
- Consistent dimensions → reproducibility every time
- Flexible design → tailored diameters and optional add-ons like filters or clamps
- Stronger, cleaner, safer → fewer assembly steps, fewer risks

In short, it's a design built for sterility, strength, and peace of mind.

Materials that put safety first

Every ImaLINK™ assembly is made from carefully chosen, pharmaceutical-grade polymers. These aren't just plastics they're materials engineered to handle sensitive biologics without leaching harmful chemicals.

Common materials include:

- Polypropylene (PP): strong and chemically resistant
- Polyethylene (PE): flexible and impact-resistant
- Thermoplastic Elastomers (TPE): great for sealing and strain relief
- Silicone or elastomers: optional, depending on process needs

In addition, here's the reassurance: they're BPA-free, latex-free, phthalate-free, and ADI-free. In addition, they can withstand sterilisation methods like gamma, e-beam, or autoclave. All assemblies are built in ISO Class 7 cleanrooms, so sterility is baked in from the start.

Built for compliance

In pharma, compliance isn't optional it's survival. ImaLINK™ assemblies are designed to tick all the right boxes:

- **USP <87> & <88>:** cytotoxicity and biological reactivity
- **ISO 10993:** biocompatibility
- **FDA 21 CFR 177/2600:** approved polymeric materials
- **European Pharmacopoeia (EP 3.1.9)**
- **USP <381>:** elastomeric closures for injection
- BPOG standardised extractables testing

On top of that, AMI Polymer runs a tight ship under ISO 13485 quality management, ensuring full traceability, change control, and sterilisation validation.

Real-world applications

1. Sterile fluid transfer: From bioreactor feeds to chromatography and buffer prep, ImaLINK™ assemblies keep fluids moving safely.

- No leaks
- No contamination
- Minimal hold-up volume
- Stable flow and pressure

2. Sampling manifolds: Need to test process fluids without breaking sterility? These manifolds make it easy.

- Integrated sample ports
- Minimal dead volume
- Repeatable geometry
- Less operator intervention

Perfect for QC sampling, in-process checks, and media fill validation.

3. PUPSIT Assemblies: Filter integrity testing after use is a regulatory must under EU GMP Annex 1. ImaLINK™ assemblies make it straightforward.

- Dedicated pressure and vent pathways
- Direct filter housing connections
- Support for bubble point, diffusion, or pressure decay tests

The result? Repeatable, reliable testing with less manual hassle.

Operational guidance

To get the best out of ImaLINKTM assemblies:

- **Pre-use:** inspect, verify, and confirm sterilization.
- **Integration:** Use validated connectors, support mechanically, and align properly.
- **Operation:** Respect pressure/temperature limits, avoid sharp bends, and keep flow laminar.
- **PUPSIT:** Follow SOPs carefully, ramp pressure gradually, and document everything.

Conclusion

ImaLINK™ overmoulded assemblies aren't just another piece of equipment they're a smarter way to handle sterile fluids. By combining clever design, trusted materials, and strict compliance, they give pharma and biopharma manufacturers confidence in every transfer, sample, and test.

Rajkumar Aghera
Deputy Manager- Domestic Marketing, Ami Polymer Private Limited
rajkumar.a@amipolymer.com

Risk Mitigation at a Glance

Risk	How ImaLINKTM Helps
Contamination	Closed, seamless fluid path
Leakage	Permanent overmoulded joints
Variability	Tight molding tolerances
Product loss	Reduced hold-up volume
Validation load	Standardized, documented materials

ACG Packaging Materials joins World Economic Forum's Global Lighthouse Network as World's first pharma packaging company

ACG Packaging Materials today announced that its Shirwal facility has been named a global Lighthouse and welcomed into the World Economic Forum's (WEF) Lighthouse Network (GLN). This marks ACG's second Lighthouse recognition, following its first in 2023 for the Pithampur capsules manufacturing facility. The distinction underscores ACG's leadership in leveraging smart manufacturing to make medicines safer, sustainable, and more affordable globally.

Commenting on the recognition, Karan Singh, Managing Director, ACG said: "ACG has always believed that true leadership in the packaging sector comes from building smarter - not competing harder. Our Shirwal facility is now our second site to be recognised by the World Economic Forum's Global Lighthouse Network, making ACG the world's first pharmaceutical packaging company to receive this honour."

He further added, "This achievement reflects the structures and frameworks we are putting in place across the Group. All ACG business entities are converging to optimise packaging so that medicines are safer, more sustainable, and more affordable. Repetition is the test of proof - in line with our 'Make it Better' commitment, we are replicating this Lighthouse excellence across our facilities and pioneering Sustainability Lighthouses for responsible, resilient manufacturing from India."

At Shirwal, the transformation programme spans end-to-end manufacturing operations and is enabled by generative AI, machine learning, deep learning, the Industrial Internet of Things (IIoT) and digital twin technologies. Operating in a highly competitive and increasingly commoditised pharmaceutical packaging market, the facility undertook a comprehensive digital transformation journey to boost productivity, agility and quality-while also reducing energy consumption and associated greenhouse gas emissions, and supporting a safer, more empowered workplace.

The programme has strengthened day-to-day decision-making by bringing greater visibility to operations and enabling faster, more consistent responses to variation across key manufacturing processes.

These initiatives have delivered measurable improvements, including:

- 40% reduction in lead times
- 71% reduction in defects
- 31% reduction in energy consumption
- 34% improvement in on-time delivery in full

For customers, this translates into shorter lead times, fewer defects and more dependable delivery performance at scale.

S R Shivshankar, CEO, ACG Packaging Materials, said, "This recognition reflects the commitment of our teams at Shirwal and their ability to integrate advanced digital technologies into everyday manufacturing operations. It strengthens our focus on delivering consistent quality, productivity and sustainability for customers worldwide."

Balajikasiram Sundararajan, Chief Digital Officer, ACG Group, said, "Through our Build the Future programme, ACG is driving technology-led transformation across the manufacturing value chain, enabling smart manufacturing, connected products and services, and new business models. This prestigious Global Lighthouse recognition inspires us to continue scaling innovation across our businesses."

Kiva Allgood, Head, Centre for Advanced Manufacturing and Supply Chains, World Economic Forum, said:

"Competitiveness today is no longer defined by efficiency alone, but by the ability to sense, adapt and respond at speed. The Global Lighthouse Network showcases how intelligence-led operations are placing resilience and sustainability at the core of industrial performance."

About the Global Lighthouse Network

The Global Lighthouse Network is a World Economic Forum initiative recognising best-in-class operational sites and value chains that have achieved exceptional performance in productivity, supply chain resilience, customer centricity, sustainability and talent. The initiative was co-founded with McKinsey & Company and is counselled by an advisory board of industry leaders working together to shape the future of global manufacturing.

About ACG

For more than six decades, ACG has been at the forefront of developing innovative production solutions tailored for pharmaceutical and nutraceutical companies. As the world's most integrated provider of oral dosage products and services, our offerings span capsules, barrier packaging materials, manufacturing machinery, visual inspection and traceability solutions built to international standards. ACG fosters long-term collaborative partnerships with customers in 138 countries across six continents. Together, we share a common purpose: to solve the world's greatest health challenges and make it better for everybody we serve.

