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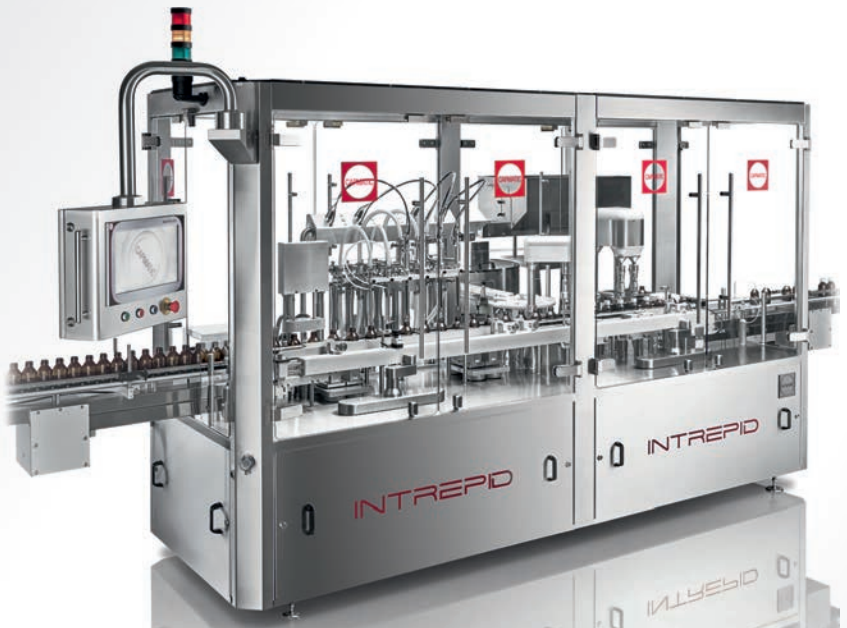

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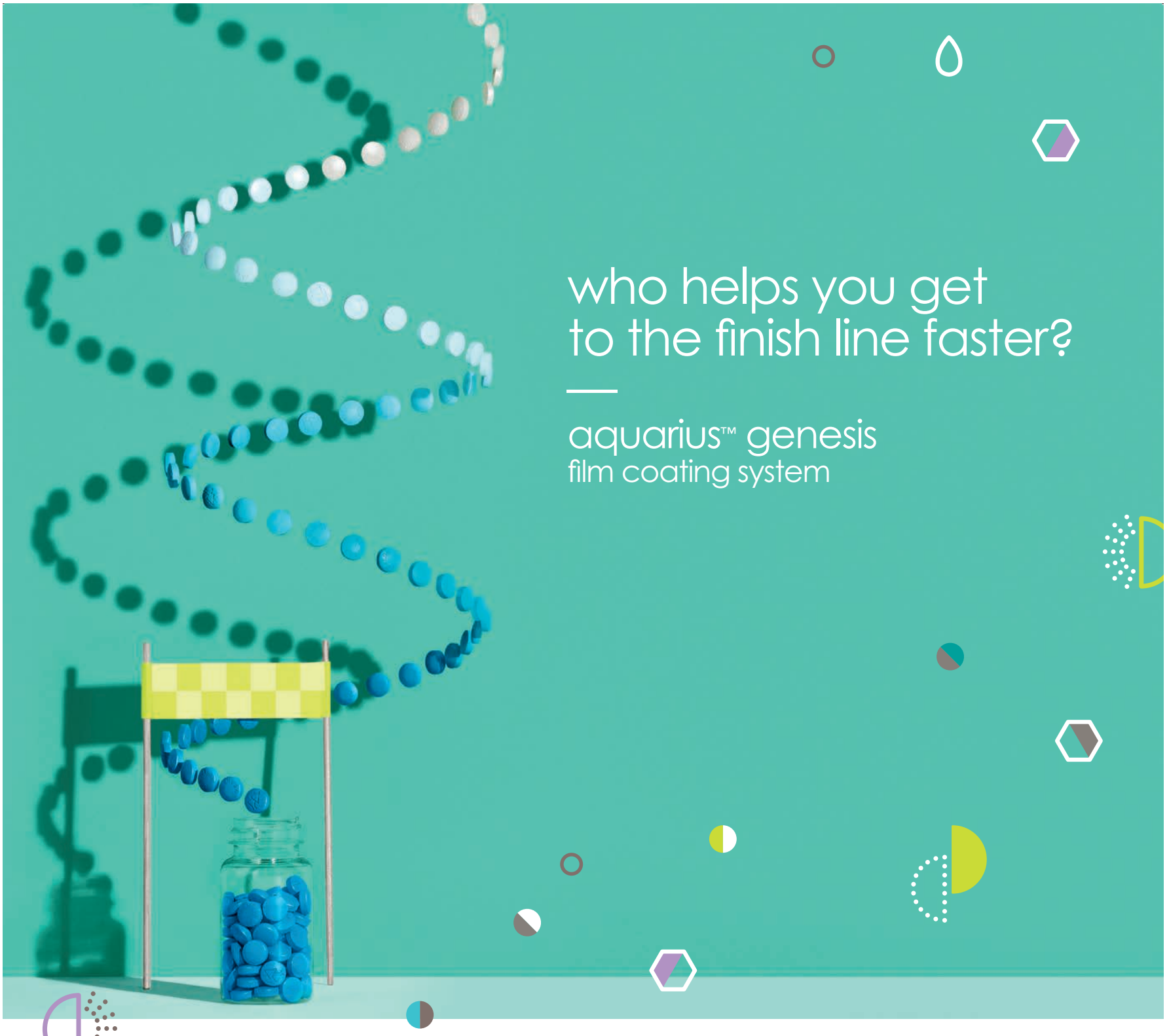

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Policy shifts test pharma's resilience

Important proposed policy changes reflect the government's commitment to make medicines more affordable for patients, weed out unethical marketing practices across the pharma supply chain and over time, hopefully rebuild trust. However, while the sluggish pace of policy change remains a concern, how will these moves impact pharma companies in the long run?

Let's consider the latest salvo on medicine prices. On October 17, the National Pharmaceutical Pricing Authority (NPPA) capped trade margins at 30 per cent for 137 non-scheduled anti-cancer medicines. This comes nearly eight years after a 2019 pilot exercise, which capped trade margins at 30 per cent for 42 non-scheduled anti-cancer medicines. According to government data, as part of the pilot, MRPs of 526 brands were reduced by up to 90 per cent. *(https://www.expresspharma.in/nppa-caps-trade-margins-at-30-per-cent-for-137-anti-cancer-medicines/)* While industry associations like IPA and OPPI have welcomed the move, both call for an assessment of the actual impact of this change on patient access and availability.

Other experts like Mayur Sirdesai, Co-Founding Partner, Somerset Indus Capital Partners, stress that affordability must be viewed across the entire cancer-care pathway, from screening and diagnosis to treatment.

In some cases, the delay in policy change has given industry time to clean up its act. On October 8, the Supreme Court directed the constitution of a three-member Committee to examine existing regulations on pharma marketing and their adequacy for curbing unethical practices. The Uniform Code for Pharmaceutical Marketing Practices (UCPMP), 2015, which was strengthened in 2024, could move from the current self-regulatory framework to a statutory regime. A final decision is still some time away, with the committee expected to submit its recommendations before the next hearing scheduled for January 2027.

Analysing the impact of this policy shift, Nandan Kulkarni and Shirsh Sawarna of Bernstein (India) point out that over the past 12-18 months, large Indian pharma companies have already been gearing up for implementation, by actively strengthening controls, documentation standards, training programmes and healthcare-professional engagement processes. If the regulatory framework ultimately moves toward a more formal statutory construct, they believe larger companies with established governance processes, stronger compliance infrastructure and ethical commercial practices are likely to be better positioned than smaller peers to navigate the transition.

While UCPMP governs manufacturers, the government is also plugging the loopholes across the pharma supply chain, by proposing to expand restrictions in advertisements of Schedule H, Schedule H1 and Schedule X drugs to retailers, wholesalers and distributors.

Will policy changes on affordability, ethical marketing and incentives translate into meaningful outcomes for patients while allowing the industry to remain sustainable?

Again, like the trade margin caps on cancer medicines, this is good news for patients. The proposal is along the lines of the March 2026 advisory from CDSCO prohibiting direct and surrogate advertisements and promotional activities for Glucagon-like Peptide-1 (GLP-1) receptor agonists.

But as a recent analysis by Anushree Kataria, Tanya Kukade and Dr. Milind Antani of Nishith Desai Associates (NDA) points out, these proposed steps could increase the compliance burden for retailers, and could overlap with prior Central Government permissions already taken by manufacturers for the same prescription products.

The fact that non-compliance with the proposed advertising restriction may expose retailers, wholesalers and distributors to regulatory action, including suspension or cancellation of their sale and distribution licences, indicates the serious nature of the proposed draft amendment.

The NDA analysis also points out that the proposed amendment may cover promotional communications concerning Schedule H, Schedule H1 and Schedule X drugs disseminated through digital platforms like online pharmacies.

The November edition of Express Pharma does a status check on another evolving policy initiative, the Pharmaceutical Production Linked Incentive (PLI) scheme, and touches on an important issue: can the next phase incentivise pharma MSMEs to invest more to become globally competitive?

The grouse of pharma MSMEs has been that since its launch in February 2021, the bulk of PLI funds were bagged by big Indian pharma companies while pharma MSMEs, who actually need the funds to upgrade and move to the next level, continued to languish on the sidelines. In response to this feedback, PLI 2.0 was launched in 2024, with some tweaks to make it more accessible for pharma MSMEs. But as the story reveals, MSME leaders are pushing for different, broader metrics to evaluate the scheme's success/impact.

As regulators seek to clean up the pharma sector focused on patient safety and affordability, industry will have to find new ways to be as sustainable as possible. The saga continues....

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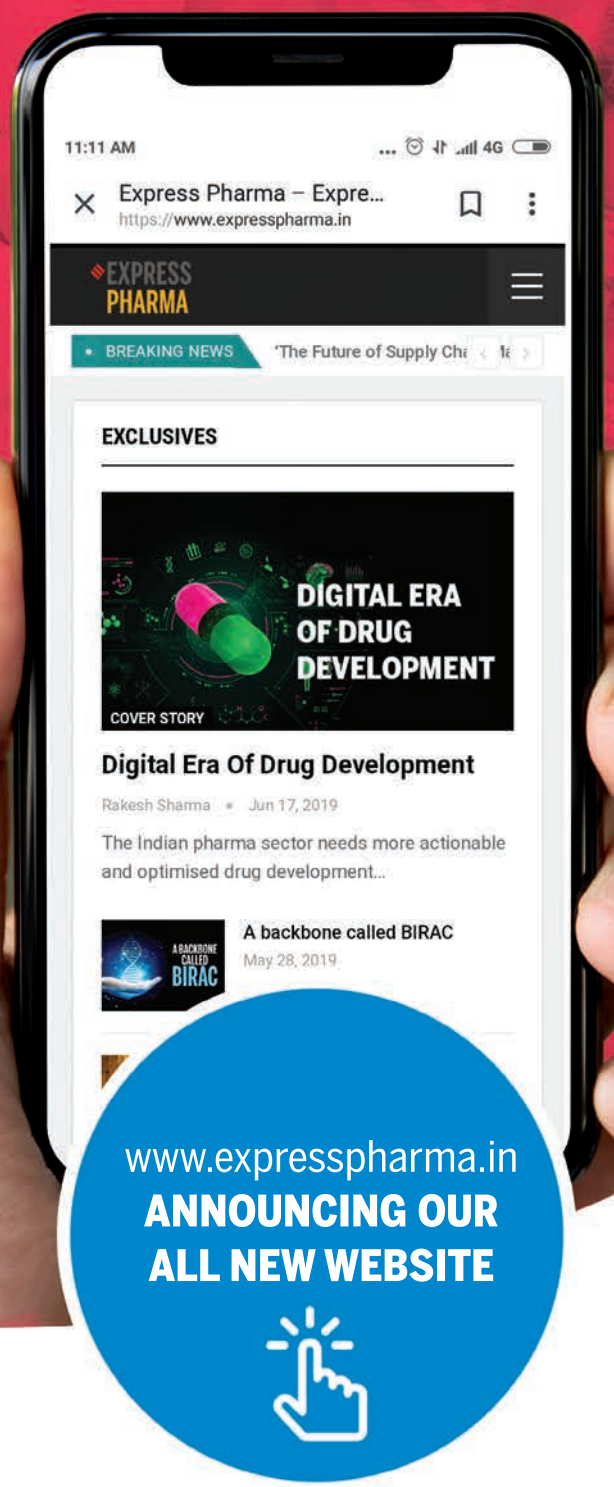

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Indian pharma needs to balance innovation, scale and integration for sustained growth

Dr Simta Jadhav, VP, Raay Neopharma, highlights how AI, formulation-led research and backward integration could shape the next phase of Indian pharma's growth, and discusses why companies need to rethink R&D investment, risk and long-term planning, in an in-person interaction with **Neha Aathavale**

India built much of its global pharmaceutical position on the ability to manufacture affordable generics. But as competition increases and the economics of conventional generics come under pressure, is formulation-led innovation becoming the next logical growth engine for Indian pharma?

Absolutely yes, considering the current market dynamics and geopolitical uncertainties, I believe formulation-led research is no longer just a logical progression for the Indian pharmaceutical industry; it has become a strategic necessity.

There are two major reasons driving this shift. First, the increasing price competition and commoditisation of generics are making it difficult for companies to sustain profitability by relying on volume alone. To remain competitive, companies need to differentiate their products through advanced formulations, improved drug delivery systems and complex generics that offer greater value.

Second, government support and enabling policies are becoming increasingly important in encouraging innovation. Initiatives such as the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) scheme have created opportunities for pharmaceutical companies, including established industry players, to strengthen their R&D capabilities and participate in innovation.

> The future of Indian pharma will depend not only on how much we invest in R&D, but also on how effectively we innovate, differentiate our products and learn from our experiences.

Given the substantial investment and risk associated with developing new chemical entities, formulation-led research offers Indian companies a more practical pathway to build on their existing expertise while developing differentiated, commercially viable products.

Therefore, I believe we will see a stronger shift towards formulation-led innovation in the coming years. This is not to say that new chemical entity research is unimportant, but rather that formulation-led research aligns more closely with the capabilities and commercial realities of many Indian pharmaceutical companies today.

Ultimately, formulation-led innovation is no longer simply an opportunity for growth; it is becoming essential for competitiveness, sustainability and the long-term survival of Indian pharmaceutical companies.

India is increasingly being spoken about as a potential innovation hub rather than only the 'pharmacy of the world'. What, in your view, needs to change within pharma companies themselves for that transition to happen, particularly in how R&D is funded, evaluated and given room to take risks?

Speaking from my experience in R&D, I believe Indian pharma needs to strike the right balance between its traditional strengths and the changing demands of the industry.

Since 2010, Indian pharmaceutical companies have largely built their growth on the generics business, particularly exports to the US. However, with changing trade policies, increasing competition and saturation in several generic segments, the industry is now moving towards complex generics and more differentiated products.

In this scenario, I believe Indian companies should increasingly focus on formulation-led innovation rather than immediately moving towards new chemical entities (NCEs), which require significantly higher R&D investments and involve greater financial risks. By leveraging our existing strengths in formulation development, drug delivery systems and complex generics, we can build differentiated products without necessarily taking on the investment burden associated with developing a completely new molecule.

However, beyond investment, one of the most important changes required is to build a culture of innovation within Indian pharmaceutical companies. Innovation should not be viewed as an occasional initiative but as an integral part of the organisation's R&D strategy.

Equally important is developing a culture that accepts risk and failure as part of the innovation process. In research, not every project will succeed, and not every investment will translate into a commercial product. A project that fails can still provide valuable scientific insights and learning for future development. Instead of

treating failure as a reason to terminate the innovation journey, companies should view it as an opportunity to learn, reassess and improve their approach.

Ultimately, the future of Indian pharma will depend not only on how much we invest in R&D, but also on how effectively we innovate, differentiate our products and learn from our experiences. We need to move from being purely volume-driven generic players to innovation-led companies, while continuing to leverage our existing strengths in manufacturing, affordability and formulation expertise.

What do you think might be the major reasons for many companies to downsize their R&D?

From what I have observed, the current downsizing across several pharmaceutical companies is closely linked to the challenges in their export businesses in specific US market. Traditionally, companies have followed a growth trajectory that begins with the domestic market, expands into the emerging markets, and eventually moves into highly regulated markets such as the US and Europe.

Since around 2010, India has established itself as a major player in the global generics market. However, entering and sustaining a presence in US regulated markets has also meant dealing with increasing scrutiny around manufacturing practices, GMP compliance and product quality, particularly from the US FDA. In highly competitive segments, especially where generic products compete directly with innovator brands, regulatory compliance and manufacturing quality become critical factors. At the same time, the market has continued to operate under complex commercial and regulatory dynamics.

In my view, one of the major reasons for the current shift is the increasing saturation of the US generics market. Changing US trade policies, tariff-related uncertainties and intensifying competition are putting pressure on the traditional export-driven business model. Since export revenues have historically supported a significant portion of Indian pharmaceutical companies' growth and R&D investments, any slowdown in this business directly affects their ability to sustain those investments.

The domestic market presents a different set of challenges. Price controls under the DPCO and regulation by the NPPA can limit the commercial returns companies achieve on certain formulations. Consequently, even when a company invests in formulation-led or innovation-led research, it may not be able to realise the same value from the product in India as it could in international markets. This creates a fundamental challenge: companies are expected to invest in innovation, but the commercial environment does not always allow them to recover those investments adequately.