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Growing demand for healthcare analytics professionals

Dr P R Sodani, President (Vice Chancellor), IIHMR University, Jaipur highlights that analytics expertise is a critical tool to improve outcomes, efficiency and policy planning in healthcare

India's healthcare sector is undergoing a quiet yet profound transformation. Beyond specialists, doctors, and nursing staff, a new class of professionals is rapidly becoming central to how health systems are planned, managed, and improved-healthcare analytics professionals. As data becomes the backbone of decision-making, demand for skilled experts who can convert raw health data into actionable insights is growing at an unprecedented pace.

This shift is not incidental; it is structural. India today generates massive volumes of health data-from public health programmes, hospitals, insurance claims, laboratories, digital health platforms, and wearable technologies. Initiatives such as Ayushman Bharat Digital Mission (ABDM), PM-JAY, disease surveillance systems, and digital health records have accelerated this data explosion. However, data alone does not improve health outcomes. It is analytics-interpretation, prediction, and insight-that drive smarter decisions.

Why healthcare analytics matter more than ever

Healthcare systems are inherently complex, grappling with uncertainty, limited resources, diverse populations, and competing priorities. Traditional decision-making approaches, often reliant on fragmented or delayed data, are no longer sufficient. Healthcare analytics professionals bring a critical capability: integrating clinical, financial, operational, and population-level data to inform timely and effective action.

India faces a significant shortage of trained healthcare analytics professionals. While data scientists and IT specialists are available, healthcare analytics requires a unique blend of skills-understanding of health systems, epidemiology, health economics, clinical processes, and policy environments, along with proficiency in data science and analytical tools

For governments, analytics supports the better targeting of public health programmes, the early detection of disease outbreaks, the efficient allocation of resources, and the monitoring of programme performance. For hospitals, it enables improvements in quality of care, patient safety, cost control, and operational efficiency. For the insurance and pharmaceutical sectors, analytics informs pricing, utilisation management, and outcome measurement. In short, healthcare analytics sits at the intersection of care delivery, policy, and economics.

India's unique demand drivers

India's demand for healthcare analytics professionals is driven by several distinctive factors. First, the sheer scale and diversity of the population create complex health needs that require granular, data-driven approaches. Second, the rapid expansion of health insurance coverage under PM-JAY has generated vast datasets that must be analysed to detect fraud, control costs, and improve service quality. Third, the growing burden of non-communicable diseases demands long-term planning, predictive modelling, and population health analytics.

At the same time, public health emergencies-from pandemics to climate-sensitive diseases-have underscored the importance of real-time data analysis and forecasting. Policymakers increasingly recognise that analytics is not a support function but a strategic capability essential to health system resilience.

A talent gap with serious implications

Despite growing demand, India faces a significant shortage of trained healthcare analytics professionals. While data scientists and IT specialists are available, healthcare analytics requires a unique blend of skills-understanding of health systems, epidemiology, health economics, clinical processes, and policy environments, along with proficiency in data science and analytical tools.

This skills gap has serious implications. Without domain-informed analytics professionals, data risks are misinterpreted, underutilised, or disconnected from real-world decision-making. The result is missed opportunities to improve efficiency, equity, and outcomes.

New career pathways for young professionals

Healthcare analytics is emerging as one of the most promising career paths for young professionals in India. Roles such as health data analyst, population health analyst, health economics and outcomes researcher, policy analyst, and digital health consultant are increasingly in demand across government agencies, hospitals, consulting firms, insurance companies, pharmaceutical organisations, and global development institutions.

What makes this field particularly attractive is its social relevance. Healthcare analytics professionals do not merely analyse numbers; they contribute directly to improving lives, strengthening systems, and informing public policy. For students seeking meaningful careers at the intersection of technology, management, and social impact, healthcare analytics offers a compelling choice.

The role of universities and institutions

Meeting this growing demand requires a fundamental shift in how we educate future health professionals. Universities must move beyond siloed programmes and develop interdisciplinary curricula that integrate public health, health management, data analytics, and digital technologies. Exposure to real-world datasets, applied research, and policy engagement is essential.

Institutions such as IIHMR University have been working to bridge this gap by aligning education with the needs of the health system. By integrating health economics, public health, management, and analytics, these programmes aim to produce professionals who can speak the language of both data and decision-makers.

Looking ahead

As India advances towards its vision of becoming a developed nation by 2047, the strength of its health system will depend not only on infrastructure and workforce numbers but also on intelligence-how well data is used to guide action. Healthcare analytics professionals will play a pivotal role in this transformation. The growing demand for these professionals signals where healthcare is headed: towards evidence-based governance, value-driven care, and accountable systems. Investing in healthcare analytics talent today is not just a workforce strategy-it is a strategic imperative for India's health future.

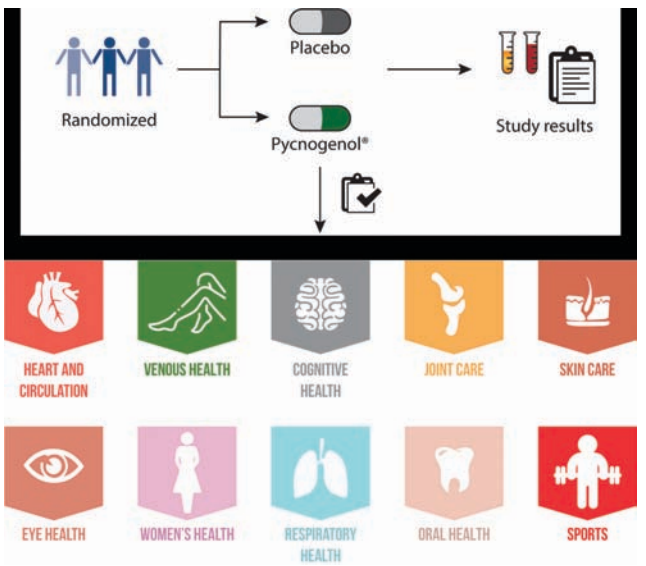
Pycnogenol®: The power of science backed by 40 gold-standard clinical Trials

The efficacy of any intervention is best validated in clinical studies. The highest ggold standard h for study designs is randomized, double-blind, and placebo controlled. In these studies, the participants are first randomly assigned to either take an active medication or placebo. Double-blind refers to the fact that not only the participants but also the researchers carrying out the study do not know which group the respective participants were assigned to. The so-called placebo effect is a known biological response of the body to an expectation of benefits from non-active remedies, which releases endorphins and dopamine, leading to pain relief and potentially the relief of other symptoms. Studies using placebo as a control are investigating any efficiency of the treatment that exceeds the placebo effect.

With a remarkable foundation of scientific rigor, PycnogenolR has been extensively studied in 40 randomized, double-blind, placebo-controlled clinical studies involving over 2,000 participants, establishing its effectiveness and safety across diverse health applications. [1]. In these trials lasting up to six months, PycnogenolR was shown to be safe and efficacious in 10 different fields of applications.

These evidence-based applications include cardiovascular health [2-12], chronic venous insufficiency [13-15], cognition [16-23], joint health [24-26], skin health [27, 28], eye health [29, 30], women fs health [4, 31, 32], respiratory health and allergies [33-35], oral health [36] and sports performance [37-41].

The mechanisms of action that explain these beneficial effects on different conditions in the human body were investigated in several studies. PycnogenolR has been shown to have four main properties: its antioxidative effects [2-4, 21, 22], its anti-inflammatory action [42, 43], its positive impact on blood circulation and endothelial function [2, 6-8, 44, 45] and its reinforcing effects on the extracellular matrix [46, 47].