Another important factor is the evolving regulatory landscape in Europe and the UK following Brexit. Regulatory requirements and submission pathways have changed, and companies may need to reassess their existing regulatory strategies, documentation and dossiers to meet the respective requirements. For example, a regulatory dossier or marketing authorisation approach previously used for the EU may not automatically be sufficient for the UK. Such changes can increase compliance costs, development timelines and the resources required to maintain market access.

Therefore, I believe the current reduction in R&D investment is not attributable to a single factor. It reflects a combination of saturation in the US generics market, changing trade policies, domestic price controls and evolving regulatory requirements across international markets.

Ultimately, the key challenge for Indian pharma is that the traditional export-driven model, which helped fund growth and R&D for many years, is becoming more difficult to sustain. Companies now need to reassess their market strategies, diversify their revenue streams and focus on differentiated products and innovation, while ensuring that the commercial returns justify the investments required.

There is now a lot of talk about complex generics, differentiated drug delivery and reformulation

as the middle ground between conventional generics and discovering a completely new molecule. Do you think Indian pharma is sufficiently willing to invest in this space, or is the industry still too focused on volume and speed to market?

Here, I believe Indian pharma needs to strike the right balance between volume and innovation. Our traditional strength has been large-scale manufacturing and the ability to provide affordable medicines. However, with the US increasingly focusing on strengthening domestic manufacturing under its Make in America agenda, relying solely on scale and volume may not be a sustainable long-term strategy. We need to move up the value chain by investing more in innovation.

While India is making progress in this direction, the challenge lies in generating adequate returns on R&D investments, particularly when the domestic market alone may not be sufficient to justify the cost and risk involved. Developing a niche product does not necessarily translate into commercial success, and this uncertainty can act as a significant barrier to innovation.

At the same time, ensuring access to affordable medicines remains critical. The question is how we balance affordability with the need to create a commercially viable environment for innovation. This is where government policy becomes important—not just in encouraging R&D investments, but also in creating mechanisms that enable companies to recover those investments and generate sustainable returns.

Ultimately, we should not move away from our strength in generics and manufacturing scale; rather, we need to build on it by strengthening our innovation capabilities.

Indian pharma needs to strike the right balance between its traditional strengths and the changing demands of the industry

For a company trying to move beyond the conventional generics playbook, the challenge is not just developing a different product but deciding which problems are actually worth solving. From a leadership perspective, how do you decide where to take an R&D bet and where not to?

From an R&D and leadership perspective, I believe the first step is to clearly understand an organisation's core capabilities and strengths. Every company has its own areas of expertise, and strategic decisions should be built around those strengths rather than driven purely by industry trends. For instance, biologics and biosimilars are receiving significant attention today, but that does not necessarily mean every company should enter these segments without first assessing its capabilities and preparedness.

One of the key challenges is the availability of skilled talent. While biotechnology is gaining momentum in India, the pool of professionals with deep, hands-on experience in biologics and biosimilars remains relatively limited compared with the established expertise available in conventional formulation development. Some companies have already invested in these areas, but building the necessary technical capabilities and developing a skilled workforce takes time.

Therefore, as leaders, we need to take a two-pronged approach. First, we should strengthen our existing core competencies through innovation, platform technologies and formulation-led research that can create differentiation and establish a sustainable competitive advantage. Second, if we want to enter emerging areas such as biologics and biosimilars, we must invest in the right talent, technical expertise and infrastructure required to succeed.

Equally important is the need to evaluate the commercial viability of every R&D investment right from the beginning. We must assess the investment required, the development timelines, the market potential, the expected returns and the competitive landscape. In the generics business, for example, understanding the market forecast, anticipated price erosion and the likely entry of other generic players is critical to making informed decisions.

We often see projects being put on hold or discontinued after substantial investments have already been made. This can happen when the initial assessment does not adequately account for development costs, commercial risks or changes in market dynamics. By the time a product is ready for launch, the market opportunity may have diminished significantly.

Ultimately, leadership in R&D is not just about deciding what to develop; it is about deciding where to invest, when to invest and whether the investment can deliver sustainable value. A thorough assessment of technical capabilities, talent, timelines, financial commitments and market potential is essential to ensure that innovation is not only scientifically successful but also commercially viable. This is how companies can protect their resources, minimise risks and build a sustainable R&D pipeline for long-term growth.

If you look five to ten years ahead, what do you think will distinguish the Indian pharma companies that successfully move up the value chain from those that remain dependent on the traditional generics model? And what leadership choices need to be made now to get there?

Looking ahead over the next five to ten years, I believe AI will play a transformative role in the pharmaceutical industry, much like the impact we have already witnessed in the software sector.

We are already seeing a shift in how AI platforms are being developed and applied across pharmaceutical R&D. Initially, the focus was largely on compatibility, but today, these platforms are expanding into areas such as formulation stability prediction, clinical study outcomes and biopredictability. For instance, in formulation development, AI-driven platforms have the potential to significantly reduce the number of experimental trials required. What might traditionally take 10 to 15 trials could potentially be narrowed down to just two or three targeted experiments, depending on the formulation and the complexity of the product. Several excipient companies are also developing platforms based on Biopharmaceutics Classification System (BCS) principles, offering ready-to-use formulation approaches that companies can further optimise for their specific requirements. Similar advancements are taking place in predicting in-vivo performance and biopredictability.

Therefore, adopting AI will increasingly become a strategic necessity rather than simply a technological advantage. However, successful adoption will depend not only on the availability of these platforms but also on hiring the right talent, building internal capabilities and integrating AI effectively into existing R&D workflows.

Another major challenge for pharmaceutical innovation is backward integration and the security of the supply chain, particularly for active pharmaceutical ingredients (APIs), key starting materials and other critical raw materials. Geopolitical disruptions, including conflicts in regions such as West Asia, have highlighted how vulnerable supply chains can be. In some cases, sourcing APIs, raw materials or even specific impurities can take three to four months, potentially delaying development timelines and product launches.

Therefore, going forward, pharmaceutical companies need to focus on two critical priorities: leveraging AI to improve the speed and efficiency of R&D, and strengthening supply-chain resilience through better sourcing strategies and backward integration wherever commercially viable. Ultimately, the future competitiveness of Indian pharma will depend on how effectively we combine technology-driven innovation with supply-chain security. AI can help us develop products faster and more efficiently, while stronger control over critical raw materials can help ensure that these innovations reach the market without unnecessary delays.

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From lab to market: Bridging India's pharma innovation gap

India has the scientific talent and research infrastructure to move beyond its generics leadership, but turning academic discoveries into commercially viable products remains a challenge. **Dr Richa Dayaramani,** Scientist Grade F at NIPER Ahmedabad, discusses the gaps between academia and industry, the challenges of scaling research, and how stronger industry partnerships, quality systems and commercialisation pathways can help India build its innovation ecosystem, in an interview with **Lakshmipriya Nair**

India wants to move from being a global generics hub to a leader in pharma innovation. From your vantage point in academia, what is holding that transition back?

With our vast talent base and premium manufacturing capacities we can accelerate our path to global leadership by actively tackling four foundational pillars in research and academia. A seamless, trust-based collaboration between industry and research institutions to fund frontier innovation, synergistic partnerships where industry confidently backs early-stage, visionary academic research is the need of hour. Simultaneously, academia can evolve its metrics of success- moving beyond publication counts to celebrate tangible outcomes like patent commercialisation, technology transfers, and thriving spin-offs that reward every contributor. We have a tremendous opportunity to scale up our R&D investment from the current 0.6 per cent to 0.7 per

cent of GDP toward the two to three per cent benchmarks seen in nations like the US, China, and South Korea. Our academic laboratories are equipped with world-class capabilities in pharma, biopharma and molecular research. The next vital step is to surround our scientists with a robust translational ecosystem while simultaneously empowering senior faculty and institutional leaders to embrace this new era of commercialisation using industry norms of quality management system establishment in research laboratories. By pairing this infrastructure with more agile, modern regulatory pathways for advanced therapeutics and biologics, we can match the velocity of global innovation hubs like Boston or San Francisco and dramatically shorten the journey from the lab bench to the patient. This will develop a mature network of scientist-entrepreneurs who can successfully take a novel drug to market and can mentor the next generation so as to channel this immense intellectual capital into our own rapidly evolving innovation ecosystem.

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Pharma companies are under pressure to innovate faster and manage R&D costs. What can academia realistically do to help industry solve problems faster?

To accelerate innovation and curb soaring R&D costs, academia and pharma companies can function as dynamic, agile research partners. Although, in realistic terms, universities may not keep up the pace and match the scale of industrial development, but they can fundamentally derisk the early stages of discovery. Embracing a culture of open innovation and pre competitive consortia academia can work with multiple pharma companies on shared, non-proprietary challenges. Implementing clear, pre-negotiated, and industry-friendly licensing frameworks allows companies to quickly pick up academic discoveries and move them into pipeline development without legal friction. Replacing a publication first mindset to a patent and proof of concept validation will reduce target failure rates.

Instead of every pharma company investing in niche, expensive equipment universities can operate as centralised, state-of-the-art "core facilities" providing rapid testing services to industry partners at a fraction of the cost. Academia can co-design curriculum and PhD programs with industry inputs. Creating seamless pathways for academic faculty to spend sabbaticals inside pharma R&D labs-and vice versa-ensures that academic research stays aligned with actual, practical commercial bottlenecks.

There is still a gap between a promising academic discovery and something industry can develop at scale. Where does that gap usually emerge?

The gap between a promising academic discovery and a scalable industrial product is known as the "Translational Valley of Death". For instance, an academic lab might successfully synthesise milligrams of a complex molecule using expensive, low-yield, or highly toxic chemical steps while the industry requirement is in kilograms or tons produced via highly reproducible, safe, and cost-effective processes. A compound that successfully kills cancer cells in a petri dish frequently fails inside a complex living organism. Academic researchers in India often lack the specialised resources to test Pharmacokinetics and Pharmacodynamics.

Industry requires data generated under strict Good Laboratory Practice (GLP) standards. When pharma companies attempt to replicate breakthrough academic findings under rigid industrial conditions, a startlingly high percentage of the results cannot be reproduced, killing the project instantly. While academia rewards novelty industry rewards clinical utility for a drug that is safer, cheaper, or easier to administer than what is already on the pharmacy shelf. The IP blind spot further gaps this valley because academic scientists often publish their findings too early and without an airtight patent protection, industry cannot justify spending hundreds of millions of dollars to bring the discovery to market.

NIPER was created to strengthen specialised pharma education and research. How do you see its role evolving as the industry moves towards complex generics, biologics, advanced drug delivery and other newer technologies?

As the Indian pharma sector transitions from volume-based traditional generics to a high-value, innovation-driven biopharma powerhouse, the National Institute of Pharmaceutical Education and Research (NIPER) is shifting its core focus toward specialised R&D, advanced therapeutics, and industry collaboration. With national initiatives like the ₹10,000-crore biopharma manufacturing push, NIPER campuses are expanding infrastructure for non-communicable diseases (such as cancer, diabetes, and autoimmune disorders) to build domestic expertise in biologics. Responding to specialised industrial demand, NIPER has integrated dedicated streams and testing infrastructure for medical device engineering and regulatory compliance. Moving away from routine manufacturing support, NIPER acts as an incubation and grant-support hub for faculty-led and student-led deep-tech pharma startups. To catalyse the transition of NIPERs and the wider ecosystem toward complex therapeutics, the Government of India has deployed a multi-layered support architecture. These flagship initiatives directly bridge the gap between academic research, regulatory compliance, and commercial market entry. With a ₹5,000 crore total financial outlay, the PRIP scheme managed by the Department of Pharmaceuticals is the cornerstone of India's innovation push. Allocates ₹700 crores to establish dedicated Centres of Excellence (CoEs) across all seven NIPER campuses. Each campus focuses on a specialised domain. A newly formed institutional bridge led by the Secretary of the Department of Pharmaceuticals. It brings together all major industry associations and NIPER heads to ensure academic curricula and research directly match the industry's shift toward biologics and advanced engineering. By intentionally linking financial backing, infrastructure building, regulatory handholding, and intellectual property support, the framework targets the historical bottlenecks that previously slowed down Indian pharma innovation.

Coming to your own work, what is the specific problem your research is trying to solve, and why does it matter to patients or the pharma industry today?

My research focuses directly on bridging the gap between advanced formulation science and real-world execution, specifically within injectables and specialty formulations. In the current landscape, formulation is becoming the primary value driver and differentiator. My work focuses on designing future formulations that support self-administration through wearable injectors, pre-filled syringes, and next-generation delivery systems. My dual role as a Scientist & Project Manager for the PRIP Centre of Excellence (CoE) in Medical Devices, combined with my credentials as an ISO 13485 Lead Assessor, allows me to bridge the critical gap between academic prototyping and global commercialisation under the guidance and visionary leadership at institute level. The primary reason many innovative medical device prototypes fail to reach the market is a lack of compliance with international Quality Management Systems (QMS). As a certified ISO 13485 Lead Assessor, I embed global compliance requirements directly into our scientific workflows. Establishing a Quality Management System (QMS) and securing NABL accreditation (ISO/IEC 17025:2017) for specialised testing laboratories is the definitive step in transforming a research laboratory into a globally recognised conformity assessment body. At the PRIP Centre of Excellence in Medical Devices at NIPER Ahmedabad, we executed this exact roadmap. The NIPER-A Testing Laboratory (NTL) achieved national milestone status as India's first NABL-accredited facility for specialised mechanical orthopedic implant testing. I spearhead the establishment of our Quality Management System (QMS) and direct the end-to-end documentation pipeline required to secure NABL accreditations across our specialised mechanical, analytical, and biocompatibility testing laboratories. Ultimately, our goal at the CoE is to prove that when academic research embraces a rigorous, regulatory-first approach, it creates intellectual property that the pharma and MedTech industries can rapidly scale, commercialise, and bring directly to patients.

When research moves closer to commercialisation, what tends to become the biggest challenge-funding, scale-up, validation, regulatory requirements or finding the right industry partner?

Moving research out of the lab and into the market-a risky transition known as the "Valley of Death"-presents a complex web of hurdles rather than a single isolated challenge. While the exact bottleneck varies by sector, deep-tech and science-based innovations are primarily choked by regulatory compliance and validation, where navigating rigorous FDA/EMA approvals and multi-phase clinical trials requires years of effort and carries the highest risk of failure. Furthermore, companies must conquer industrial scale-up by translating delicate lab protocols into stable, cost-effective manufacturing processes, while simultaneously achieving market validation by securing channel partners or enterprise customers to prove the scientific breakthrough solves a genuine, profitable problem.

If you could change one thing about the way Indian academia and pharma industry work together today, what would you change-and what difference could that make to India's innovation ambitions?

Evolve a co-owned, co-delivered, and co-evaluated translation models by expanding the policies that allow academic researchers and professors to actively spin off or lead commercial ventures while retaining institutional ties. By implementing flexible, tiered licensing agreements allows industry partners to take commercial risks while ensuring universities receive fair royalties and empowering scientists to transition smoothly between teaching and industry roles creates a dynamic exchange of ideas and upskilling.

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AI and the future of pharmacy education

Prof. (Dr) Satish Sardana, Director, Amity Institute of Pharmacy, Amity University Haryana speaks to **Kalyani Sharma** about how AI is shaping pharmacy education and the skills future pharmacists will need in an evolving healthcare landscape

AI is moving beyond drug discovery into areas such as clinical decision-making and pharmacy practice. How is this changing the skill sets expected from the next generation of pharmacists?
AI is shifting the pharmacist's role from someone who mainly dispenses and checks to someone who interprets, verifies, and takes responsibility for what automated systems recommend. Pharmacists will use tools that flag interactions, predict adverse events, and suggest dosing. Basic biostatistics and the ability to assess a validation study could become routine.

When systems can recall interactions instantly, need for memorisation will be reduced. Deciding when to trust an alert, when to override it, and when a recommendation doesn't suit a particular patient matters more. Over-reliance on it can cause errors, so pharmacists must verify AI outputs. As routine verification is automated, pharmacists move toward medication therapy management, deprescribing, polypharmacy review, and co-managing chronic disease. This needs strong pharmacology and therapeutics, since they must explain why a recommendation makes sense.

New questions may arise specially, when an AI-informed recommendation harms a patient. More concerns will be about how data is protected, whether algorithms are biased, and how AI use is disclosed. Knowledge of privacy, consent, and regulation will be essential. Communication, empathy, and trust-building cannot be replaced by AI. With less time on dispensing, pharmacists will counsel more, improve adherence, and address misinformation.

As precision therapeutics and personalised medicine gain ground, what changes are needed in pharmacy education to prepare students for more individualised approaches to treatment?
Precision medicine is shifting healthcare from a one-size-fits-all approach to treatments tailored to a patient's genetic, clinical, and lifestyle profile. To prepare students for this shift, pharmacy education must strengthen training in pharmacogenomics, genetic variation, biomarkers, epigenetics, and tumor genomics, particularly in areas where precision therapies are advancing rapidly.

Students should learn how gene-drug interactions influence treatment outcomes and gain experience interpreting pharmacogenomic reports to support therapy decisions.

The curriculum should also build skills in biostatistics, data analytics, evidence appraisal, and the use of EHRs and clinical decision-support tools, while encouraging consideration of factors such as genetics, age, comorbidities, and patient preferences. Equally important are topics such as ethics, patient privacy, informed consent, and the limitations of genomic data, particularly in a diverse country like India. Regular faculty upskilling and curriculum updates will be essential to prepare graduates to deliver personalised, evidence-based care.

How is AI being integrated into pharmacy curricula today, particularly in areas such as drug discovery, pharmacovigilance, formulation development, and clinical pharmacy?
AI is becoming an integral part of pharmacy education through the revised Pharmacy Council of India (PCI) curriculum, which introduces students to programming, data analytics, machine learning, AI applications, and ethical considerations. The learning progresses semester-wise, beginning with Python programming and pharmaceutical data analysis in Semester I, followed by biostatistics and data analytics in Semester II, machine learning applications in Semester III, AI applications in pharma sciences in Semester VI, AI in clinical practice in Semester VII, and ethical and translational aspects of AI in Semester VIII.

This structured approach equips students to apply AI in drug discovery, formulation development, pharmacovigilance, pharma manufacturing, and clinical pharmacy, while developing the skills needed for evidence-based decision-making and the responsible use of emerging technologies in healthcare.

> Precision medicine is shifting healthcare from a one-size-fits-all approach to treatments tailored to a patient's genetic, clinical, and lifestyle profile. To prepare students for this shift, pharmacy education must strengthen training in pharmacogenomics, genetic variation, biomarkers, epigenetics, and tumor genomics, particularly in areas where precision therapies are advancing rapidly

What gaps do you see between the skills being taught in pharmacy institutions and what the pharma industry now expects from graduates?
With the growing adoption of AI, automation, and digital technologies, the gap between pharmacy education and industry expectations is becoming more evident. While institutions provide strong theoretical knowledge, the pharma industry increasingly seeks graduates who can apply this knowledge in real-world settings.

Key gaps include limited exposure to industry practices such as Good Manufacturing Practices (GMP), regulatory compliance, quality systems, and digital tools used in manufacturing, research, and clinical operations. Employers also expect skills in data analytics, problem-solving, critical thinking, and the use of emerging technologies like AI. In addition, graduates often need stronger training in clinical application, pharmacovigilance, and patient-centered decision-making. For example, students may know the names of regulatory guidelines but struggle to interpret them or apply them to real documentation, inspections, and compliance scenarios; students may be trained to reproduce known results rather than independently solve complex scientific and technical problems, or they may know how to perform an analytical test but lack the investigative and documentation skills required when results deviate from specifications or a quality system fails.

Bridging these gaps will require greater emphasis on practical training, industry internships, digital literacy, interdisciplinary learning, and hands-on experience with modern pharma processes. This will help ensure graduates are workforce-ready and equipped for the evolving needs of the industry.

With pharma becoming increasingly interdisciplinary, how can universities strengthen collaboration between pharmacy, biotechnology, data science and other technology disciplines?
Universities can strengthen interdisciplinary collaboration by integrating cross-disciplinary courses, joint projects, and problem-based learning into the curriculum. They should establish shared research centres and laboratories, encourage partnerships with pharma and technology companies, and provide industry internships. Universities can also pair an academic supervisor with an industry scientist or technology specialist, giving students experience with pharma R&D, biotech startups, clinical research organisations, health-tech firms, and AI companies.

Creating incentives for collaborative research and innovation will further help students and faculty work across disciplines to address real-world healthcare challenges.

What role can academic institutions play in preparing pharmacists to work with emerging technologies while ensuring that scientific rigour and ethical considerations remain central?
Academic institutions have a critical role in preparing future pharmacists for a technology-driven healthcare landscape. They must equip students with knowledge of AI, precision medicine, genetic testing, and digital health tools, while fostering critical thinking to evaluate technology-driven insights. Pharmacy education should also emphasize ethics, patient privacy, interdisciplinary collaboration, and practical industry exposure. Ultimately, the goal is to develop pharmacists who can responsibly leverage emerging technologies to improve patient outcomes and drive healthcare innovation.

Looking ahead, which areas of pharma research and practice do you believe will see the biggest impact from AI, precision medicine and other emerging technologies, and how should pharmacy education prepare for this shift?
AI, precision medicine, and emerging technologies will significantly impact areas such as drug discovery and design, clinical trials, pharmacovigilance, regulatory compliance, and personalised medicine. These innovations can help accelerate research, improve diagnosis, reduce medication errors, and enable more targeted and effective patient care.

To prepare for this shift, pharmacy education should incorporate foundational knowledge of AI, digital health, and data analytics, along with practical exposure through hospital training, laboratory work, and industry training and real-world examples. Students must also learn to critically assess AI-generated information, protect patient privacy, and use technology ethically. Regular curriculum updates and faculty training will be essential to ensure graduates are equipped to use these technologies confidently and deliver safer, better patient care.

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How consumers' demand for transparency will raise the scientific standard of dermocosmetics

Will Indian consumers finally get products formulated for their skin types? **Professor Dr. Gabriel Serrano,** Founder, Sesderma shares insights on how global formulations may not always address the needs of Indian skin types, why precision dermatology and delivery can address these gaps and why in an email interaction with **Viveka Roychowdhury**

How do Indian skin types and physiology differ and where do global dermacosmetic formulations, even though some may be innovative, fall short?

India is not one skin type. There is enormous diversity in phototypes, pigmentation, climate, humidity and individual skin behaviour. However, in Indian and other Asian skin, pigmentation disorders such as melasma and post-inflammatory hyperpigmentation are particularly important, and inflammation or procedures can sometimes leave pigmentation behind.

This is where a global formulation can fall short: it may be scientifically excellent, but not necessarily designed around the specific biology and daily environment of Indian skin. We must formulate according to the skin need, not simply according to geography or marketing trends. In India, I would pay particular attention to pigmentation, photoprotection, barrier integrity, sensitivity and tolerance. The same active, at the same concentration and delivered in the same way, does not necessarily produce the same result in every population.

For me, the future is precision dermatology: understanding the individual skin and adapting the formulation, delivery system and regimen accordingly.

Why does formulation science matter when it comes to dermocosmetics?

Because an ingredient on an INCI list is not the same thing as an effective treatment. This is one of the most important lessons I have learned during my career. You can have an excellent active ingredient, but if it is unstable, poorly delivered, released too quickly, or present in a formulation that irritates the skin, the final result may be disappointing.

Formulation science connects the active ingredient with the biological target. We have to understand the molecule, its concentration, stability, compatibility, penetration, release and interaction with the skin. This is why I have always considered delivery technology fundamental. At Sesderma, we use nanotechnology and liposomes to encapsulate active ingredients, with the aim of improving their penetration, stability, efficacy and tolerance.

Dermocosmetics should not be "magic in a jar". They should be the result of dermatology, chemistry, biology, technology and clinical experience working together. That is what transforms an interesting ingredient into an effective formulation.

India's consumers are now educating themselves and moving from blindly following trends and fads to asking for evidence-based solutions to support label claims. How has this changed the dermacosmetics business model for researchers, developers and manufacturers?

This is a very positive evolution. An educated consumer is demanding something that dermatologists have always demanded: evidence. We cannot build the future of dermocosmetics on fashionable ingredients or attractive packaging. We must demonstrate that the active ingredient is stable, that it reaches the skin where it is needed, that the formulation is well tolerated and, most importantly, that it produces a measurable benefit.

For researchers and manufacturers, this changes the entire development model. Research must begin with a real dermatological problem and continue through formulation, delivery technology, safety and clinical evaluation. At Sesderma, this philosophy has always been important because we came from dermatology and from the needs of patients. Our collaborations with universities, hospitals and research centres reflect this approach.

Consumers today are asking the industry to be more transparent. I see this not as a challenge, but as an opportunity to raise the scientific standard of dermocosmetics.

Most consumers, at a minimum, want 'Clean Beauty' products. What are the other asks: personalisation, etc.? What are the latest consumer trends in skin care formulation science?

Clean beauty is important, but consumers increasingly want something beyond a clean ingredient list: they want results, tolerance, transparency and personalisation. They want products that understand their skin rather than simply products that follow a trend.

I see several important developments. First is personalised skincare, with formulations and routines organised around individual concerns such as pigmentation, ageing, sensitivity, dehydration or acne.

Second is skin-barrier science: consumers increasingly understand that an effective product must also respect the skin. Third is biotechnology, including exosomes and other advanced biological systems. Fourth is intelligent delivery, because the active ingredient alone is not enough; we must control how it reaches the skin.

There is also growing interest in multifunctional formulations that combine several complementary benefits without unnecessarily increasing irritation. At Sesderma, we increasingly think in terms of the skin's needs rather than simply the product category. That is where personalisation becomes meaningful.

What are the next-generation drug delivery modes in skincare products and dermocosmetics?

The future will be about precision delivery, and not simply putting more active ingredients into a cream. We need to transport the right molecule, in the right concentration, to the right biological location and release it at the right time.

We have already seen the importance of liposomes and nanotechnology. At Sesderma, we began applying NANOTECH technology in 2008, using liposomes to encapsulate active ingredients and improve their delivery into the skin while maintaining good tolerance.

The next evolution is biotechnology. Exosome-based systems are particularly interesting because these small vesicles are involved in communication between cells and can transport biological molecules. Sesderma has developed EXOSES using Lactobacillus-derived exosomes.

I also see significant potential in functionalised carriers, targeted delivery, biomimetic systems, microneedling-assisted delivery and regenerative approaches. The objective is always the same: more precision, greater efficacy and better tolerance.

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DALPL: Building India's next-gen of specialised testing capabilities

From a food and agricultural testing laboratory to a specialised pharma testing facility, the company's journey reflects the evolution of India's analytical testing industry. In this conversation, **Ashay Mehta,** Founder & Managing Director of Doctors' Analytical Laboratories Pvt Ltd (DALPL) discusses regulatory compliance, data integrity, emerging testing requirements, talent challenges and plans to expand into peptides, topical products and medical device testing with **Swati Rana**

DALPL was established in 2006 with a food and agricultural testing laboratory and has since expanded into pharmaceutical testing and other verticals. How has the journey been, and what have been the key milestones?

We started in 2006 in Pune as a food and general testing laboratory, when food regulations in India were still developing. At the time, regulatory requirements were largely linked to exports of certain commodities to Europe. I joined the business in 2008. It was a family investment that we subsequently spearheaded and developed into what it is today.

In 2011–12, we decided to move the facility from Pune to Mumbai. Since we were based in Mumbai, the move offered better operational control and opportunities for expansion. Mumbai also provided a strategic advantage because of its connectivity to ports and its accessibility to customers and sample sources across Gujarat, Goa and other regions. We re-established our operations in Mumbai in 2012.

Although India's food safety law had been enacted earlier and came into effect in 2011, awareness remained limited. The Maggi controversy in 2015 brought food safety and testing into sharper public focus, and the industry has continued to develop since then, although growth has been uneven.

> The growth of laboratory infrastructure has not always been matched by the development of specialised talent. The industry needs experienced professionals who understand complex analytical techniques, regulatory expectations, quality systems and the demands of international inspections

Around 2012–13, we also began exploring pharmaceutical testing. We entered the segment gradually, starting with one area where regulatory requirements were still evolving.

In 2016, we underwent our first US FDA inspection at a facility where we were conducting both food and pharmaceutical testing. The experience made us realise that if we wanted to pursue pharmaceutical testing seriously, we needed a dedicated facility, team, standard operating procedures (SOPs) and quality management systems (QMS). Food and pharmaceutical testing require different operating environments and approaches, and we felt that both could not be managed effectively within the same facility.

We therefore took the decision to shut down our pharmaceutical testing operations temporarily and invest in a dedicated facility, even though it meant losing the business we had built in that segment. We developed the new facility and opened it in September 2017.

In May 2018, we received our first US FDA Establishment Inspection Report (EIR), following an inspection conducted shortly after we moved to the new premises. We were inspected again in 2022. During the COVID-19 period, one of our clients was facing delays in securing approvals because our facility had not been reinspected. We approached the FDA, explained the situation and requested an inspection on our client's behalf. The agency conducted the inspection, and we received a Form 483 with observations.

We have since continued to strengthen our compliance capabilities. Our facility has undergone audits supporting work for clients in Canada and Europe, including an audit by a Qualified Person (QP) representing a client. Our regulatory experience spans the US, European and

Canadian markets, as well as Australia.

How has India's analytical testing ecosystem evolved over the past two decades?
When we entered the market, there were very few laboratories serving the highly regulated pharmaceutical testing segment. In 2017, there were only around six or seven laboratories in India with US FDA approval, based on our understanding at the time.

Today, the landscape has changed considerably. There has been a substantial increase in the number of testing laboratories, particularly in pharmaceutical hubs such as Hyderabad. Food testing has also expanded rapidly, with new laboratories entering the market regularly.

However, the growth of laboratory infrastructure has not always been matched by the development of specialised talent. The industry needs experienced professionals who understand complex analytical techniques, regulatory expectations, quality systems and the demands of international inspections.

Regulatory compliance is another important consideration. Establishing a laboratory is one thing; sustaining compliance through inspections and consistently meeting regulatory expectations is another. Laboratories must invest continuously in people, systems, equipment and processes.

The ecosystem is developing rapidly, and I believe the availability of specialised talent and expertise will improve over time. For now, however, workforce development remains an important area of focus.

What are the biggest challenges pharmaceutical companies face when it comes to analytical testing in India?
The encouraging development is that Indian laboratories can now provide a wide range of specialised testing services that companies previously had to seek from laboratories in Europe or the US. These include in vitro release testing (IVRT), in vitro permeation testing (IVPT), nitrosamine analysis, extractables and leachables studies, and peptide-related testing.

Companies no longer need to depend as heavily on overseas laboratories or face the same waiting periods for many of these services. The domestic ecosystem has developed the infrastructure and expertise needed to support increasingly complex testing requirements.

The industry is also seeing greater government participation in laboratory development. Support schemes and subsidies for setting up testing infrastructure can help expand capacity in areas where specialised facilities are required.

The opportunity now is to ensure that this infrastructure continues to evolve alongside regulatory requirements, emerging technologies and the growing complexity of pharmaceutical products.

With increasing regulatory scrutiny, what changes are you seeing in documentation and quality systems across pharmaceutical testing laboratories?
We began seeing a significant shift in 2016–17, which was one of the reasons we decided to establish a dedicated pharmaceutical testing facility.

Regulatory testing requires extensive documentation, whether in food or pharmaceuticals. In pharmaceutical testing, traceability must be maintained throughout the process, from sample receipt and registration to testing, reporting and eventual sample disposal.

Our systems are designed to maintain complete traceability. The analytical instruments and associated systems are configured with appropriate user access controls and privileges. These controls help prevent unauthorised deletion or manipulation of records and chromatographic data.

Regulatory expectations have become increasingly stringent, but customer expectations have evolved as well. A decade ago, laboratories could encounter resistance when they explained that a particular request could not be accommodated because of regulatory requirements. Customers might point to another laboratory that was willing to do it differently.

Today, customers increasingly recognise the importance of compliance, data integrity and reliable testing, particularly given the investment involved in pharmaceutical development and regulatory approvals. Responsible customers understand that compromising testing integrity can create significant risks for their products and businesses.

Overall, regulatory expectations and customer awareness are moving in the same direction, encouraging better practices across the ecosystem.

Are Indian testing laboratories keeping pace with global regulatory standards?
Yes, India is keeping pace with global regulatory standards, and the development of the domestic testing ecosystem reflects that progress.

Regulatory requirements should not be viewed simply as a burden on the industry. They ultimately help ensure product quality and patient safety. The challenge is to develop the capabilities, infrastructure and expertise needed to meet those requirements consistently.

India continues to face competitive pressures, including from China, which has significant manufacturing scale and an established industrial ecosystem. However, Indian laboratories are strengthening their capabilities and working to meet international expectations.

Continued investment in infrastructure, technology and skilled professionals will be essential to sustaining this progress.

Pharmaceutical companies often have their own analytical testing laboratories. What role do independent testing laboratories play?
Pharmaceutical companies generally use their in-house laboratories for routine quality control testing. Independent laboratories complement these capabilities by providing specialised services, particularly method development and method validation.

Developing and validating an analytical method can be time-consuming and requires specialised expertise and equipment. Once the method has been developed and validated, companies may send their samples to an independent laboratory for testing, allowing them to focus their internal resources on other activities.

Some analytical instruments are also extremely expensive, and it may not be practical for every pharmaceutical company to invest in multiple systems for specialised testing. As commercial laboratories, we can make these investments across a broader client base.

Our work is not limited to Indian companies. We serve international customers from markets including Turkey, Bangladesh, Saudi Arabia and Canada.

Customer audits are another important part of the relationship. In addition to regulatory inspections, customers typically audit our facility before starting work with us and may conduct periodic audits thereafter. This provides an additional layer of oversight and helps maintain confidence in the laboratory's systems and capabilities.

Data integrity is a major regulatory concern. What does maintaining data integrity mean in practical terms for a testing laboratory?
Data integrity can be compromised in different circumstances. Sometimes, an employee makes an honest mistake and attempts to conceal it out of fear of reprimand. In other cases, data may be deliberately manipulated.

We address the first situation by creating an environment in which employees are encouraged to report mistakes immediately. We tell our teams that making a mistake is not necessarily the biggest problem; concealing it can create a much greater risk.

If an employee reports an error, we can investigate it, assess its impact, implement corrective measures and prevent it from recurring. If people feel pressured to hide mistakes, neither the individual nor the organisation can learn from the incident or mitigate the risk effectively.