Thanks to its unique specification, its botanical source, its standardized extraction process, and specific composition, research findings obtained from these studies are unique to PycnogenolR.

Cardiovascular and endothelial health

The effects of PycnogenolR on cardiovascular and endothelial health have been investigated more than any other health condition [2-12]. As the endothelium . the inner lining of blood vessels . is actively involved in many physiological functions, like controlling blood pressure, blood clotting and signaling during inflammation, endothelial function is crucial for cardiovascular health [48]. A PycnogenolR metabolite was shown to be actively taken up by endothelial cells, exerting anti-inflammatory effects from within the blood vessels, explaining its beneficial effects [45]. PycnogenolR intake was shown to normalize blood pressure and platelet function, to improve blood lipid profile as well as blood sugar levels and microcirculation. The effects of PycnogenolR were investigated in healthy people, individuals with borderline high-risk factors but also as an adjunct in people taking prescription medicine for cardiovascular health issues.

Chronic venous insufficiency

Three placebo-controlled studies on chronic venous insufficiency and vein health have shown another important clinical application of PycnogenolR [13-15]. In fact, venous health has been the first and one of the key applications for PycnogenolR.

PycnogenolR supplementation relieved heaviness, swelling and discomfort in the legs of chronic venous insufficiency patients. In addition, PycnogenolR has been shown to counteract vein insufficiency, reduce edema and prevent thrombosis by improving microcirculation, blood flow and platelet function as well as exerting its beneficial effects on endothelial function and its anti-inflammatory action.

Cognition

In eight publications on placebo-controlled studies investigating the effects on cognitive function, PycnogenolR has shown beneficial effects in all age groups from children with ADHD to elderly people with memory-based cognitive challenges [16-23]. The broad spectrum of benefits of PycnogenolR for ADHD were validated in placebo-controlled studies showing reduced hyperactivity and inattention in children with ADHD [16-21]. PycnogenolR also contributes to preserving healthy mental performance, including memory-based cognitive functions and to managing mild cognitive impairment in elderly people [22, 23].

Joint health

In three randomized double-blind placebo-controlled studies, PycnogenolR intake has been shown to act beneficially in patients with osteoarthritis [24-26]. Osteoarthritis is a condition, in which joint cartilage and the underlying bones are impacted by breakdown events, resulting from mechanical degradation [49]. This can activate inflammation processes, which accelerate degradation of the joint cartilage, causing pain, swelling and stiffness [49]. Half a billion people worldwide are affected by this debilitating condition.

Studies with PycnogenolR showed that discomfort, knee stiffness and physical function improved and the need for analgesic medication in patients presenting with signs of osteoarthritis was reduced after PycnogenolR intake. The mechanisms by which PycnogenolR supports joint health include promoting the expression of collagen and hyaluronic acid synthase, resulting in increased hyaluronic acid and collagen within the extracellular matrix. Additionally, PycnogenolR reduces inflammation by lowering levels of pro-inflammatory and tissue-degrading markers. Anti-inflammatory metabolites of PycnogenolR have also been detected in the knee cartilage fluid, allowing it to target inflammation directly at the site of need. [46, 50].

Skin and hair health

Two studies on skin and hair health have shown PycnogenolR fs versatile effects on beauty in placebo-controlled studies [27, 28]. PycnogenolR intake reduced skin water loss, showing an improvement of skin barrier function, while also enhancing skin elasticity and skin

moisture levels in urban outdoor workers, who are routinely exposed to pollution and sun irradiation. In addition, the development of skin darkening was prevented with PycnogenolR[27]. Increased hyaluronic acid synthase and collagen content as well as the reduction of pigmentation-related mediators after PycnogenolR intake explain these observations [46, 47].

Furthermore, PycnogenolR significantly increased hair density, reduced water loss from subjects f scalp and positively affected microcirculation in the scalp [28]. PycnogenolR fs anti-inflammatory [42, 43] and antioxidant activities[2-4, 21, 22] contribute to protecting hair follicles by capturing free radicals, generated either by stress, sun rays, pollution, or inflammation.

Eye health

Owing to its effects on microcirculation, endothelial function, inflammation and oxidation, PycnogenolR was found to have positive effects on eye health[29, 30]. PycnogenolR showed effects to stop further progression of retinopathy and ameliorate the eyesight of diabetics by stabilizing and sealing leaky capillaries of the retina, stopping further leakage of blood [29, 30]. PycnogenolR supplementation was shown to help protecting retinal capillaries in diabetic retinopathy by improving perfusion of the retinal tissue resulting in the restoration of vision loss in diabetic retinopathy patients.

Women fs health

To evaluate the efficacy of PycnogenolR on the health of women, two placebo-controlled studies focused on menopausal symptoms [4, 31] and one on menstrual discomfort [32] have been conducted.

Menopausal symptoms such as tiredness, hot flashes, night sweats, mood swings, memory and concentration issues, vaginal dryness and sleep problems were improved after intake of PycnogenolR[4, 31]. In addition, blood pressure as well as cholesterol levels were normalized after PycnogenolR intake in these women. Interestingly, PycnogenolR supplementation had no effect on blood plasma levels of different sexual hormones.

PycnogenolR fs validated effects on blood circulation and endothelial health partly explain its beneficial effects on symptoms like hot flashes and sexual behavior.

Additionally, PycnogenolR supplementation significantly reduced abdominal pain in women with dysmenorrhea [32]. They needed less analgesic medication and the number of days on which analgesics were required was significantly reduced with PycnogenolR. PycnogenolR has potent anti-inflammatory properties [42, 43], explaining its efficacy for discomfort caused by menstrual periods, during which the tissue lining of the uterine cavity is replaced, leading to wound healing and inflammation.

Respiratory health and allergies

PycnogenolR has been shown to have beneficial effects on asthma and allergic rhinitis symptoms [33-35]. Recurrent episodes of coughing, shortness of breath, wheezing and chest tightness are typical symptoms of asthma, one of the most common respiratory diseases worldwide [51].

Breathing capacity, as well as allergic rhinitis symptom severity improved and the need for rescue inhalers in asthma patients and for rescue antihistamines in allergy patients was reduced after PycnogenolR intake. Furthermore, PycnogenolR supplementation significantly reduced pro-inflammatory mediators (leukotrienes) in the blood of patients. PycnogenolR fs anti-inflammatory effects are suggested to be responsible for its anti-allergic and anti-asthma efficacy.

Oral health

A study on oral health examined the effects of a chewing gum containing PycnogenolR specifically on persistent bacteria-induced malodor [36]. After chewing the PycnogenolR containing gum, malodor, tongue-coating as well as hydrogen sulfide-producing bacteria in saliva were reduced compared to using the placebo gum. The mechanism behind these effects has been suggested to be the previously observed bacteriostatic properties of PycnogenolR [52].

Sports

In five placebo-controlled studies, PycnogenolR supplementation was shown to enhance sport endurance and performance [37-41].