Our approach is to encourage transparency and make employees understand that reporting an error is the right thing to do. We take responsibility for investigating the issue and determining the appropriate corrective action.

At the same time, deliberate manipulation must be prevented through robust quality systems, appropriate access controls, traceable records and a culture of accountability. Technology and procedures are important, but the right organisational culture is equally essential to maintaining data integrity.

What will pharmaceutical companies expect from analytical testing laboratories over the next

five years?
Customers will increasingly expect laboratories to provide a broader range of services under one roof, along with stronger regulatory credentials and expertise across different markets.

As pharmaceutical companies expand internationally, they must comply with the requirements of individual countries and regulatory authorities. These requirements may differ, and companies need laboratory partners that understand the relevant standards and can support their testing needs.

Consequently, laboratories will need to expand their service portfolios, invest in specialised equipment, strengthen their regulatory capabilities and provide more comprehensive technical support.

The ability to respond to evolving requirements quickly and consistently will become an important differentiator.

Which areas should India's pharmaceutical testing ecosystem prioritise over the next five to ten years?
Medical devices, peptides and topical products are three important areas.

Medical device manufacturing is receiving greater attention in India, but there is a need for more specialised testing infrastructure. Many existing laboratories offer routine testing services, while advanced and specialised requirements will call for dedicated capabilities.

Peptides also have significant potential because of their applications across pharmaceuticals and nutraceuticals. As the market develops, laboratories will need to strengthen their expertise and infrastructure to support the associated analytical and regulatory requirements.

Topical products represent another important growth area. Specialised studies, including IVRT and IVPT, help assess drug release from formulations and the permeation of active ingredients through the skin. These capabilities are important for the development and evaluation of topical pharmaceutical products.

Building specialised services around these three areas will be important to meeting future industry demand.

What are your company's expansion plans for the coming years? How do you see the company's growth trajectory over the next five years?
We are planning to expand both our food and pharmaceutical testing capabilities.

In 2027, we intend to move our food testing division into a larger facility next door. The additional space will allow us to introduce RT-PCR testing for genetically modified organisms (GMOs) and animal species identification.

In pharmaceutical testing, we plan to expand our work in peptides. We have already established facilities for specialised in vitro testing of topical products, including IVRT and IVPT.

We are also keen to establish a dedicated medical device testing division. However, that investment is likely to form part of a longer-term plan, potentially in the third or fourth year of our expansion programme.

Our focus remains on the life sciences, food testing and pharmaceutical testing sectors, with medical devices representing a potential future area of diversification.

We have been growing at approximately 25–30per cent year on year. For the 2026–27 financial year, we are targeting growth of at least 50–60per cent.

Given the changes taking place in food safety requirements and pharmaceutical testing, we see opportunities to expand our business. Our planned investments in additional infrastructure and specialised services are intended to support this growth.

The objective is to build on our existing capabilities while entering areas where we can offer specialised expertise and differentiated services.

Could you elaborate on the specialised pharmaceutical testing services you currently offer?
Our pharmaceutical testing portfolio covers active pharmaceutical ingredients (APIs), intermediates, finished formulations and packaging materials.

One important area is the development and validation of analytical methods for nitrosamines and nitrosamine drug substance-related impurities (NDSRIs), which are potential carcinogenic impurities that require careful assessment. We also undertake elemental impurity testing and extractables and leachables studies, which evaluate substances that may migrate from packaging materials into pharmaceutical products.

For topical products, we conduct IVRT and IVPT studies to assess drug release from formulations and the permeation of active ingredients through the skin.

We also undertake gastric and feeding-tube studies for medicines administered through feeding tubes, which may be used by post-operative patients and others who cannot take medication orally in the usual manner. These studies help evaluate drug recovery and the amount of medicine delivered through the tube. Our work can include particle-size evaluation and high-performance liquid chromatography (HPLC) assays.

Another area involves in vitro binding studies for certain gastrointestinal medicines, including products such as sucralfate and phosphate binders. These studies help assess interactions between medicines under specified conditions.

We also conduct particle-size evaluations and other specialised analytical assessments. Several of these services support product development and bioequivalence-related investigations where appropriate in vitro methods can provide useful evidence without requiring a clinical study for that particular assessment.

Our approach is not to compete purely on the number of instruments we operate. We invest in the equipment, expertise and infrastructure needed to deliver specialised projects that meet our technical and commercial requirements. We focus on areas where we can provide meaningful value rather than attempting to handle every project regardless of its complexity or commercial viability.

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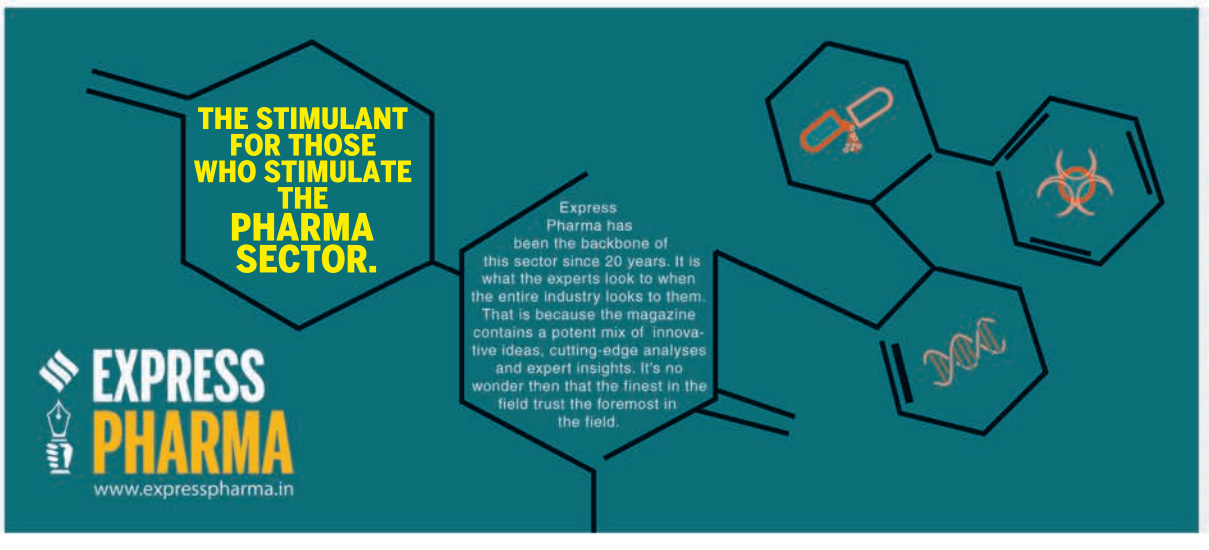

Our ambition is to be a trusted partner at each stage of that journey

Ms Payal Agrawal, MD - India & South Asia, PerkinElmer, discusses the evolving analytical needs of India's pharmaceutical industry, PerkinElmer's LC-MS/MS offering and the role of advanced technologies, application expertise and laboratory services in supporting pharma R&D and quality testing, in an exclusive interview with **Express Pharma**

What pharma and life sciences trends do you see shaping India over the next three to five years, and where does PerkinElmer see the biggest opportunities in this changing landscape?
India's pharmaceutical industry is moving into a new phase of growth, driven by complex generics, specialty formulations, API manufacturing and research-led drug development, underpinned by an increasing focus on quality and innovation. As Indian companies strengthen their presence in regulated global markets, the ability to consistently demonstrate product quality and meet evolving regulatory expectations will become an even greater competitive differentiator.

We see three core trends shaping the industry. First, India's ambition to move up the pharma value chain is creating greater demand for advanced analytical technologies and scientific expertise. Second, the growing focus on impurity profiling, trace-level contaminants and analytical rigour is raising the bar for pharma testing. Third, manufacturers are looking to improve laboratory productivity through more efficient method development efficiency and reliable analytical data.

For PerkinElmer, these trends present opportunities across chromatography, mass spectrometry, spectroscopy and other analytical technologies that support pharma R&D and quality testing. Our focus is on helping customers address their specific analytical challenges with the right combination of technology, application expertise and service support.

More broadly, beyond its status as a major pharma manufacturing hub, India is increasingly becoming a centre for scientific development and global pharma supply. We see considerable potential through our OneSource Laboratory Services team to deepen partnerships with Indian pharma companies as they invest in more sophisticated analytical capabilities. As research and quality operations become more global, ensuring instruments perform consistently and compliantly becomes just as important as the technology itself.

> The objective is not simply to provide more sophisticated instruments, but to help pharma companies build stronger analytical capabilities that support product quality, operational efficiency and scientific progress

PerkinElmer is entering the pharma space with its LC-MS/MS offering and new software. What is driving this move, and what gap in pharma analytical testing are you looking to address?
The QSight LC-MS/MS platform making inroads into the pharma segment marks an important step in expanding PerkinElmer's presence in India's pharma market. We see a clear opportunity to address the growing need for sensitive, selective and reliable quantitative analytical solutions as pharma companies work with increasingly demanding testing requirements.

For pharma R&D and analytical laboratories, challenges such as trace-level impurity quantification, nitrosamine analysis where suitable methods are established, and complex sample investigations can require analytical capabilities beyond conventional approaches. Triple-quadrupole LC-MS/MS is particularly valuable for targeted quantitative applications that demand high selectivity and sensitivity.

QSight brings together triple-quadrupole mass spectrometry, StayClean™ ion-source technology and a dual ESI/APCI source configuration designed to offer flexibility across suitable applications. Complementing the platform is Simplicity 3Q software, which supports workflows spanning method development, data acquisition, processing and reporting.

Our approach goes beyond the launch of a new instrument. We are building pharma application readiness and helping laboratories evaluate technology against their specific analytical needs through relevant rigorous application development and expert technical support. We also recognise the importance of appropriate software configuration, validation and documentation for regulated laboratory use.

Ultimately, our objective is to give pharma laboratories another strong analytical option for addressing challenging quantitative applications while supporting dependable performance and greater laboratory productivity.

As Indian pharma moves towards complex molecules, biologics and higher-value R&D, what gaps do you see in the industry's analytical capabilities, and how is PerkinElmer addressing them?
One of the key challenges for Indian pharma is ensuring analytical capabilities keep pace with increasingly complex products, more demanding impurity requirements and the expectations of global regulatory markets.

For small-molecule drugs, APIs and finished formulations, laboratories must address a series of critical challenges, including impurities, degradation products, method selectivity, reproducibility and data quality – while at the same time managing sample volumes, turnaround times and resource constraints.

We see opportunities in

three areas: access to fit-for-purpose analytical technologies, greater efficiency in method development and routine testing and stronger application expertise within laboratories. Advanced instruments can deliver considerable value, but only when the method, workflow and supporting expertise are aligned with the analytical question.

PerkinElmer addresses these needs through a broad portfolio of analytical technologies, supported by application knowledge, as well as software and service capabilities delivered through OneSource. Depending on the application, this can include chromatography for routine assays and related-substances testing, mass spectrometry for demanding targeted quantitative analysis, and complementary techniques for other pharma testing requirements.

We also believe that customer support and knowledge transfer are critical. Our role is to help laboratories identify the right analytical approach, develop robust workflows and make effective use of their technology. The objective is not simply to provide more sophisticated instruments, but to help pharma companies build stronger analytical capabilities that support product quality, operational efficiency and scientific progress.

You have led business turnarounds and commercial transformations across multiple markets. What are you bringing from those experiences to your mandate at PerkinElmer India and South Asia?

My experience operating across international markets has reinforced a fundamental principle: sustainable growth comes from understanding customers deeply, making clear strategic choices and executing consistently.

India and South Asia are diverse markets, with pharma companies operating at varying scales and serving different segments. A successful strategy needs to recognise these differences, identify where we can create the greatest value and align our portfolio, people and capabilities with those opportunities.

My focus is always on bridging the gap between customers insights and our business approach. In practice, that means spending time in customers' labs to understand their most important challenges – whether that is throughput, regulatory compliance or access to skilled analysts – and make sure our commercial, application and service teams respond as one team rather than three.

For PerkinElmer in India and South Asia, the opportunity is to combine our scientific strengths with the customised and execution-oriented service that customers expect.

With India emerging as a larger R&D and manufacturing hub, how do you see PerkinElmer's role evolving in supporting the next phase of pharma growth in the region?

As India strengthens its position in global pharma R&D and manufacturing, analytical science will play an increasingly important role in enabling quality, innovation and competitiveness. Pharma companies will need to combine robust testing capabilities with efficient laboratory operations and the ability to meet the expectations of international markets.

We see PerkinElmer's role evolving through closer collaboration with pharma manufacturers, API producers, contract research organisations and contract development and manufacturing organisations. Our objective is to help customers identify the technologies and workflows best suited to their requirements, based on their specific needs.

This involves much more than supplying instruments. Application expertise, reliable service, training and ongoing technical support are essential to helping laboratories realise the full value of their analytical investments. We also see opportunities to deepen engagement with customers as their needs evolve – whether in expanding analytical development capabilities, strengthening quality-control operations or investigating more challenging impurities.

Our broader analytical portfolio across chromatography, mass spectrometry and spectroscopy positions us to support a range of pharma applications, from routine laboratory testing to more advanced analytical investigations. We will continue to focus on making our technologies relevant to local customer needs while drawing on our wider scientific and technological capabilities.

India in particular represents a significant long-term opportunity for PerkinElmer. The industry is moving up the value chain, from generics and APIs towards complex generics, biosimilars and novel drug discovery, and the scientific and regulatory demands grow at every step. Our ambition is to be a trusted partner at each stage of that journey, helping pharma companies strengthen their analytical capabilities, improve laboratory performance and compete with confidence in global markets.

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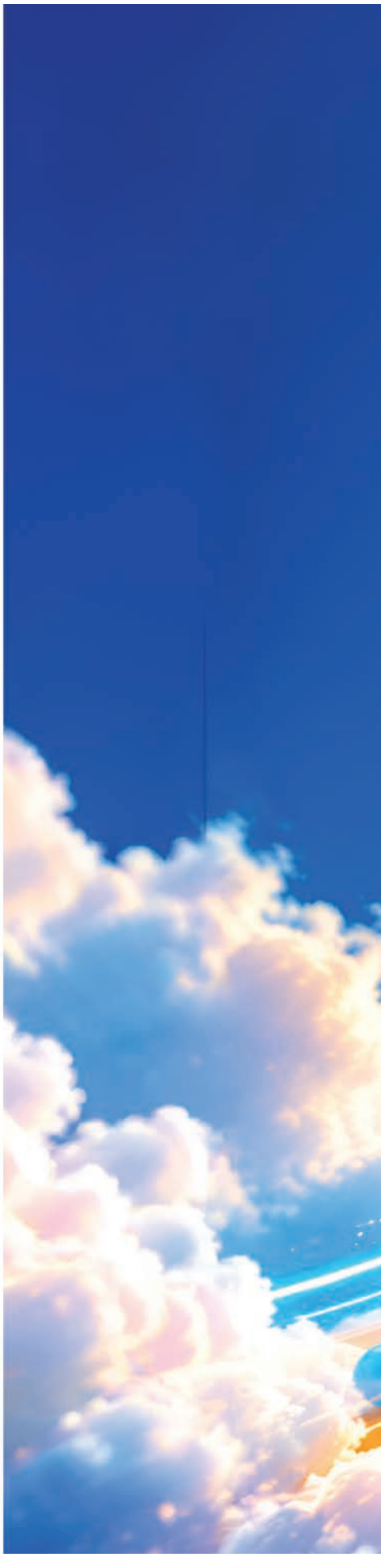
#AtTheHeartOfPharma

PLI 2.0 CAN MSMES CATCH UP?

Is the scheme translating manufacturing investments into global competitiveness for pharma MSMEs, or does the next phase need to do more to bridge the gap between smaller manufacturers and larger exporters?

By Swati Rana



MSME

India's Pharmaceutical Production Linked Incentive (PLI) scheme was designed to strengthen domestic manufacturing, attract investment and encourage companies to move towards higher-value pharmaceutical products. With a financial outlay of ₹15,000 crore, the scheme has supported manufacturing expansion across the pharmaceutical sector. But for India's micro, small and medium enterprises (MSMEs), the bigger question is whether this investment is translating into stronger technological capabilities, improved quality systems and sustainable export growth.

The challenge is significant. Smaller pharma manufacturers play an important role in domestic medicine supplies, contract manufacturing, employment generation and exports. However, they often operate with tighter budgets and have less access to capital, research facilities, advanced technology and specialist regulatory expertise. This can make it difficult for them to compete with larger Indian companies and international manufacturers.

The government has recognised these differences in the design of the pharma PLI scheme. Of the 55 applicants selected, 20 are MSMEs, accommodated within Group C, which has a dedicated framework for smaller manufacturers.

However, industry representatives argue that a separate framework is only the starting point. Smaller companies need practical access to finance, technology, quality expertise and export markets if they are to turn manufacturing investment into sustainable growth.

MSMEs do not necessarily need protection from competition; they need the financial and technological capabilities to compete

Ajay Singh Dassundi
Secretary,
MP Small and Medium Drugs Manufacturers Association

Manufacturing investment and production remain important, but they should be viewed as intermediate outcomes rather than the ultimate measure of success

Namit Joshi
Chairman,
Pharmexcil

Clear eligibility criteria, streamlined documentation, transparent evaluation processes and predictable timelines for incentive disbursement can help businesses plan investments with greater confidencenvestments with greater confidence

Bhavin Mehta
Whole-Time Director, Kilitch Drugs (India) and Vice-Chairman, Pharmexcil

Ajay Singh Dassundi, Secretary of the MP Small and Medium Drugs Manufacturers Association, says the scheme is a positive initiative, but its benefits have been relatively limited for MSMEs compared with companies that have the financial strength and scale to make large investments.