Endurance time on the treadmill and during biking increased after regular PycnogenolR intake. In addition, PycnogenolR improved muscle contractile performance, power output and velocity during resistance training (six sets of back squats). Furthermore, PycnogenolR intake had beneficial effects on the rating of perceived exertion, on heart rate, blood lactate concentration during performance and on serum NAD+ levels. These results confirm previously shown antioxidant properties of PycnogenolR [2-4, 21, 22] and its protection against the high post-exercise oxidative stress. Another property of PycnogenolR explaining its effect of increased performance is the improved tissue perfusion by enhancing microcirculation[11] and its effects on endothelial function [2, 6-8, 44, 45] contributing to improved blood flow by relaxing blood vessels.

PycnogenolR French maritime pine bark extract is a safe, natural and evidence-based solution to efficiently support a broad range of health applications. The anti-inflammatory and antioxidant properties of PycnogenolR contribute to joint and respiratory health, cognitive function, menopause, dysmenorrhea and sports. Furthermore, PycnogenolR optimizes blood flow by improving endothelial function.

Since blood vessels run through all tissues, the effects of PycnogenolR were seen in cardiovascular and venous health, as well as skin, hair and eye health. For more information on this health supplement allrounder, visit *www.pycnogenol.com* .

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

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Showcasing the future of smart manufacturing at B&R Innovations Day 2026

Pune, February 24, 2026 – B&R India, the Machine Automation division of ABB, hosted its flagship Innovations Day 2026 in Pune, bringing together customers, OEMs, industry experts, and technology leaders to explore new possibilities that are shaping the future of machine automation and smart manufacturing.

The event served as a dynamic platform for knowledge exchange, showcasing innovations, and collaborative dialogue, highlighting how machine builders and manufacturers can enhance agility, productivity, and sustainability through integrated automation solutions.

A key highlight of the event was the leadership address by Florian Schneeberger, Division President of ABB's Machine Automation division (B&R), who shared a global perspective on the future of machines and intelligent manufacturing ecosystems. This was complemented by insights from India leadership, outlining the region's growth trajectory and the increasing role of advanced automation in enabling competitive manufacturing.

"Innovations Day reflects our continued commitment to empowering manufacturers and machine builders with future-ready automation solutions. By bringing together industry stakeholders on a common platform, we aim to accelerate the adoption of intelligent technologies that drive efficiency, flexibility, and sustainable growth."

The event also marked the India introduction of ACOPOS D1, B&R's next-generation servo drive, de-signed to enable intelligent motion control and scalable machine performance for OEMs. Through interactive experience zones and expert consultations, attendees gained first-hand exposure to emerging automation technologies tailored to evolving industrial needs across sectors. Innovations Day 2026 underscores B&R India's commitment to strengthening collaboration within the manufacturing ecosystem while advancing digital transformation across industries.

Inauguration of India Innovations Day

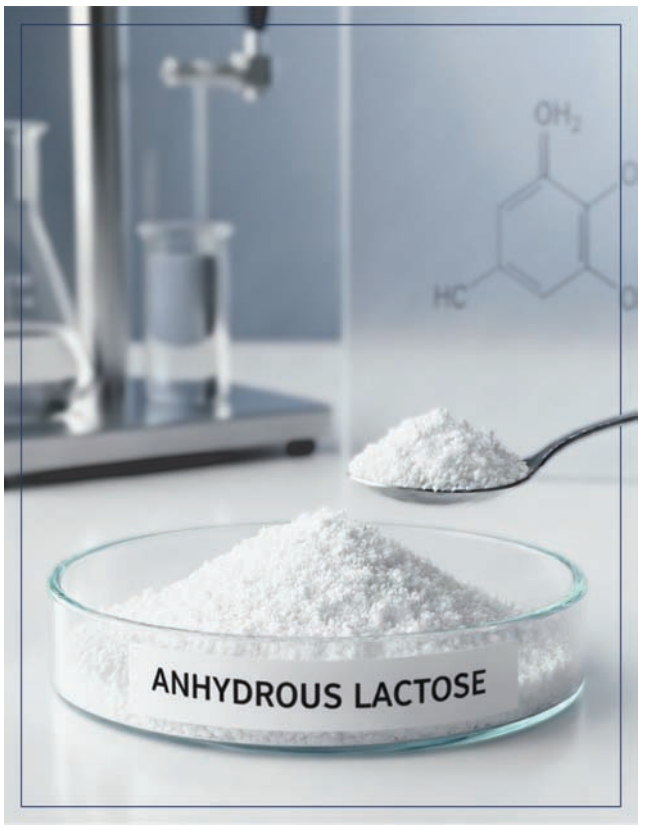
About Machine Automation, ABB

ABB's Machine Automation division delivers automation solutions and services for machine and factory applications across industries such as consumer-packaged goods, printing, life sciences, plastics, energy and maritime. With its B&R's product portfolio, the division delivers integrated control and software, motion control, mechatronics, and machine automation technologies designed to simplify processes and optimize factory operations.

The Curious Case of a White Powder That Nobody Talks About

Most headlines are loud. Most real change isn't. It arrives quietly, through small decisions and overlooked capabilities, and only becomes obvious in hindsight. This note is about one such change.

There are some achievements that don't announce themselves with ribbon cuttings or press conferences. No ministers, no hashtags, no victory laps. They just... happen. And by the time you notice them, they've already changed the terrain.



Lactose India manufacturing advanced ANHYDROUS LACTOSE at scale feels a bit like that

Now, lactose isn't new. Pharma companies have used it forever. It sits quietly inside tablets, capsules, inhalers—doing its job, asking for no attention. Much like public infrastructure, you only notice it when it fails. Which is why nobody ever wrote breathless thought-pieces about where lactose came from.

Until someone had to

As formulations became more complex, APIs more sensitive, and manufacturing speeds more unforgiving, the "boring" excipient started behaving like a bottleneck. Moisture sensitivity, variability, inconsistent performance across batches—suddenly, the white anhydrous powder mattered.

For a long time, the solution was imported material and expertise. That was just how things were done. Not because India couldn't make it—but because nobody had bothered to make it this precisely.

And that's what Lactose India changed

With the introduction of new anhydrous lactose grades by Lactose India, we're seeing something quietly significant: India moving from replicating excipients to engineering them. Grades designed not just to exist in a formulation, but to behave predictably under pressure—mechanical, regulatory, and commercial.

This evolution isn't about adding SKUs. It's about helping formulators design better products with fewer compromises.

None of this fundamentally changes the nature of excipients. They remain supporting actors. But their reliability is now doing more of the heavy lifting than before. The margin for unpredictability has reduced. Global filings, lifecycle management, and cost pressures leave little room for surprises that are individually minor but collectively expensive.

In the end, the best excipient may still be the one that does nothing. The difference is that the industry is paying closer attention to how it manages to do that — consistently, predictably, and at scale.

The unintended consequence?

The future of pharma won't be built on APIs alone. It will be built on the quiet precision of excipients like ANHYDROUS LACTOSE proudly manufactured in India —and on manufacturers willing to think beyond commodity supply.

Indian pharma companies no longer have to design formulations around what's available globally. They can design them around what works locally—and export with confidence.

This won't make headlines. Excipients have not suddenly become more interesting. But a decade from now, it'll be obvious why it mattered.

When the curtain finally lifts, don't be surprised if Lactose India Limited's anhydrous lactose turns out to be one of those quiet breakthroughs that changed the script long before anyone applauded.

For samples, technical details, or formulation support related to anhydrous lactose, please reach out to sales@lactoseindialimited.com. Our team will be glad to assist with specifications, application guidance, and any product-related queries.