"The next phase must ensure that the benefits of the PLI Scheme reach not only large manufacturers but also the thousands of MSMEs that form the backbone of India's pharmaceutical industry," he says.

Investment, but for whom?

A government update published in January 2026, reporting progress through September 2025, said the scheme had attracted investment of ₹40,294 crore against a targeted ₹17,275 crore. Cumulative sales stood at ₹3,08,408.60 crore, including exports of ₹1,98,509.49 crore. The government also reported an employment generation of approximately 97,000 people, including contractual and apprentice workers.

For Namit Joshi, Chairman of Pharmexcil, this distinction is crucial.

"The impact of the scheme is more clearly visible in terms of manufacturing investment and capacity creation," he says, cautioning that it would be premature to attribute a substantial expansion in international market presence specifically to PLI-supported MSMEs without more detailed data.

"Investment and production figures indicate whether manufacturing activity is expanding. They do not necessarily show whether smaller companies are adopting advanced technologies, entering new markets or developing higher-value products. The next phase should focus on helping these businesses convert manufacturing capabilities into tangible and sustained export outcomes," Joshi adds.

"The ultimate test is whether MSMEs are becoming stronger businesses that can invest independently, create employment, develop better products, enter new markets, and sustain their growth beyond the incentive period," he says.

Group C: A step towards a level playing field?

The creation of a dedicated MSME framework within Group C reflects the government's recognition that smaller manufacturers cannot always meet investment requirements designed for large pharmaceutical companies.

The changes introduced to the scheme's operational guidelines in 2024 were intended to improve access for MSMEs. However, a separate eligibility framework does not automatically eliminate the financial and administrative challenges of participating.

Suveer Shrivastava, Ex-CQO & Sr VP - Regulatory Affairs, Aragen Life Sciences, believes the changes are a positive step, but their effectiveness will depend on implementation.

"Introducing a separate framework is only the first step. Its effectiveness will depend on how well the provisions are implemented and monitored," he says.

Shrivastava argues that eligible MSMEs need to receive the intended benefits without being disadvantaged by limited financial resources or administrative capabilities. He also recommends greater involvement of independent third-party experts and relevant State Food and Drug Administrations in monitoring implementation and assessing outcomes.

For Bhavin Mehta, Whole-Time Director of Kilitch Drugs (India) and Vice-Chairman of Pharmexcil, accessibility and predictability are equally important.

"Clear eligibility criteria, streamlined documentation, transparent evaluation processes and predictable timelines for incentive disbursement can help businesses plan investments with greater confidence," he says.

Dassundi welcomes the separate framework but stresses that the eligibility criteria, investment thresholds, incentive structure and application procedures must be realistic for smaller manufacturers.

"For a small or medium manufacturer, even an investment of a few crores can be a significant financial commitment," he says.

Mehta says the framework should be practical enough for eligible companies to navigate while retaining performance requirements to ensure that public incentives support genuine manufacturing activity. He recommends clear guidance, efficient administration and regular assessment of the capabilities being developed.

As Dassundi puts it, "MSMEs do not necessarily need protection from competition; they need the financial and technological capabilities to compete."

The cost of catching up

One of the biggest challenges facing pharma MSMEs is the cost of upgrading existing manufacturing facilities.

Pharma production requires qualified equipment, validated processes, reliable documentation and effective quality management systems. Companies seeking to supply regulated international markets must also meet the requirements of their target markets, which can require substantial investment in infrastructure, technology and personnel.

For a smaller manufacturer, such investment can be difficult to finance alongside day-to-day operations.

Narotam Juneja, Technical Advisor at Uniserum Lifesciences, identifies infrastructure modernisation as a major concern, particularly for businesses operating older f acilities. Upgrading these plants to meet current good manufacturing practice (GMP) requirements and international regulatory standards requires substantial capital expenditure.

Investments in quality, innovation, and digitalisation are not merely compliance expenses; they are essential to sustainable growth and access to higher-value markets

Suveer Shrivastava
Ex - COO and Sr VP,
Regulatory Affairs,
Aragen Life Sciences

Developing complex generics and other advanced pharmaceutical products can require significant expenditure on research and development, specialised equipment, regulatory documentation and compliance

Narotam Juneja
Technical Advisor,
Uniserum Lifesciences

Companies unable to make the necessary changes may face regulatory action, including suspension of operations or cancellation of manufacturing licences. The result is a difficult investment choice: a company may need to spend heavily simply to maintain its existing manufacturing capabilities, leaving fewer resources for new products, automation or export expansion.

Dassundi identifies high investment requirements as one of the principal barriers to MSME participation. Modern pharmaceutical manufacturing requires spending on plant and machinery, laboratory facilities, automation, validation and regulatory compliance. At the same time, high borrowing costs, collateral requirements, working-capital constraints and long payment cycles can prevent smaller companies from financing expansion.

The challenges extend beyond capital expenditure. Smaller businesses may not have dedicated teams to manage incentive applications, compliance requirements and the documentation needed for international markets. Many also lack the resources to establish sophisticated research facilities or maintain specialised research and development teams.

Juneja also points to the challenges MSMEs face when attempting to enter higher-value product categories.

Developing complex generics and other advanced pharmaceutical products can require significant expenditure on research and development, specialised equipment, regulatory documentation and compliance. For a smaller company, the financial risk can be considerably higher than for a large manufacturer with a broader portfolio and greater access to capital.

Research-driven MSMEs may also face a first-mover disadvantage when they have to finance trials and generate regulatory data before commercial returns become visible. These challenges suggest that the next phase of PLI should pay closer attention to the quality and purpose of investment, rather than focusing primarily on the amount committed.

Shrivastava argues that MSMEs need to move beyond a narrow focus on production volumes and short-term financial performance.

"Investments in quality, innovation, and digitalisation are not merely compliance expenses; they are essential to sustainable growth and access to higher-value markets," he says.

He identifies automation, data integrity, robust quality management and workforce development as important areas for improvement. For smaller manufacturers, however, adopting these capabilities may require technical expertise that is difficult to recruit or retain in-house.

Shrivastava therefore proposes a structured technical guidance and mentoring programme involving experienced pharmaceutical professionals. Such a programme could help companies identify compliance gaps, develop improvement plans and implement stronger manufacturing and quality systems. Shared technical infrastructure, specialised training and independent assessments could also help smaller businesses address capability gaps without bearing the full cost of developing every resource independently.

Dassundi recommends a more integrated support system. Alongside incentives, he wants government-backed credit guarantees, interest subvention and concessional financing to help MSMEs fund technology upgrades and capacity expansion.

He also proposes affordable research and development facilities, common testing laboratories, pilot-scale manufacturing facilities and technology-transfer programmes developed in collaboration with government-supported research institutions.

Opportunity comes with risk

Moving towards higher-value pharma products is a key ambition of the PLI scheme. It offers Indian manufacturers an opportunity to develop specialised capabilities and compete in segments where technology, quality and regulatory expertise are critical.

For MSMEs, however, entering these categories is not simply a matter of installing new equipment.

Depending on the product, companies may need to invest in research, process development, specialised analytical capabilities, validation, regulatory submissions and skilled personnel. These investments can take time to generate revenue and may not always lead to commercial success.

Juneja argues that smaller manufacturers can be structurally disadvantaged because of

the higher capital and compliance costs associated with developing complex products. He also highlights the difficulty of funding innovation when the first applicant bears substantial costs for trials and regulatory data, while subsequent entrants may have access to less expensive regulatory pathways.

The next phase of PLI could address this challenge by encouraging product diversification alongside targeted technical and regulatory support.

Mehta believes the long-term impact of PLI will depend on whether manufacturing investment translates into sustainable business growth.

"In segments such as sterile injectables, this requires more than production capacity alone," he says. "Companies must build strong process validation systems, maintain consistent product quality, secure regulatory approvals and establish dependable supply relationships with customers across markets."

Dassundi also believes that the next phase should support MSMEs in moving up the value chain, developing differentiated products and building sustainable export businesses rather than simply increasing the volume of conventional products.

Can MSMEs crack exports?

India's pharma industry has an established presence in international markets. According to the Ministry of Commerce and Industry, pharmaceutical exports reached approximately $30.47 billion in FY2024-25, registering growth of 9.4 per cent over the previous financial year.

For smaller manufacturers, moving from domestic production to international sales requires capabilities that extend beyond manufacturing.

Companies must secure the necessary product registrations, meet the regulatory requirements of their target markets, maintain consistent quality and supply, and develop distribution or customer relationships overseas. These activities require time, money and specialised knowledge. Smaller exporters may struggle to absorb the costs, particularly when they have a limited product portfolio.

Joshi says Indian MSMEs must compete on cost, quality, consistency of supply and compliance with international regulatory standards.

"Manufacturing competitiveness and export competitiveness are not the same," he emphasises.

He points to the advantages enjoyed by countries such as China in manufacturing scale, supply-chain integration and access to raw materials. For smaller Indian companies, technology upgrades, regulatory approvals, product development and market entry can create substantial additional costs.

"Tariff and non-tariff barriers add to the challenge. Changes in regulatory requirements, product-registration procedures and market-access conditions can make exporting more expensive and time-consuming for businesses with limited resources. Larger exporters are generally better placed to spread these costs across multiple products and markets. MSMEs often have less flexibility," Joshi says.

"Manufacturing investment and production remain important, but they should be viewed as intermediate outcomes rather than the ultimate measure of success," he says.

Joshi recommends greater emphasis on incremental exports, international product registrations, technology adoption, productivity improvements and the development of higher-value products. These measures, he argues, would help determine whether PLI-supported businesses are developing the capabilities required to compete internationally, rather than simply expanding domestic capacity.

Dassundi agrees that MSMEs can play a larger role in pharmaceutical exports, but says growth requires regulatory preparedness, consistent quality, product development, international marketing and reliable working capital.

"The next phase should help MSMEs move up the value chain, develop differentiated products, and build sustainable export businesses rather than simply increase the volume of conventional products," he says.

Mehta also stresses the need to align manufacturing investments with international demand. Companies must understand the requirements of their intended markets and ensure that their products, facilities and supply systems can meet them.

Quality is non-negotiable

For pharma companies, quality is central to market access and commercial credibility.

Manufacturers must maintain effective quality management systems, validate processes, qualify equipment, preserve reliable records and ensure that employees are trained to perform their responsibilities. For MSMEs seeking to enter highly regulated markets, gaps in documentation, data integrity or process control can become significant obstacles.

Shrivastava believes one of the biggest challenges is translating regulatory requirements into consistent practice on the manufacturing floor. He identifies quality management, documentation, data integrity, process validation, equipment qualification, automation and workforce competence as areas requiring attention.

Dassundi proposes common skill-development centres that provide practical training in advanced manufacturing, automation, quality assurance, regulatory compliance and modern pharmaceutical technologies. Such shared facilities could give smaller businesses access to training and expertise that may be difficult to fund independently.

Mehta similarly argues that modern infrastructure, automation and robust quality systems are essential if Indian manufacturers are to remain competitive. For MSMEs, quality improvements should not be treated as a one-time exercise. They must become part of everyday manufacturing practice.

Is the framework tilted towards larger companies?

A central concern among industry representatives is whether companies with greater financial strength are better positioned to benefit from incentive-linked manufacturing schemes.

Large pharma companies generally have more resources to fund capital expenditure, recruit specialist teams and manage complex documentation and reporting requirements. Smaller businesses may struggle to make substantial upfront investments while continuing to finance routine operations.

Juneja argues that qualifying thresholds and investment commitments need to reflect the practical realities of smaller manufacturers. MSMEs may find it difficult to fund eligible greenfield projects or major expansions and wait through prolonged gestation periods before the investment begins generating returns.

His recommendation is for a more MSME-focused assessment of eligibility thresholds, qualifying investments and performance measures. The objective should be to help smaller companies upgrade existing facilities, meet higher regulatory standards, invest in product development and progressively increase the share of higher-value products in their portfolios.

Shrivastava also believes that the framework should focus more on technical capability, quality performance and the potential for sustainable growth.

THE PLI SCORECARD

India's pharmaceutical PLI scheme has reported significant investment, sales and export growth since its implementation.

- **15,000 crore** — Total scheme outlay
- **46,744 crore** — Investment realised through June 2026, against a target of 17,275 crore
- **4,02,869 crore** — Cumulative sales through June 2026
- **2,57,370 crore** — Cumulative exports through June 2026
- **1,21,294** — Employment generated through June 2026
- **278 applications** — Received under the scheme
- **55 applicants selected** — Including 20 MSMEs
- **5,433 crore** — Cumulative incentives disbursed as of October 2025

Source: Department of Pharmaceuticals, Annual Report 2025–26; Press Information Bureau.

WHERE DOES THE MONEY GO?

The pharma PLI scheme has an outlay of 15,000 crore, distributed across three groups.

Group	Allocation
Group A	11,000 crore
Group B	2,250 crore
Group C	1,750 crore
Total	15,000 crore

Source: Department of Pharmaceuticals

"The objective should not be to give smaller companies an advantage simply because they are small, but to ensure that technically capable MSMEs are not excluded because they lack the financial and administrative resources of larger competitors," he says.

Dassundi calls for a dedicated MSME incentive window with a defined allocation and proportionate eligibility criteria. He believes this would help ensure that eligible smaller manufacturers receive meaningful access to the scheme.

He also recommends simpler application procedures, predictable incentive payments and dedicated facilitation mechanisms. For MSMEs with limited administrative resources, a complicated application process can become an additional barrier even when a project is technically suitable.

The policy challenge is to balance accountability for public spending with a process that smaller companies can realistically navigate.

What should PLI 2.0 measure?

Joshi wants the next phase to place greater emphasis on incremental exports, international registrations, technology adoption, productivity and higher-value products.

Mehta highlights sustainable business growth, modern manufacturing infrastructure, quality systems and export readiness. Juneja stresses the need to address investment barriers, facility upgrades and the costs of developing higher-value products.

Shrivastava calls for a robust and transparent mechanism to measure the scheme's actual benefits, including independent impact assessments comparing companies' performance before and after receiving support.

Dassundi recommends evaluating a wider range of outcomes, including investment in infrastructure, incremental production, technology adoption, research and development, API manufacturing, exports, employment, quality and compliance, financial sustainability, MSME participation and movement towards higher-value products.

"I would particularly emphasise incremental exports, technology adoption, innovation, and sustainable financial performance," he says.

Together, these recommendations suggest several areas for a more comprehensive assessment such as :

Investment and production: Has the scheme encouraged additional manufacturing investment and eligible sales, and how much of that activity is attributable to participating MSMEs?

Technology and productivity: Have MSMEs adopted modern equipment, automation or digital systems, and have these changes improved manufacturing performance?

Quality and compliance: Have companies strengthened quality management, data integrity, process validation and workforce competence?

Product development and exports: Have manufacturers introduced higher-value products, obtained international registrations, entered new markets or expanded repeat export business?

Financial sustainability: Can businesses maintain upgraded facilities, finance future investment and compete commercially after the incentive period ends?

MSME participation and employment: How many eligible MSMEs have received incentives and completed their projects? Have the investments generated skilled jobs and improved workforce capabilities?

Beyond incentives

India's pharma PLI scheme has helped stimulate manufacturing investment and create opportunities for domestic producers. Its dedicated framework for MSMEs recognises that smaller companies face different financial and operational constraints from larger manufacturers.

But the industry's challenge now is to translate participation into capability.

Dassundi's recommendations include government-backed credit guarantees, interest subvention and concessional financing; affordable research and development facilities; common testing and skill-development centres; technology upgrades; support for API manufacturing; and stronger export facilitation. He also calls for closer collaboration between MSMEs and research institutions to make advanced technologies and product-development capabilities more accessible.

For Joshi, the priority is to link manufacturing support more closely with export readiness and measurable improvements in competitiveness. Mehta similarly sees the opportunity in helping manufacturers develop more specialised capabilities and participate more meaningfully in global value chains.

For Shrivastava, the ultimate measure is whether the scheme creates stronger, more innovative and quality-driven businesses. Juneja's recommendations underline the need to ensure that investment requirements and eligibility criteria reflect the circumstances of smaller manufacturers.

As Dassundi concludes, the objective should not simply be to create a few large manufacturing capacities. It should be to build a broad base of technologically advanced, financially sustainable and globally competitive Indian pharma manufacturers.