Complete environmental monitoring solution – testo Saveris Pharma

There are several critical applications in the industry like research and development that demand for continuous & reliable monitoring of important environmental parameters. From medical, bio-technical, chemical and pharmaceutical laboratories to cleanrooms, biobanks up to blood and tissue banks, a holistic monitoring system is very necessary which reliably records different measurement parameters in these rooms and at equipment. Wherever there is a need to adhere to necessary standards, ensure traceability and audit compliance, especially Pharma, these solutions become crucial in the facility operation.

The most efficient way to address this requirement is the implementation of fully automated environmental monitoring system testo Saveris Pharma. It monitors and documents temperature, humidity, differential pressure, and other parameters without interruption and compliantly with GxP so that audits and inspections are conducted smoothly. As a complete solution, testo Saveris Pharma combines.

- High-precision measurements with secured data communication
- Intuitive and pro validation software
- Comprehensive services.

The system consists of following components

Data logger and communication modules

Data loggers are the components that measure / log the data continuously at different locations in the facility. They communicate with the base unit to transfer the recorded data. Because there are numerous tasks to fulfil in research and development, there are various models of data logger to measure different parameters.

Another important task is data transfer and for that communication modules are used. Each data logger can be flexibly connected to one of the three communication modules.

- WLAN Module
- LAN Module
- Radio via Testo Ultra range communication Module

testo UltraRange ensures that a strong and robust radio signal is available even over long distances or in closed rooms. All data loggers can be exactly calibrated, and depending on the model, can record temperature and relative air humidity. As per the applications, Data Loggers are selected for Environment Monitoring for Warehouse, Analytical/ Microbiology Lab, Animal house or Equipment Monitoring like Refrigerator, Freezer, Chiller, Walk in chamber, etc.

The base station

The base is literally the heart of testo Saveris Pharma system. It can connect with 1000 different Data Loggers at a time. It collects measurement values and analyse it limit value violation or any other critical event occurs. It plays an important role in prompt alarm management. The base unit can be positioned centrally at a given facility location or office. Base station delivers alarms to users via an alarm relay and an LTE stick that enables alarms by SMS as well in addition to visual and audible alarms.

Digital and analog sensors

The instrumentation utilised to measure parameters like temperature and humidity is in the form of variety of digital and analog sensors that are easy to handle and install. The Digital sensors has advantage over analog sensors as it can be quickly exchanged during continuing operation for calibration or defect correction. Calibration of Digital Sensor is independent of its Logger. Thus, it ensures no gap in the measurement values or documentation. The measuring ranges of the temperature probes extends from -200 °C to +1300 °C, covering almost any possible scenario in the field of research & development.

The integration of other measurement parameters such as differential pressure, particles etc. also work smoothly with the analog coupler as a standardized interface.

System software

Once the data is recorded by Loggers and analysed by the base station, the testo Saveris Pharma software comes into play where all readings are collated, stored, visualized, and backed up seamlessly. Automatic reports are generated and sent over email to concerned users. Some important features are applied like electronic signature, Electronic Record, Access Control, Audit Trail, Alarm Logs. There are two versions of the testo Saveris software;

- testo Saveris PRO software- It is suitable for the automated and uninterrupted data monitoring with less stringent regulations, normally other than Pharma Industry.
- testo Saveris CFR software – It guarantees unconditional adherence to US 21 CFR Part 11 as well as Annex 11 of the EU guidelines for GMP. In addition to the range of function of the PRO version, it offers Audit Trail and electronic signatures.

In addition, we provide Web access to the data with testo Saveris Pharma Cockpit - a web based and intuitive user interface which allows data access from different end devices. Alarms can be identified and acknowledged via a smartphone, tablet or PC at any time. It also supports features like digital signature post any action as well as a mandatory comment on the event.

Comprehensive Services

The most important aspect of any solution is after sales service. This is one of the strongest values offered by Testo to its customers. Testo extends its support from site survey, Installation commissioning, IQ-OQ documentation to annual maintenance work and recalibration. So, all the end-to-end services are offered under one roof as an OEM by Testo. Thus, user do not have to run pillar to post to get support, Testo ensures rich user's experience throughout life cycle of the system.

Areas of application

- Area Monitoring in Labs, Production, Warehouse, Animal House in Pharma
- Equipment monitoring for QA/QC, Microbiology in Pharma
- Clean room area Monitoring in Pharma
- Refrigeration and deep-freezer applications in Pharma
- Uninterrupted cold chain monitoring & controlled freezing in blood and bio banks
- Applicable for lab equipment from laboratory extractor to water bath
- Data centre Area Monitoring
- Calibration and Testing Lab area monitoring

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

LUBRITAB® - A versatile excipient from natural origin

Being a solid lipid, LUBRITAB® has various applications pertaining to pharmaceuticals

To design a pharma or nutra formulation, excipients are selected according to their properties, advantages, risks, regulatory status and many more attributes. Due to the benefits of low safety concerns, lipids have become an interesting and promising category of excipients for multiple purposes.[1]

The term "lipid" describes a family of products with diverse physicochemical properties. Their composition includes oils, fats, waxes, fatty acids and their derivatives, and biosynthetically or functionally-related substances to these compounds.[1] Naturally occurring lipids are typically triglycerides (triacylglycerols or triglycerides, TAGs), esters of glycerol and three fatty acids.

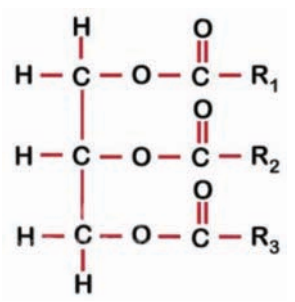


Image 1: Structure of a Triglyceride

The nature and compositions of three fatty acid chains of a TAG molecule, defined as R1, R2 and R3, determine its chemical property. An important characteristic of TAGs is their crystallisation behaviour. The crystallisation behaviour (crystallisation rate, crystal sizes and their network, crystal morphology and crystallinity) of the TAG is directly influenced by polymorphism, and by several external factors such as temperature, pressure, solvent, rate of crystallisation, impurities, etc. Due to the conformation differences, they present different melting points.[1] This difference helps in identifying particular TAG grade (eg Glyceryl monostearate and distearate, Hydrogenated vegetable oil Type I and Type II, various grades of Polyoxylglycerides). This phenomenon is also important to define applications and process of specific TAG moiety.

In pharmaceutics, short chain and unsaturated long chain fatty acids (liquids, semisolids and solids) are approved for use in creams, ointments, emulsions, dispersions and suppositories. Long chain triglycerides, which have no practical ability to self-disperse, are digested rapidly in the intestine (lipolysis). Furthermore, their fatty acids and monoglycerides digestion products are solubilised by bile salt - lecithin mixed micelles, which are then absorbed. The lipid excipients used in pharma development are derived predominantly from the food industry where they are used as additives for emulsification, solubilisation, stabilisation and lubrication since long. Besides, lipid excipients have been refined and fine-tuned for the pharma industry to provide solutions to drug delivery challenges including drug solubility, drug dissolution properties and also to resolve manufacturing issues. Over the last four decades, naturally occurring triglycerides have been modified physicochemicaly to develop excipients suitable for the development of drug delivery systems.[1]

In like manner, solid lipids became more and more interesting as pharma excipients for solid dosage forms. They are normally crystalline in nature and have melting ranges or melting points determined by their chemical structure (and composition).[1] They are chemically inert and their properties such as high hydrophobicity, high melting point and low density can be used -

- to lubricate pharma dry powder blends
- as sustained release agent either alone or in combination
- to mask bitter-tasting drugs
- to solubilise lipophilic drugs [1]

Furthermore, solid lipids used as sustained release agents provide different biopharma properties compared to polymers. Fundamentally, the drug release mechanism is different and this provides formulators with broader options for controlling drug release scope to develop innovative dosage forms.[1] They can be used either alone or in combination with other agents.