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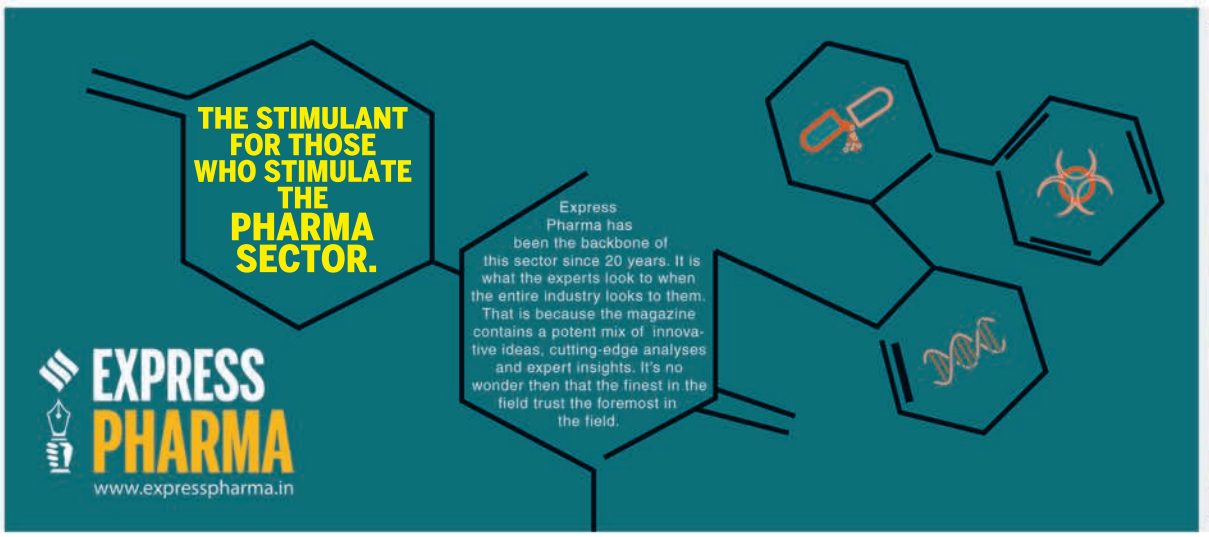
THE MSME CATCH-UP CHECKLIST

What will smaller manufacturers need to compete?

- **Affordable capital:** Funding for expansion, modernisation and capacity building.
- **Technology upgrades:** Investment in automation and more efficient manufacturing.
- **Quality compliance:** Systems and processes that meet stringent regulatory requirements.
- **Skilled workforce:** People equipped to manage advanced manufacturing and quality systems.
- **Economies of scale:** The ability to manufacture competitively without compromising quality.
- **Export readiness:** Capabilities to meet overseas regulatory requirements and access global markets.



From product knowledge to responsible engagement: What pharma's frontline workforce needs today?

Anindita Banik, Co-Founder & CEO, SmartWinnr, discusses why pharmaceutical companies need to move beyond product knowledge and equip medical representatives to handle doctor interactions with accuracy, confidence and compliance

In a crowded OPD, a medical representative (MR) gets a few minutes with the doctor. The MR knows the brand's data cold. The doctor asks, "Is this safe for my elderly patients?"

The quickest reply perhaps is "Completely safe, doctor." That answer can land the pharmaceutical company in trouble. Under the Uniform Code for Pharmaceutical Marketing Practices (UCPMP 2024), the word "safe" must not be used without qualification. The code holds companies responsible for their MRs' conduct. The CEO answers for adherence, and the company's executive head files an annual disclosure and compliance declaration.

The scrutiny is growing. In September, the Supreme Court reserved its order on a plea to regulate pharma marketing. The Centre proposed a three-member committee to examine whether a law is needed, and the code applies until then. Since May 2025, as per the DGHS order, MRs are not permitted in central government hospitals. It says they may share updates "by email or other digital media".

Product knowledge gets an MR initial access, but what the MR says next determines whether the doctor trusts the brand or not. Those few minutes have to be accurate, compliant, and useful to the doctor.

Too much field training is still judged by completion rates and quiz scores. Both show what an MR remembers, not how they handle a doctor who pushes back.

That gap shows up in a handful of moments: a safety question, a query about an unapproved use, a comparison with a competitor, or a request that crosses a line, such as a doctor asking the company to sponsor a conference trip. The code bars that unless the doctor is speaking at a CME or CPD program.

Product knowledge gets an MR initial access, but what the MR says next determines whether the doctor trusts the brand or not. Those few minutes have to be accurate, compliant, and useful to the doctor

On safety, the evidence is sobering. When doctors in Canada, France and the US reported on 1,692 sales-rep promotions, serious side effects came up in only 5 to 6% of them, according to a 2013 study in the Journal of General Internal Medicine. Managers can't hear most calls, so moments like these rarely get coached.

Imagine the same MR in a team that gets trained for these scenarios. The safety question would not be a surprise.

Weeks earlier, at the cycle meeting, the brand, medical affairs and compliance teams list the questions MRs are most likely to fumble and agree on what good answers sound like. "Is it safe for my elderly patients?" is on the list. So is the doctor who asks about an unapproved use, and the one who wants a conference trip sponsored. The list keeps changing. When the prescribing information is updated, or a new question starts coming up in the field, the scenarios change with it.

The MR rehearses each scenario with an AI-simulated doctor on the phone and gets scored every time. The feedback is specific: "You called it safe without qualifying it." "You skipped the side effects in the prescribing information." "You didn't offer the leaflet."

The bar is agreed in advance with medical and compliance. The answer has to be accurate, every safety statement has to be qualified, and the MR has to recognize when a question belongs with the medical team. Every MR is held to the same bar. A new joiner may simply need more attempts to reach it than a veteran.

The area manager watches a couple of those attempts before joint field work, coaches the one habit that matters, and signs off only when the MR clears the bar. In the field, the manager checks the same things.

The manager stays in the loop for a reason. A randomized field experiment with sales agents outside pharma, published in the Journal of Marketing, found that AI coaching combined with a manager's coaching beat either one alone.

This does not make the doctor's question easier. It means the MR has practiced it and is better prepared for the actual conversation with the doctor.

When the DGHS order came out last year, the Indian Pharmaceutical Alliance asked for "a balanced, structured and transparent engagement model".

The government may yet write one into law. Companies don't need to wait. The model can start inside the field force: a short list of scenarios that matter, practice before the first call, and managers who coach from what they've seen.

For a sales head, the test is simple. Before an MR walks into a doctor's chamber, can you show they can handle the questions most likely to go wrong? If the only evidence is a quiz score, it's time to measure something else.

From making vaccines to inventing them: India's next challenge

India's vaccine manufacturing strength provides a strong foundation for moving into discovery and innovation. **Ajay Mahipal,** Co-Founder and General Partner, HealthKois, examines what it will take to bridge this gap, from patient capital and industry-academia collaboration to regulatory predictability, and build a globally competitive vaccine discovery ecosystem

When a country accounts for 60 per cent of the world's vaccine production, the statistic is usually interpreted as an indication of manufacturing scale. But there is another way to look at it. This scale represents decades of scientific knowledge, development expertise, specialised infrastructure, regulatory experience, and an understanding of how vaccines move from laboratories to large-scale delivery.

That makes India's position in global vaccines more than a manufacturing achievement, representing an ecosystem built around one of the most complex areas of healthcare. The question now is how far that ecosystem can extend upstream, towards the discovery and development of the next generation of vaccines.

This requires recongising that the manufacturing capabilities can create a strong foundation for scientific origination, while also creating the conditions for capital to participate much earlier in the value chain.

The advantage of an ecosystem built around vaccines

Vaccine discovery does not happen in isolation. It depends on a network of scientific research, clinical development, regulatory expertise, manufacturing capabilities, and an understanding of population-level healthcare needs. India's experience across these areas gives it a distinctive base for exploring the next phase of vaccine innovation.

There are already indications of a broader shift in Indian life sciences. Over the past decade, the country has witnessed significant growth on many fronts, including its innovation pipeline, biotech ecosystem, and patent activity. Alongside this, Indian corporations and institutes have witnessed the emergence of novel therapeutic assets.

For vaccines specifically, this evolution is important because the distance between discovery and scale can be shorter when capabilities across the value chain exist within the same ecosystem. Scientific ideas can be developed with a clearer understanding of manufacturability, cost, access, and eventual deployment. These considerations are important for vaccines, where global impact depends as much on reach as scientific efficacy.

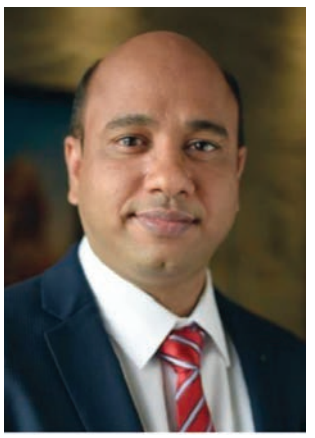
It also changes the economics of innovation. When research, development, manufacturing and distribution capabilities are closer together, companies can potentially move from scientific validation to commercial scale with fewer structural gaps. That can make the ecosystem more efficient at converting scientific opportunity into economic and societal value.

Moving further upstream

The next opportunity, therefore, may lie in moving further upstream without moving away from the strengths India has already developed.

Discovery requires a different investment horizon from manufacturing. Early scientific programs can take years to demonstrate proof of concept, Many will not progress to a market-ready product. This makes patient capital important, alongside investors and institutions that understand scientific risk and can support companies through long development cycles.

It also calls for a different approach to risk. Not every discovery program will lead to a successful vaccine. Early-stage investments come with inherent uncertainty and long timelines, making predictable short-term returns an unrealistic expectation. A stronger ecosystem is one where multiple scientific bets can be made, the strongest programmes can attract follow-on capital, and successful platforms can generate value beyond a single product.



Similarly, stronger connections between academic research and industry can help promising discoveries move beyond the laboratory, while shared infrastructure will enable early-stage companies to access capabilities that would otherwise be difficult to build independently. India has already begun developing such mechanisms through industry-academia programs, technology-transfer networks, and research initiatives spanning the innovation lifecycle.

For vaccine discovery, these connections become especially valuable. The ability to understand a scientific problem, validate it clinically, develop the technology, and eventually manufacture at scale needs to function as a connected pathway rather than as separate capabilities. The stronger that pathway becomes, the more efficiently capital, talent, and scientific expertise can move through it.

Regulatory predictability will be equally important as India moves further upstream. For companies investing in novel vaccine platforms and early-stage discovery, the regulatory pathway needs to be sufficiently clear from the outset, with well-defined guidelines, predictable review processes, and reasonable timelines for approvals. The objective should not be to lower the regulatory bar, but to provide greater clarity on the path to meeting it. This is particularly important for emerging technologies, where uncertainty around applicable guidelines or prolonged processing timelines can add significant cost and delay to programmes that are already exposed to scientific risk.

A more predictable regulatory environment can also improve the ability of investors to underwrite early-stage innovation. When companies and investors have greater visibility on the evidence required, approval pathway and expected timelines, they can make better-informed decisions on capital allocation and development milestones. Clear regulatory pathways can therefore become an important part of the innovation infrastructure—helping ensure that scientific breakthroughs are not held back by avoidable uncertainty between discovery, clinical development and eventual deployment.

From manufacturing strength to discovery potential

The most interesting question for India is not whether it can replicate established global models of pharmaceutical innovation. It is whether it can build on what is already distinctive about its own ecosystem.

India currently has over 10,000 pharmaceutical manufacturing facilities and more than 650 USFDA-compliant plants, the highest number outside the US. Its combination of scientific talent, development capabilities, cost efficiency, a large and diverse population, and established manufacturing depth creates the possibility of connecting discovery with scale for global relevance.

That possibility should also be viewed with a long-term lens. The emergence of a discovery ecosystem is unlikely to be defined by one breakthrough or one company. Its real measure will be whether scientific ideas originating in India can move through a consistent pathway from research to global deployment.

This is where the opportunity becomes larger than any individual vaccine. A mature discovery ecosystem can create intellectual property, technology platforms, specialised talent and companies capable of generating multiple innovations over time. The resulting value is not limited to the product that eventually reaches the market; it also lies in the capabilities and assets created along the journey.

India's vaccine manufacturing leadership has already demonstrated what becomes possible when scientific capability, entrepreneurship, infrastructure, and scale converge around a healthcare need. The next opportunity is to build further on that foundation by creating an environment where scientific risk can be taken earlier, capital can stay invested longer, and successful innovation can scale globally.

The aspiration, then, need not be to move from "made in India" to "discovered in India" as though one replaces the other. It is to make the two increasingly connected.

The larger opportunity is to build an ecosystem where India not only participates in the final stages of global vaccine value creation but increasingly captures value from the ideas, technologies, and companies that shape those products from the beginning.

Beyond expiry dates: Building a more transparent and traceable medicine supply chain

Devashish Singh, Co-founder and CEO of MrMed, highlights how end-to-end medicine traceability can strengthen supply-chain accountability, improve medicine safety and ensure critical medicines can be tracked from manufacturer to patient

A medicine does not become a patient-safety risk only when it crosses its expiry date. The risk can begin much earlier, when its source cannot be verified, when a batch cannot be traced, when storage conditions are unknown, or when a product recalled by the manufacturer cannot be reliably located across the supply chain.

India has made significant progress in putting systems in place to address some of these challenges. QR and barcode-based identification have been part of the regulatory framework for several years, and the government has recently expanded the traceability framework to cover critical categories including anti-cancer medicines, vaccines and antimicrobials. Under the amended framework, these products will carry QR or barcodes containing key information such as product identification, manufacturer, batch number, manufacturing and expiry dates, and licensing details.

The next challenge is not creating more traceability infrastructure. It is ensuring that the information captured at the manufacturing stage remains usable and verifiable all the way to the point where a medicine reaches a patient.

That distinction matters. A medicine may pass through manufacturers, distributors, warehouses, pharmacies and hospitals before it is finally dispensed. At each stage, its identity, batch, expiry, storage conditions and ownership can potentially become less visible. When that happens, even a well-regulated product can become difficult to track when something goes wrong.

For ordinary medicines, this can lead to avoidable wastage, stock-outs or inefficient inventory management. For oncology, biologics, transplant and rare-disease therapies, the consequences can be considerably more serious. India has the technology to track medicines. The open question is whether the industry can make traceability a continuous responsibility, from manufacturer to patient, rather than a set of checkpoints along the way.

Where batch-level tracking breaks down

Most pharmacies, hospitals and distributors record a purchase and a sale. Far fewer consistently capture the batch number and expiry date at both ends of that transaction, and fewer still reconcile the two.

A medicine is a traceable unit with a specific manufacturing history, shelf life and chain of custody, not just a product. Once batch identity is lost at any point, everything downstream becomes harder to verify. A recall cannot be executed with precision, near-expiry stock cannot be proactively moved or removed, and a suspicious pack becomes difficult to distinguish from a genuine one.

Strengthening this does not necessarily require another layer of complexity. It requires making existing practices non-negotiable.

Batch number and expiry should be captured when goods are received rather than reconstructed later from invoices. Inventory should follow a strict first-expiry-first-out principle, with systems preventing a dispense that violates it rather than merely flagging the issue afterwards. Physical stock should be reconciled against digital records at defined intervals, and discrepancies should trigger investigation.

Procurement is equally important. Pharmacies and hospitals should source medicines only from manufacturers or authorised distributors, with invoices and batch details that can be traced back through the supply chain.

For hospitals, this discipline needs to extend beyond the central pharmacy. Ward-level inventories, emergency stocks and crash carts also need the same level of visibility, because a medicine that is correctly tracked in a warehouse can still become a patient-safety risk if its expiry is not monitored once it reaches the point of care.

Authenticity is only one part of the equation

Traceability is often discussed in the context of counterfeit medicines, but authenticity is only one part of the problem. A medicine can be genuine when it leaves the manufacturer and still become unsuitable for use if it is improperly stored, mishandled or allowed to cross its expiry date.

This is particularly important for temperature-sensitive therapies. A product that has been exposed to conditions outside its prescribed cold chain may look no different from a properly stored product. The packaging does not necessarily tell the patient what happened to the medicine between manufacturing and dispensing.

That is why end-to-end traceability needs to include more than a batch number. Where storage conditions are critical, temperature and handling records should also form part of the chain of custody and be available when required.

For the patient, the question should ultimately be simple. Can the authenticity, provenance, storage history and expiry status of a critical medicine be established with confidence? Today, that answer is not always yes.

Why expiry management matters even more for super-specialty medicines

Expiry management becomes particularly consequential when dealing with super-specialty and life-saving therapies.

Oncology medicines, biologics, transplant therapies and rare-disease treatments can be extremely expensive, temperature-sensitive and clinically critical. They are also often prescribed as part of tightly sequenced treatment regimens where delays or interruptions can have serious consequences.

For these medicines, the issue is not simply financial wastage. A medicine nearing expiry may technically remain within its labelled shelf life, but that does not necessarily make it appropriate for every patient or treatment schedule. A patient beginning a long-term therapy should not be

handed stock with an impractically short remaining shelf life.

The industry needs to move from asking whether a medicine is expired to asking whether it is fit, authentic, properly stored and appropriate for the intended treatment window.

This is where minimum remaining-shelf-life thresholds can play a role, particularly for high-value and critical therapies. Cold-chain compliance should also be demonstrable rather than assumed simply because a shipment arrived cold.

For patients and caregivers, these may appear to be backend supply-chain issues. In reality, they directly influence treatment continuity and patient safety.

The gaps in the current medicine supply chain

Three gaps require particular attention.

The first is reverse logistics. Medicines move down the supply chain with relatively detailed documentation, but expired, damaged and returned stock can move back with considerably less visibility. That creates an opportunity for diversion, repackaging and reentry into the legitimate market. The answer is to treat reverse logistics with the same seriousness as forward distribution. Every returned or expired batch should have a documented status, location and final disposition.

The second is the last mile. Unlicensed sellers, unverified online listings and retailers sourcing from unknown channels create points in the system where the provenance of medicines becomes difficult to establish. Stronger procurement controls and more frequent verification are required at these points.

The third is fragmented use of traceability infrastructure. India is now expanding QR-based traceability to more critical medicine categories, but the value of such infrastructure will ultimately depend on how consistently the information is accessed and acted upon across the supply chain. A traceability system that records information but does not use it to make decisions is only partially solving the problem.