Several processing methods could be applied using solid lipids, such as -

- Direct compression
- Dry and wet granulation
- Melt granulation
- Melt pelletization
- Molding
- Spray congealing
- Hot melt coating

Choosing the appropriate TAG for the use in pharma process requires an understanding of their physicochemical properties and its associated effect on lubrication efficiency, API release and taste-masking effect.[1]

TYPICAL PROPERTIES [5]

Structure	Refer to Image 1; R_1, R_2 and R_3 are mainly C_{15} and C_{17}
Acid value	Max. 2.0
Iodine value	Max. 5
Melting range	57° to 70°C
Loss on drying	Max. 0.1 %
Saponification value	175 to 200

Hydrogenated vegetable oil is a mixture of triglycerides of fatty acids. The two types defined in the USP-NF are characterised by differences in their physicochemical properties like melting range and Iodine value. LUBRITAB® complies with Hydrogenated vegetable oil Type I. It is made from the seeds of varieties of Gossypium hirsutum (L) or other Gossypium species by refining, and hydrogenation.[1][2]

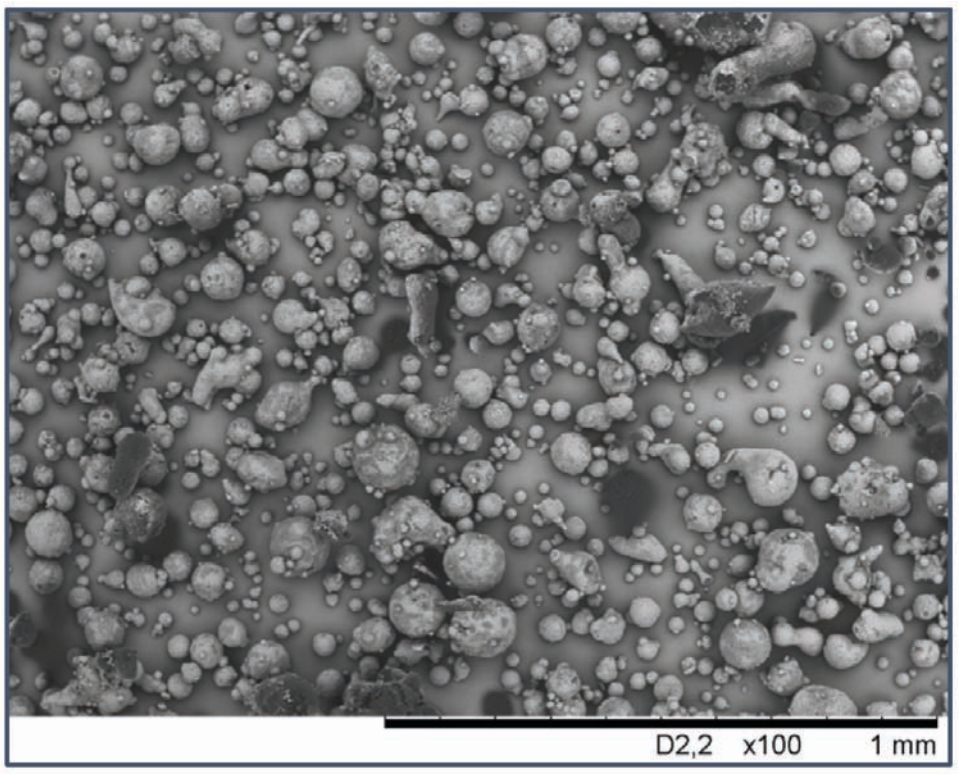


Image 2: SEM image of LUBRITAB® [4]

Applications

LUBRITAB® is used in food products and oral pharma formulations, and is generally regarded as a non-toxic and non-irritant excipient. As discussed in previous section, being a solid lipid, LUBRITAB® has various applications pertaining to pharmaceuticals.

Lubricant: The primary function of lubricants in tableting is to reduce the force required to eject the compressed tablet from the die cavity. In capsule filling, where a plug is formed, lubricants perform essentially the same function by reducing

the force required to transfer the plug from the dosators into the capsule. Without lubricants, these processes would be difficult or impossible and would result in significantly shorter tooling lifespan. LUBRITAB® is used as a lubricant in oral solid dosage forms at a concentration range of 1 - 6 % w/w. It acts as a liquid film-lubricant. It can be used alone or in combination with other commonly used lubricants.[2][3]

Sustained release matrix: LUBRITAB® is additionally used as the matrix-forming material in lipid-based controlled-release formulations; it may also be used as a coating aid in controlled-release formulations. It has also been investigated in hydrophobic melt agglomeration. This application may find more relevant space, where usage of traditional polymers is restricted or limited due to patent or percentage level (regulatory) constraints.[2]

Taste masking: Being hydrophobic lipid in nature, LUBRITAB® does not dissolve into oral cavity. Hence, it can be used as a barrier to mask bitter and/or unpleasant taste of APIs by various methods like melt granulation, hot melt coating and spray-congealing where drug particles can be entrapped in wax matrix or covered by wax layer.

Viscosity modifier: Hydrophobic nature and miscibility with various oily materials, its use as a viscosity modifier in the preparation of oil-based liquid and semi-solid formulations is unique. It imparts this useful property during manufacturing of suppositories, to reduce the sedimentation of suspended components and to improve the solidification process; and in the formulation of liquid and semisolid fills for hard gelatin capsules.[2]

Wax nature of LUBRITAB® makes it a suitable alternative to hard waxes in cosmetics and topical preparations.[2]

Binder: LUBRITAB® may be used alone or in combination as a binder in dry and wet granulation processes. It helps to solve capping and lamination during tableting.[3]

Summary

LUBRITAB® is a plant-derived excipient made by hydrogenation of cottonseed oil. It serves as a lubricant in tablet and capsule formulations. It can also be used as a binder, a taste-masking agent, and in controlled release matrix tablets. It is used in oily liquid and semi-solid dosage forms to alter viscosities.

References

[1] Petrovick, G.F. (2015) Orodispersible Tablets Containing Taste-Masked Lipid Pellets with Metformin Hydrochloride for Use by Elderly Patients. The Faculty of Mathematics and Natural Sciences, The Heinrich Heine University in Düsseldorf.
[2] Sheskey, P.J., Cook, W.G., Cable. C.G. (2017) Handbook of Pharmaceutical Excipients, 8th edition, Pharmaceutical Press, 1007-1009.
[3] LUBRITAB® | Hydrogenated Vegetable Oil- JRS Pharma (https://www.jrspharma.com/pharma_en/products-services/excipients/lubricants/lubritab.php)
[4] SEM Images Lubricants-JRS Pharma (https://www.jrspharma.com/pharma_en/resources/sem-images/lubricants.php)
[5] United States Pharmacopoeia, USP 43-NF 38 (2019).

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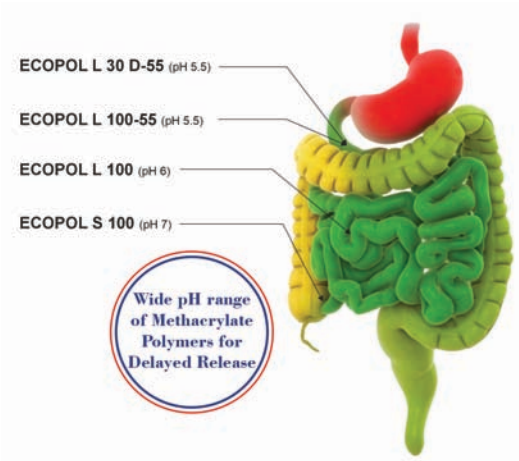
ECOPOL®: A reliable enteric coating solution for delayed-release drug delivery from Ideal Cures - Engineered for Performance, Consistency and Compliance

Enteric Coating: Protecting value until the right site

Enteric (delayed release) coatings are designed to play a critical role in modern oral drug delivery by shielding the drugs from the acidic environment of the stomach and ensuring release in the desired intestinal pH. They are essential for:

- Protection of gastro-sensitive active ingredients (e.g., Omeprazole, Pantoprazole)
- Protection of gastric mucosa from aggressive actives (e.g., Aspirin, Diclofenac Sodium)
- Gastrointestinal targeting (e.g., Clarithromycin, Mesalamine)

An effective enteric coating ensures therapeutic efficacy, patient safety, and regulatory compliance.



"Ideal Cures offers ECOPOL®, a range of go-to-solution comprising methacrylic acid copolymers designed as ready-to-use enteric coating systems that meet pharmacopeial standards and demonstrate performance comparable to established global brands."

ECOPOL®: Ideal Cure's Enteric Coating Platform

Ideal Cures provides ready-to-use enteric (delayed-release) coating systems under the ECOPOL® brand. These systems are based on methacrylic acid copolymers.

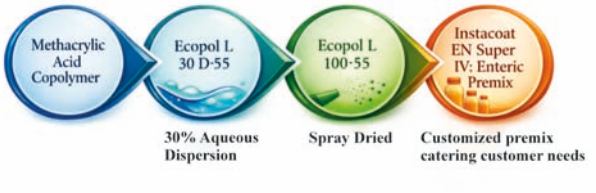
The portfolio includes both aqueous dispersions and solid grades offering flexibility in formulation development and scale-up. They can serve as an equivalent option to the marketed formulation.

Polymer That Delivers

Ecopol® L30D-55 is an anionic copolymer composed of repeating units bearing free carboxylic acid functionalities and ester groups in an approximate 1:1 molar ratio. It is supplied as a 30% (w/w) aqueous polymeric dispersion, pre-formulated with appropriate surfactants to ensure colloidal stability and facilitate direct use in pharmaceutical coating applications.

These copolymers offered as both aqueous dispersions and solid grades, enable flexibility across formulation development, process scale up, and commercial manufacturing. Thus, making Ecopol® formulator friendly.

The carboxylic acid groups ionize in aqueous media at pH 5.5 and above, causing the polymer to remain insoluble in the acidic gastric environment and dissolve once it reaches intestinal pH.



Proven Performance: Comparative with Marketed Brands

Physicochemical Equivalence

- USP and EP monographs: ECOPOL® grades comply with pharmacopeial requirements and match marketed brands.

Why ECOPOL® Should be a Preferred Choice?

ECOPOL® is positioned as a standardized enteric polymer platform designed to meet the integrated expectations of formulation scientists, regulatory teams, and quality professionals.

It offers:

- Regulatory assurance, supported by pharmacopeial monographs Ph. Eur, USP-NF, JPE and a Type IV USDMF, facilitating streamlined global submissions and lifecycle management.
- Formulation versatility, through ready-to-use aqueous dispersions and solid grades that simplify development and manufacturing.
- Formulation readiness via ready to use aqueous and solid grades (Pre-mix).
- Equivalency, demonstrated by physicochemical comparability and performance equivalence with established methacrylic acid copolymers

Sr. No.	Dispersion Properties	Specification USP, EP and JP	Result
1	Description	Milky white liquid of low viscosity with a faint characteristic odour	Complies
2	Solubility	Miscible in water in any proportion; Dissolves in 1:5 parts of acetone, methanol, ethanol and IPA; Dissolves in 1:2 parts of 1N NaOH solution	Complies
3	Identification	A: Infrared absorption; B: Assay	Complies
4	Film formation	A clear brittle film	Complies
5	pH	2.0-3.0	Complies
6	Viscosity (cps)	Max. 15	Complies
7	Loss on drying (% w/w)	NMT 68.5-71.5	Complies
8	Residue on evaporation (%)	28.5 - 31.50	Complies
9	Residue on ignition (%)	Max. 0.2	Complies
10	Coagulum content/ Particulate (mg/100 g)	Max. 1000	Complies
11	Heavy metals (ppm)	NMT 20	Complies
12	Monomers (%)	Max.0.01 in dispersion	Complies
13	Assay (%)	46.0 to 50.6	Complies
14	Acid value (mg KOH/g DS)	300 - 330	Complies
15	Microbial contamination	Total aerobic microbial count - 1000cfu/g; Total combined yeasts and moulds count - 100cfu/g; S. aureus, P. aeruginosa, salmonella & E coli - absent	Complies
16	Residual solvent (Ethanol)	NMT 5000 ppm (In house)	Complies

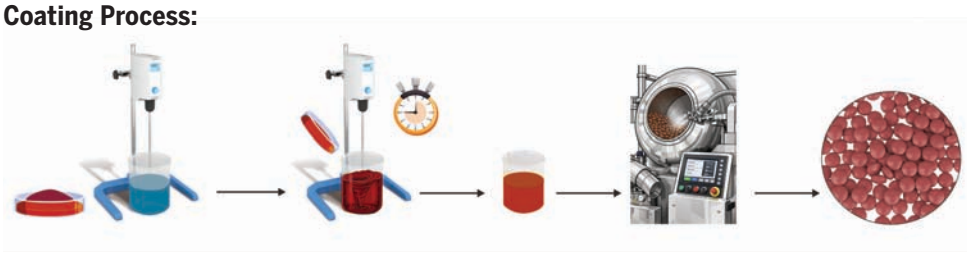
● Reliable scale-up and supply continuity, ensured by consistent manufacturing processes and robust quality certifications.
● Supply security, as it is manufactured in India, making the lead time very less.
● Manufacturing excellence you can trust: It is an ISO 9001:2015 and EXCiPACT certified facility which has commercial production since 2013.

Beyond functioning as an alternative sourcing option, ECOPOL® enables strategic platform standardization. By adopting a single methacrylic acid copolymer system across multiple delayed-release products, organizations can reduce development complexity, strengthen regulatory justification, and simplify long-term product maintenance and lifecycle control.