What pharmacies, hospitals and distributors can do

The industry does not need to wait for every regulatory requirement to take effect.

Pharmacies can strengthen batch-level inventory by recording batch and expiry information at inward and dispensing stages, implementing first-expiry-first-out systems and conducting regular physical reconciliation. Distributors can improve visibility by maintaining batch-level records through both forward and reverse logistics, ensuring that returned or damaged stock is appropriately quarantined and disposed of, and limiting procurement to verified channels. Hospitals can extend these practices into wards, emergency departments and other locations where medicines may be stored outside the central pharmacy.

For critical therapies, the ability to establish not only where a product came from but also how it was stored can be particularly important. These are operational changes, but they can have a direct impact on patient safety.

What regulators can do next

The recent expansion of QR-based traceability is an important step. The government has now brought vaccines, antimicrobials, anti-cancer medicines and specified narcotic and psychotropic drugs under the expanded framework, with phased implementation timelines beginning in 2027.

The next step is ensuring that this infrastructure creates an actionable, connected system rather than another compliance requirement.

First, QR-based traceability should progressively cover more medicines, with priority given to high-value, temperature-sensitive and clinically critical therapies.

Second, verification should happen at meaningful points in the supply chain. Pharmacies, hospitals and other licensed dispensing points should be encouraged, and for higher-risk categories, potentially required, to scan and verify medicines before dispensing. A code that exists on a package but is never checked provides limited protection.

Third, India needs a more centralised and real-time recall mechanism. When a particular batch is found to be defective, spurious or unsafe, information should reach licensed pharmacies, hospitals and distributors quickly and in a standardised format. Batch-level alerts can help reduce the dependence on information moving manually through multiple layers of the supply chain.

Fourth, the disposal loop needs to be closed. Expired medicines should move through authorised disposal channels, with destruction or disposal documented against the original batch. This matters because expired and returned stock can otherwise become a source of material for fraudulent repackaging.

Finally, enforcement needs to focus on vulnerable points in the chain. Warehouses, distribution facilities and other high-risk nodes need appropriate licensing checks, audit mechanisms and inspection frequency. The objective should not only be to identify violations after they occur, but to make diversion and reentry increasingly difficult.

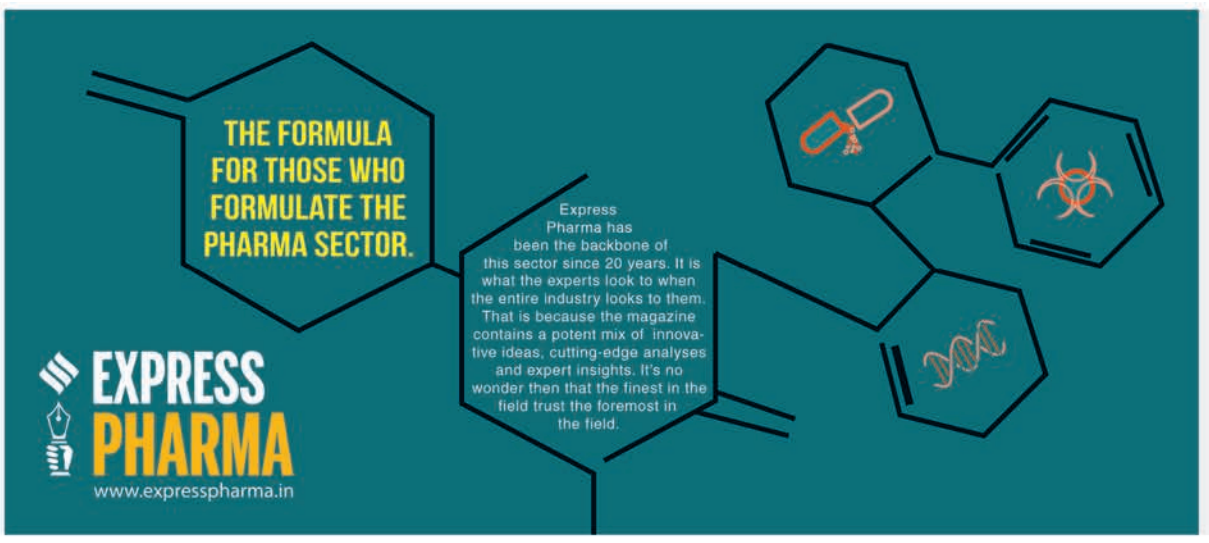
From compliance to accountability

None of these interventions depends on technology that does not yet exist. The infrastructure for barcoding, digital inventory management, batch-level tracking and QR-based verification is already available, and its regulatory scope is expanding.

The larger shift required is operational. The industry needs to treat batch and expiry information as a living part of a medicine's identity, not data recorded once and forgotten. Pharmacies need to verify what they receive, hospitals need visibility beyond their central stores, and distributors need stronger controls over forward and reverse movement. Manufacturers need greater visibility into where products ultimately travel, and regulators need systems that connect these individual points into a more coherent chain.

Medicine safety is not determined only at the point of manufacture. It is protected, or compromised, at every handover that follows.

The goal should be bigger than preventing the sale of an expired medicine. It should be a supply chain where every critical medicine can be authenticated, its batch and expiry can be verified, its handling can be traced, and its movement can be accounted for from manufacturer to patient. That is the level of transparency and accountability that patient safety demands.



EXPRESS PHARMA WORLD EXPO

The platform for India Pharma Inc's next leap

Scheduled as a three-day event **(March 3-5, 2027)**, the expo is not just a traditional trade show, but a media-powered business platform built to facilitate high-value conversations, enable partnerships and accelerate decision-making across the pharma ecosystem

India's pharma industry is at a turning point. Long defined by its scale and cost advantage, the sector is now being reshaped by more complex forces like biologics, stricter regulatory expectations, shifting global supply chains, and the growing importance of innovation-led growth. The next phase will demand not just capacity, but capability.

Recognising this shift, Express Pharma is launching Express Pharma World Expo, a new industry platform designed to bring together the people, ideas and technologies that will define the future of Indian pharma.

Scheduled as a three-day event (March 3-5, 2027, the expo is not just a traditional trade show, but a media-powered business platform built to facilitate high-value conversations, enable partnerships and accelerate decision-making across the pharma ecosystem.

Why this platform, why now

As regulatory scrutiny tightens and global competition
intensifies, Indian pharma companies are being pushed to rethink manufacturing quality, compliance readiness, and innovation strategies. At the same time, emerging areas such as biosimilars, specialty pharma and digital transformation are opening new opportunities.

What has been missing is a credible, neutral platform that can bring all stakeholders together, not just to showcase solutions, but to address the sector's most pressing challenges in a structured, outcome-driven manner.

This is what *Express Pharma* aims to build. A space where industry dialogue translates into business action.

Who will attend

The expo is expected to attract over 10,000 professionals from across India's major pharma hubs, including Mumbai, Hyderabad, Ahmedabad, Pune, Bengaluru, Chennai, and Baddi.

Attendees will include:

- CXOs and business leaders from pharma and biopharma companies
- R&D, manufacturing, plant, and operations heads
- Quality, regulatory, and compliance leaders
- Engineering, technical services, and project heads
- Packaging, validation, and cleanroom specialists
- EHS and sustainability leaders
- Supply chain and procurement strategists
- CDMO and contract manufacturing leaders
- Digital and technology transformation heads

Alongside them will be regulators, policymakers, investors, and solution providers, enabling a cross-functional, decision-making ecosystem under one roof.

The expo floor

The exhibition floor is designed to reflect the full pharma value chain, with participation from:

- API, excipients and KSM manufacturers
- Processing and manufacturing equipment providers
- Packaging solution companies
- Quality, validation, and analytical technology firms
- Engineering, project, and infrastructure specialists
- Cleanroom and controlled environment providers
- Utilities, water, and waste management solution c ompanies
- EHS and sustainability solution providers
- Digital, automation, and Pharma 4.0 technology companies
- Supply chain and contract service organisations

This breadth ensures that the expo is not limited to one segment, but captures the interconnected nature of modern pharma manufacturing and operations.

Turning presence into progress

The focus here is on structured engagement, ensuring that interactions are relevant and outcome-oriented.

Attendees can expect to:

- Gain insights into regulatory trends, global market access, and emerging technologies
- Discover cutting-edge solutions across manufacturing, packaging, and digital transformation
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- Identify new partnerships and business opportunities
- Benchmark their operations against industry best practices
- Stay ahead of shifts shaping the future of pharma

Conversations that matter

At the heart of the event is a leadership conference curated to address the most critical issues facing the industry.

Key themes include:

- Regulatory intelligence and global compliance readiness
- Strategies for global market access
- Innovation in biosimilars, specialty pharma, and advanced therapies
- Manufacturing excellence and scale-up capabilities
- Pharma 4.0, AI, and digital transformation
- Supply chain resilience and risk management
- Investment, partnerships, and growth opportunities
- The future positioning of Indian pharma on the global stage

These discussions signal a broader shift, from volume-driven growth to quality, innovation and reliability as differentiators.

Beyond an event: Building an ecosystem

Backed by Express Pharma's editorial, digital, and events ecosystem, the platform is designed to enable year-round engagement, extending conversations, insights, and business connections well beyond the event itself.

The launch of this platform is tied to a larger industry question: how can India move from being the 'pharmacy of the world' to becoming a global hub for innovation, quality, and advanced manufacturing?

By convening the right stakeholders and focusing on actionable outcomes, Express Pharma World Expo seeks to play a catalytic role in that transition.

In an industry where the next leap will be defined by collaboration as much as competition, the value of such a platform lies not just in who attends, but in what emerges from the conversations it enables.

Goa's bid for a bigger role in global pharma

From CDMO expansion to digital quality systems, the Goa Pharma Summit, hosted by **Express Pharma,** explored the capabilities Goa needs to move into higher-value pharma activities, reports **Neha Aathavale**

Lamp lighting ceremony: (L-R) Prof (Dr) G Shaber Ali, Professor of Law and former Principal, V M Salgaocar College of Law; Dr Prabhat Dessai, Associate Professor & Assistant Director, Placement & Corporate Relations Cell, Parul University, Goa; Uttam Kadam, Sterile Head, Zydus Lifesciences, Goa; Dr Pankaj Kumar, VP/Head R&D & Director, Wallace Pharmaceuticals; Nilesh Hegu, Site Head – Goa II, Cipla; Dr Subrata Chakraborty, Founder, INOPHAR Consulting & Training; and Dr Praveen Khullar, Executive Director, VerGo Pharma Research Laboratories

India has built its pharma strength on two formidable foundations: the ability to manufacture at scale and the capacity to reach markets across the world. In recent years, however, it has become increasingly clear that scale alone cannot determine how far the industry can go. The challenge is to keep pace with the shifts while moving beyond volume to create greater value.

For Goa, this challenge presents an opportunity to build on what it already does well. The state has an established pharma manufacturing base and a strong export orientation. The next step is to build capabilities in research and development (R&D), contract development and manufacturing organisations (CDMOs), advanced manufacturing and innovation. These priorities formed the backdrop of the Goa Pharma Summit, which brought together pharma industry leaders, policymakers, manufacturers, researchers and academic representatives to examine what it will take for Goa to move up the value chain and strengthen its position in the global pharma industry.

Goa's CDMO opportunity

One area of opportunity lies in identifying where Goa can offer greater value to global pharma companies beyond manufacturing scale. Dr Praveen Khullar, Executive Director, VerGo Pharma Research Laboratories, emphasised the importance of building on the state's export base while developing capabilities that would enable it to participate in more specialised development and manufacturing programmes.

This would mean moving from manufacturing as a standalone capability to building long-term partnerships with global companies. A focused approach to the CDMO market, particularly in complex formulations, specialty products and high-value, smaller-batch programmes, could help Goa address more specialised industry requirements and expand its role across the pharma value chain.

Reliability would be another part of this proposition. Continuity of supply, speed of

Dr Praveen Khullar, Executive Director, VerGo Pharma Research Laboratories

Manoj Bansal, Head - Business Development, Thermo Fisher Scientific India

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

execution and resilience in responding to disruptions can influence the choice of development and manufacturing partners. Strengthening these capabilities would allow Goa to build its position on consistent performance and long-term partnerships, rather than production capacity alone.

Achieving this, however, would require coordinated efforts beyond individual company investments. Dr Khullar also highlighted the need for industry, government and academia to work together on talent development, regulatory requirements, technology adoption and global partnerships. Bringing these elements together would be essential to building an ecosystem that supports Goa's transition towards higher-value pharma development and manufacturing.

Alongside this ecosystem-level shift, the ability to move up the value chain also depends on the technologies that turn research into scalable manufacturing processes. As Goa explores opportunities in specialised products and complex formulations, advances in formulation development, processing technologies and analytical methods will play an important role in translating these ambitions into manufacturing capabilities.

Advancing formulation technologies

Against this backdrop, Manoj Bansal, Head of Business Development, Thermo Fisher Scientific India, discussed advancements in hot melt extrusion technology, focusing on instrumentation considerations and methodologies. The technology can improve the solubility and bioavailability of drugs, supporting formulation development from R&D through to manufacturing.

Bansal also highlighted the role of molecular spectroscopy in pharma workflows. Thermo Fisher Scientific's portfolio includes Raman, near-infrared (NIR) spectroscopy and X-ray fluorescence (XRF), which enable rapid, non-destructive testing. These techniques support the analysis of materials and processes, while the integration of formulation technologies, spectroscopy, process analytical technology (PAT) and quality-control systems can facilitate faster decision-making, regulatory compliance and manufacturing efficiency.

Beyond developing formulations and monitoring processes, controlling drug release is another consideration in product development. The choice of polymers and their proportions can influence release characteristics, allowing formulators to adjust drug-release profiles to specific requirements.

Krutik Prajapati, Manager (Techno Commercial), Vikram Thermo (India), discussed drug-release modulation through DRUGCOAT RSPO/RLPO. Vikram Thermo's DRUGCOAT RL/RS polymers enable controlled and extended drug release by adjusting polymer permeability and concentration. They can also be used in wet granulation to modulate release, offering a simpler processing approach with scope for improved scalability. Optimising the ratio of DRUGCOAT RSPO and RLPO further allows formulators to tailor release profiles to specific formulation needs.

Together, these approaches highlight the role of formulation technologies in translating research into manufacturing capabilities. However, moving towards higher-value products also involves considerations beyond the technical aspects of development. Pricing frameworks, investment decisions and the availability of specialised talent will influence how effectively Goa can capitalise on opportunities in complex generics and biologics. These questions came into focus during the first panel discussion at the summit.

PPILT, patent cliffs and the biologics opportunity

The first panel discussion, moderated by Dr Subrata Chakraborty, Founder, INOPHAR Consulting & Training, brought together Nilesh Hegu, Site Head – Goa II, Cipla; Dr Pankaj Kumar, VP/Head R&D & Director, Wallace Pharmaceuticals; Uttam Kadam, Sterile Head, Zydus Life-sciences, Goa; Dr Prabhat Dessai, Associate Professor & Assistant Director, Placement & Corporate Relations Cell, Parul University, Goa; and Prof (Dr) G Shaber Ali, Professor of Law and former Principal, V M Salgaocar College of Law, to examine whether Goa's pricing model could support the next phase of pharma growth.

The key point of discussion was the role of PPILT, which combines procurement with negotiated pricing rather than operating as a standalone pricing policy. Its potential to influence investment decisions and attract new manufacturing opportunities must be considered alongside the interests of the pharma industry and the need for public transparency. Confidential pricing remains a challenge in this context, requiring a balance between commercial considerations and accountability.

The discussion also considered whether PPILT could help attract biologics manufacturing and technology transfer to Goa. As the industry responds to patent expiries and explores opportunities in more complex products, the state could benefit from investments that bring specialised manufacturing processes and technical capabilities. However, translating this potential into industrial growth would require more than a pricing mechanism. Complex generics, for instance, demand a different research and development approach, higher investment and advanced analytical capabilities. Developing these capabilities would be important for companies seeking to expand beyond conventional formulations.

Talent availability emerged as another consideration. As pharma manufacturing incorporates more specialised processes and technologies, the demand for skills is changing. Academia continues to face challenges in matching industry requirements, making closer collaboration between educational institutions and pharma companies important. Industry 4.0 and artificial intelligence are also reshaping manufacturing, increasing the need for talent equipped to work with evolving technologies and production systems.

The discussion highlighted the interdependence of pricing, investment, technical capabilities and talent development in shaping Goa's pharma ambitions. For the state to capitalise on emerging opportunities in biologics and complex generics, its pricing framework will need to work alongside investments in R&D, manufacturing technology and specialised skills. But developing these capabilities is only part of the equation.

Their long-term value will also depend on how effectively companies translate them into products that meet international market needs and build a sustained presence beyond established export destinations.

Diversifying India's pharma exports

This shift from building capabilities to converting them into market opportunities formed the basis of the next discussion.