Application and Performance Evaluation of Instacoat® EN Super IV for Enteric Coating of Pantoprazole Sodium DR Tablets

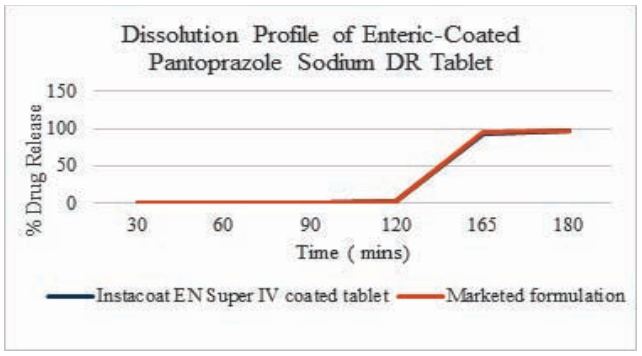
Acid-labile proton pump inhibitors such as Pantoprazole sodium require effective enteric protection to prevent degradation in gastric conditions and to ensure targeted release in the intestine. The formulation challenge lies in protecting the drug core from moisture, acid ingress, and interaction with enteric polymers, while maintaining reproducible dissolution performance.

Coating Process:



Analytical evaluation: Instacoat EN Super IV coated tablet Vs Marketed formulation		
Disintegration test	**Instacoat EN Super IV**	**Marketed Formulation**
Acid stage (pH 1.2, Should remain intact for 2 hours with acid uptake NMT 10%)	2.21 % w/w	2.20 % w/w
Buffer stage (pH 6.8, Should disintegrate within 45 minutes)	18 m 03 s	20 m 42 s

Dissolution testing was performed as per USP-NF 2025 (Test 3) to evaluate the enteric performance of the coated tablets.
Test conditions:
● **Acid stage:** pH 1.2, 0.1 N HCl for 2 hours (900 mL)
● **Buffer stage:** pH 6.8, phosphate buffer solution (PBS) (900 mL)



Inference

The combination of Instamoistshield seal coat and Instacoat EN Super IV enteric coating offers a robust, ready-to-use solution for enteric coating of acid-labile drugs such as Pantoprazole.

The system demonstrated excellent acid resistance, reproducible dissolution performance, and analytical compliance using an HPLC-based dissolution method, making it suitable for scalable commercial applications.

This case study evaluates a two-step coating strategy as follows:		
Step	**Step 1**	**Step 2**
Type	Seal coat	Enteric coat
Product	Instamoistshield	Instacoat EN Super IV (Ecopol L100-55 ready-mix)
Weight gain	2.5% w/w	8%
Reconstitution	5% w/w	20%
Solvent	Organic (IPA:35% & MDC:65%)	Aqueous
Functionality	● Acts as a moisture and migration barrier ● Prevents direct interaction between the alkaline Pantoprazole core and enteric polymer ● Improves adhesion and uniformity of the enteric coat	● No drug release in acidic media (pH 1.2) ● Rapid and complete release at intestinal pH (≥ 5.5)

Advanced Application: Mesalamine Pellets.

Bioequivalence evaluation of Mesalamine pellets is based on the following pharmacokinetic parameters: Tmax, Cmax, AUC_{0-3}, AUC_{0-t} and $AUC0-\infty$.

Mesalamine pellets require colon-targeted delivery, making bioequivalence particularly sensitive to early drug release (AUC_{0-3}).

Conclusion

ECOPOL® methacrylic acid copolymers from Ideal Cures provide a reliable, pharmacopeia-compliant, and reproducible alternative to established enteric coating polymers.

They are equivalent with current marketed Methacrylic Acid Copolymers.

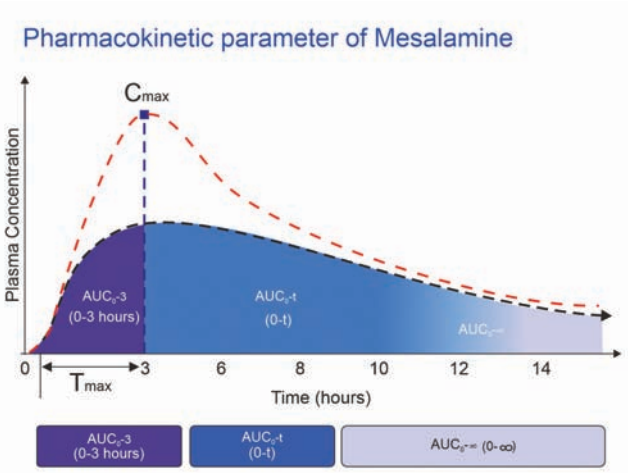
They demonstrate performance across multiple drug products, show robust stability data, and flexibility in formulation design.

ECOPOL® represents a strong solution for delayed-release and enteric coating applications.

ECOPOL® is positioned as a standardized enteric polymer platform designed to meet the integrated expectations of formulation scientists, regulatory teams, and quality professionals

Authors: Tanvi Sawant and Priya Patwa.

One polymer platform. Multiple products.
Lower risk. Greater control.



ECOPOL® coatings can be customized to fine-tune pH-dependent release, ensuring alignment with reference products and successful bioequivalence outcomes.

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ACCELERATE

COATING EFFICIENCY

BENEFITS

- Solid level up to 30% facilitate rapid coating with high productivity gains
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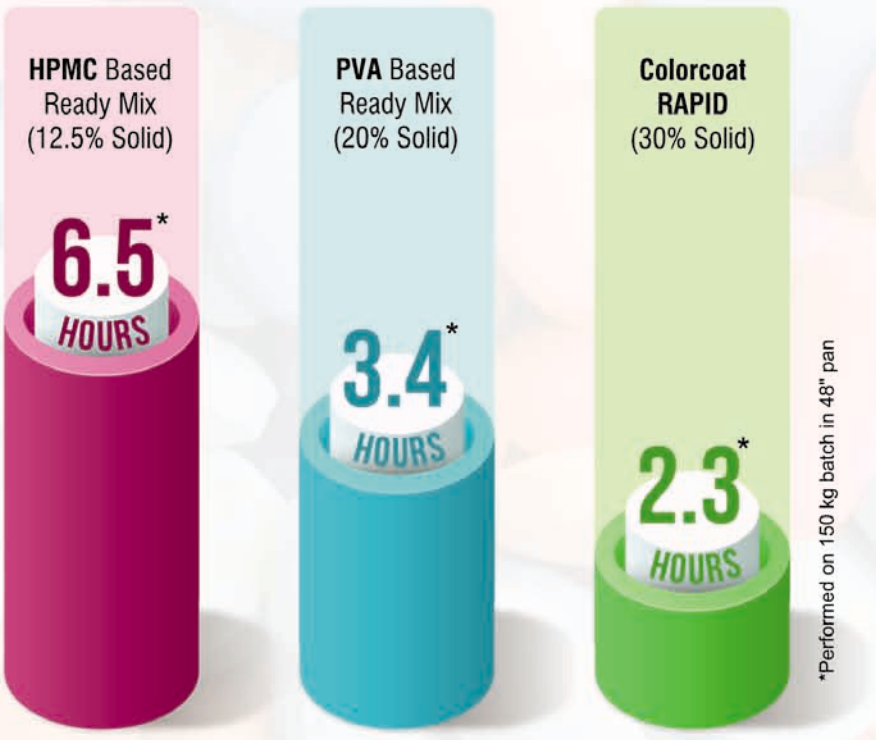
- Rapid solution preparation
- Save energy consumption
- Process Adaptability with smooth and glossy appearance
- Easy scale-up in different equipment types or manufacturing sites
- Suitable for batch and continuous processes
- Regulatory support



*Performed on 150 kg batch in 48" pan

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