Moderated by Mahesh Gurnasinghani, Executive Member, Goa Pharmaceutical Manufacturers' Association (GPMA) and Visiting Faculty,

L-R: Dr Subrata Chakraborty, Founder, INOPHAR Consulting & Training (MODERATOR); Nilesh Hegu, Site Head – Goa II, Cipla; Dr Pankaj Kumar, VP/Head R&D & Director, Wallace Pharmaceuticals; Uttam Kadam, Sterile Head, Zydus Lifesciences, Goa; Dr Prabhat Dessai, Associate Professor & Assistant Director, Placement & Corporate Relations Cell, Parul University, Goa; and Prof (Dr) G Shaber Ali, Professor of Law, Former Principal, V M Salgaocar College of Law

L-R: Mahesh Gurnasinghani, Executive Member GPMA and Visiting Faculty - Goa College of Pharmacy (MODERATOR); Maneesh Madhukar Narkar, VP - Formulations, Centaur Pharmaceuticals; Pramod Poojari, Site Head – Warehouse – Manufacturing, Cipla; Hruday Jadhav, Associate VP - Analytical R&D, Micro Labs; Sandeep Kulkarni, Associate Director APAC Sourcing Global Procurement Category, Teva Pharmaceuticals; Niket Talauliker, Head of Site Quality, Sanofi India; and Himank Narvekar, DGM – BD & Strategy, VerGo Pharma Research Laboratories

L-R: Dr Manoj Kumar Kashyap, Professor and Director, Research & Development, Parul University, Goa (MODERATOR); Dr Bhaskar Chauhan, Head R&D and Quality Management, Puniska Injectables; Dr Pradeep Kumar Vishwakarma, Associate Director - COE Manufacturing Science and Technology Respiratory, Cipla; Abhinay Ajgaonkar, DGM - Head of QA, Centaur Pharmaceuticals; Vishwas J Desai, GM - Quality Assurance, Blue Cross Laboratories; Urmila Deepak Naik, AGM, FDC Limited Goa (Unit III); and Sartaj Hanfi, Sr GM - Plant Head, Indoco Remedies;

Goa College of Pharmacy, the panel brought together Maneesh Madhukar Narkar, VP – Formulations, Centaur Pharmaceuticals; Pramod Poojari, Site Head – Warehouse – Manufacturing, Cipla; Hruday Jadhav, Associate VP – Analytical R&D, Micro Labs; Sandeep Kulkarni, Associate Director APAC Sourcing Global Procurement Category, Teva Pharmaceuticals; Niket Talauliker, Head of Site Quality, Sanofi India; and Himank Narvekar, DGM – BD & Strategy, VerGo Pharma Research Laboratories, to examine how India could identify its next export growth engines.

A key consideration was how India could translate its established manufacturing scale into greater value. While the country has developed the capacity to manufacture and supply medicines across international markets, the next phase of export growth may depend on its ability to develop products that require more specialised capabilities. Complex products and formulations could offer opportunities to move beyond competing primarily on volume, provided companies can build the technical expertise and manufacturing capabilities required to develop them.

This also changes how export diversification needs to be approached. Identifying new markets is only one part of the process; companies must also understand the requirements of those markets and develop products that address them. Market strategy and R&D, therefore, need to inform each other. Insights into demand, regulatory requirements and market-specific needs can help guide product development, while R&D capabilities can determine which opportunities a company is equipped to pursue.

Regulatory approval is an important step in entering an international market, but it does not, by itself, ensure sustained commercial presence. The ability to maintain supply, establish distribution and secure market acceptance also matters. Quality, in this context, needs to be built into product development from the outset rather than addressed only after a target market has been identified. Aligning quality requirements with product development and manufacturing can help companies prepare for the demands of their intended markets.

For Goa, these considerations point towards an opportunity to connect its manufacturing base with CDMOs, academic institutions and investment. Such collaboration could support the development of products and capabilities that respond to specific market requirements, while creating stronger links between research, manufacturing and commercial strategy.

The broader question, therefore, is no longer simply whether Goa can manufacture for international markets, but how it can participate in higher-value activities across the pharma value chain. Moving in this direction would require an export strategy that brings together product development, market intelligence, quality, supply-chain reliability and ecosystem partnerships. Translating these priorities into practice will depend on how well companies embed them into their manufacturing operations, quality systems and workforce capabilities.

From Panjim to the World: Goa's export playbook

This formed the focus of the summit's final panel discussion, moderated by Dr Manoj Kumar Kashyap, Professor and Director, Research & Development, Parul University, Goa. The panel brought together Dr Pradeep Kumar Vishwakarma, Associate Director – COE Manufacturing Science and Technology Respiratory, Cipla; Dr Bhaskar Chauhan, Head R&D and Quality Management, Puniska Injectables; Sartaj Hanfi, Sr GM – Plant Head, Indoco Remedies; Vishwas J Desai, GM – Quality Assurance, Blue Cross Laboratories; Abhinay Ajgaonkar, DGM – Head of QA, Centaur Pharmaceuticals; and Urmila Deepak Naik, AGM, FDC Limited Goa (Unit III), to discuss the capabilities required to strengthen Goa's position in international pharma markets.

A key consideration was the need to move beyond a compliance-led approach to quality. Passing audits is an important requirement, but sustained

global competitiveness calls for organisations to remain prepared for scrutiny as part of their everyday operations. This means embedding quality into processes, systems and decision-making rather than treating inspections as isolated events. Such an approach can help companies strengthen operational consistency while responding to the expectations of international regulators and customers.

Technology is also changing how quality is managed. As pharma manufacturing becomes increasingly digital, quality systems can do more than maintain records. Digital tools can help organisations analyse data, identify deviations and translate findings into action. The shift towards data-led quality management, however, also brings a requirement for people who can interpret information and apply it to manufacturing decisions. With technology advancing faster than workforce skills, talent development could become a constraint on the industry's ability to realise the full benefits of these systems.

Addressing this gap will require a stronger emphasis on practical exposure. The manufacturing shop floor can serve as an important learning environment, giving future professionals the opportunity to work with equipment, understand production processes and engage with real operational challenges. Hands-on experience can help bridge the gap between academic learning and the requirements of pharma manufacturing, particularly as plants adopt new technologies and processes.

The discussion also pointed to the need for Goa to build capabilities across a larger part of the pharma value chain, from R&D and technology transfer to commercial manufacturing. Expanding these capabilities would require companies to assess established practices critically and remain open to changing them when data and evidence support a better approach. Moving beyond legacy processes is particularly relevant in an environment where digitalisation, analytical capabilities and manufacturing technologies continue to evolve.

For this transition to take hold, collaboration between academia and industry must extend beyond formal agreements. Partnerships need to create practical opportunities for research, technical problem-solving and exposure to industrial requirements. By connecting academic expertise with manufacturing challenges, such collaborations could help develop the skills and capabilities needed to support innovation.

For Goa, strengthening its export position will therefore depend not only on meeting international quality requirements, but also on building organisations, technologies and talent capable of sustaining them.

A closer connection between quality management, digital systems, workforce development and industry-academia collaboration could help the state move towards a more integrated pharma ecosystem, with greater participation in R&D, technology transfer and higher-value manufacturing.

From scale to value

For Goa's pharma industry, the next phase of growth will depend on how effectively it connects manufacturing strength with innovation, technical expertise and global market requirements. This will require sustained investment in R&D, technology, talent and industry-academia collaboration, alongside a focus on quality and supply reliability.

The Goa Pharma Summit underscored that moving up the value chain is not a single step, but a coordinated effort to build capabilities that can support the state's long-term role in the global pharma industry.

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When health data crosses borders, trust must travel with it

As India expands its role in medical tourism and global clinical research, the movement of health data across borders is creating new challenges around privacy, consent and accountability. **Pradeep Gupta,** Partner, Deloitte India, explores how the DPDP Act, 2023, and DPDP Rules, 2025, are reshaping health data governance and why building trust must go hand in hand with enabling cross-border healthcare and research

The framework of India's Digital Personal Data Protection (DPDP) is currently reshaping how hospitals, pharmaceutical companies, Clinical Research Organisations (CROs), insurers and research institutions collect, process and share health data, making governance and accountability integral to healthcare and clinical research. This happens in parallel to raising the stakes for inadequate data protection and breach preparedness.

Health records travel with patients as they cross national borders, and accordingly, Personally Identifiable Information (PII) is also shared with overseas healthcare stakeholders.

The digital health database in India shows a rise in Medical Value Travel (MVT), which is about 5.5 per cent of all foreign tourist arrivals. As more than 450,000 patients from other countries travel to India each year, the medical tourism industry is projected to grow by $16.21 billion by 2030, posting a CAGR of 13.23 per cent. The AYUSH market is also poised to grow and is expected to reach $200 billion. Concurrently, the rising trends in the medical tourism industry reflect the growing demand for advanced clinical care and preventive wellness in India.

Such dynamic expansion of the digital health ecosystems results in the exchange of large volumes of health information among patients, healthcare providers, insurers, CROs, pharma companies and international partners.

The growth of medical tourism, cross-border healthcare services and global clinical research also increases the movement of sensitive personal health data across

jurisdictions, highlighting the importance of resilient privacy, security and governance safeguards.

This is where India's DPDP Act, 2023 and the DPDP Rules, 2025 come into the picture by providing a legal and operational framework to process digital personal data and protect the information of domestic and international patients.

As healthcare moves towards interoperable digital records, privacy, security and informed consent become the primary concerns of hospitals, health-tech firms, insurers, labs and pharma companies for the responsible use of patient-centric health information. This is done by implementing access controls, consent tools and breach response plans. Penalties of $2.5 billion for failure to implement security safeguards and $2 billion for failure to report a breach in India are consequences of the DPDP Act's robust implementation framework.

Anonymised health data supports disease tracking, monitoring of public health trends and the design of targeted health programmes. The scale is massive with over 1.2 billion linked health records, over 980 million ABHA IDs, over 1.2 million Healthcare Professionals Registries (HPRs) of medical professionals and over 500,000 verified Health Facility Registries (HFRs) as of October 2026, showing the growing digital footprint of India's domestic healthcare ecosystem.

This showcases the government's shift from policymaking to establishing an environment of trust and accountability to operationalise digital personal data governance at scale. A critical component of this trust is to make sure that data subjects can participate meaningfully in the ecosystem through accessible and inclusive engagement.

Inclusivity

While inclusivity drives engagement, strict adherence to jurisdictional boundaries ensures that this expanded access does not compromise national data sovereignty. Privacy notices and consent mechanisms need to be accessible in vernacular languages as an important part of the DPDP compliance. The BHASHINI app, for instance, supports 36+ Indian languages, 350+ AI models and 23+ language services. This helps to make privacy information and consent processes more accessible and inclusive for India's citizens.

Cross-border transfer responsibility

Organisations should proactively map cross-border data flows, conduct Data Protection Impact Assessments (DPIAs) and strengthen contractual safeguards to ensure that every international transfer is necessary, secure and compliant. DPDP Rules permit the government to restrict transfers of personal data to specified foreign states. DPIA can help identify and share essential datasets for clinical research. Contracts with pharmaceutical companies and CROs, sponsors, insurers, cloud providers, etc., should govern secondary use, onward transfers, security standards, subprocessors and timely incident reporting.

Breach preparedness

Organisations should move beyond reactive breach management by strengthening incident response readiness and investing strategically in Privacy Enhancing Technologies (PETs). This will help build resilience, reduce privacy risks and embed privacy by design into their data ecosystem. The DPDP Rules, 2025, establish clear requirements for breach notification, with Rule 7 requiring data fiduciaries to notify the Data Protection Board within 72 hours, unless an extension is permitted. This highlights the necessity for organisations to establish and operationalise robust breach-response mechanisms well in advance.

Compliance obligation

Healthcare organisations should treat data protection as a strategic priority, implementing privacy, security and responsible data governance into digital healthcare initiatives from the outset to build trust and unlock sustainable growth. Rapid expansion of India's digital infrastructure adds urgency to this transition since the scale and sensitivity of personal health data requires protection, as Internet subscriptions surpass one billion, mobile connectivity in 98 per cent of villages, covering more than 470,000 5G towers in 99.6 per cent of districts.

For clinical research, medical tourism and cross-border health data exchange, the DPDP Act, 2023, and the DPDP Rules, 2025, provide the guardrails for how personal health data should be handled, protected and shared. Their impact, however, will be determined by how consistently hospitals, pharmaceutical companies, CROs, insurers and research institutions translate these requirements into everyday decisions on consent, access, security and accountability. When health data crosses borders, trust cannot be assumed; it must be demonstrated at every stage of the data journey.

When patient burden becomes a regulatory risk

Ian Fisher, Head of Development Analytics at IQVIA, explains how assessing patient burden early in clinical trial design can help sponsors improve trial execution, preserve data quality and support regulatory decisions

New drug development typically takes close to nine years from first in-human trials to regulatory approval, although with pre-clinical development and launch activities, the total time commitment is around 15 years. The pressure of this lengthy and costly development process on drug developers is compounded by increasingly segmented disease populations and increased challenge in proving value over existing therapies, which potentially reduces success rates.

To alleviate these pressures, sponsors often seek to highly tune their trial designs and protocols to the precise needs and expectations of regulators, with approval the ultimate goal. Though meant to maximise probability of success, unnecessarily complex trial designs can easily work against that goal. Frequent visits, invasive procedures and specialised assessments can make sustained participation difficult, even when patients have a strong motivation to participate.

When these demands begin to complicate trial execution, increased patient burden becomes more than a recruitment concern; it can undermine the robustness and quality of registrational trial data and evidence. By evaluating and enhancing the relationship between patient burden, enrollment and retention, trial timelines and trial execution, sponsors can secure and retain patients and preserve the critical data they generate for regulatory review.

Patient burden does not end with recruitment

Before clinical trials begin, the trial and protocol design phases determine the procedures patients will undertake and the number of patients needed for success. These procedures can impact a patient's willingness to participate. Sponsors can improve successful trial execution by rethinking how they approach recruitment.

Rather than viewing recruitment as the primary issue, sponsors can consider and plan for recruitment challenges that could be warning signs that assumptions made during protocol development might not reflect operational reality. A trial that looks feasible on paper can become difficult to execute once patients and sites encounter its real-world demands.

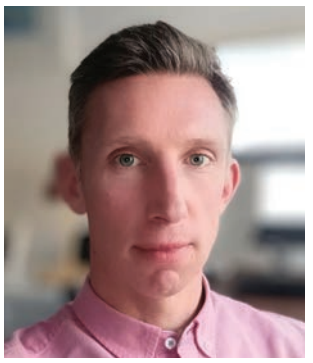
When those challenges emerge after enrollment commences, sponsors often need to revisit assumptions built into the original protocol. Changes intended to make the study more executable can create new detrimental consequences of their own. Late amendments introduce delays, inflate costs and risk the interpretability of the data. At that point, unnecessary patient burden becomes a threat to the study and therapy success.

When operational burden weakens the evidence

The purpose of a clinical trial is to generate compelling and robust evidence of clinical benefit and safety. To ensure that clinical trials remain centered on that goal, sponsors should establish checkpoints within the design phase to prevent overly burdensome protocol changes during the trial. These checkpoints include:

Endpoints: Sponsors must liaise with regulators, patients, physicians and payers to establish lean yet truly meaningful, validated and reliable endpoints needed to evaluate benefit and safety. Any ambiguity in potential acceptance or utility of the trial's endpoints represents a clear risk to success.

Patient populations: A realistic and appropriately generalisable set of eligibility criteria,



which evolves over the duration of the development program, is a critical component of program and trial design. Confidence that the right information has been gathered from the right patients over time is key to regulatory and commercial success.

Follow-ups: Clinical trials need sufficient timelines to capture initial results and time to conduct follow-up assessments of the durability of clinical benefits. Information capturing periods that end prematurely may fail to establish the benefits of a slow-acting or disease-modifying therapy.

If operational difficulties prevent critical design choices from being executed as intended, sponsors risk reaching the end of the study without the clarity needed to make confident development and regulatory decisions.

Missing or difficult-to-interpret data can change what the study can prove

Even when a trial is completed, the collected data must still support a clear assessment of clinical benefits. Sponsors should plan for gaps in data and stress-test alternative interpretations so that conclusions hold up under different assumptions. This becomes important when challenges in participation or protocol modifications affect how a study unfolds, since late changes can compromise data interpretability. Therefore, clear, robust evidence that persuades regulators that the therapy under study delivers meaningful clinical benefits.

Assess burden before the protocol is locked

Trial sponsors can resolve protocol problems by critically evaluating patient burden and willingness to participate early enough for that information to influence trial design. These feasibility assessments can incorporate valuable input from patients, trial sites and clinical operations teams. Sponsors can strengthen those insights by integrating evidence from comparable trials and actual site performance.

Historical data can also reveal feasibility risks that may not have been apparent through expert-led protocol planning. These perspectives can clarify whether eligibility criteria, endpoints and assessment schedules may create practical challenges before those requirements are finalised.

Sponsors who delay this evaluation until enrollment begins risk discovering feasibility problems when changes are far more disruptive. Technology is also providing clinical teams with new opportunities to identify risks faster, with advanced analytics increasingly supporting trial planning and even helping predict patient dropouts. Evaluating participation and retention risks before finalising protocols allows feasibility to shape the study rather than forcing the study to react to feasibility later.

Patient-centered design should also be decision-centered

Addressing the overall patient burden before adopting protocols is only one piece of building a trial that can support a regulatory decision. Sponsors must also establish early alignment with regulators on what the study must demonstrate. All regulatory feedback must be leveraged to guide the evidence-generation strategy before a program advances to a point where significant changes become difficult and costly. If sponsors gain little insight from that feedback, they'll fail to translate regulatory concerns into the study itself.

Sponsors must also consider that scientific validity alone does not guarantee that a study will answer the questions regulators need resolved. Even the most meaningful results may miss the mark if the trial was not designed around the regulatory conclusions it ultimately set out to support. Sponsors should prioritise maintaining ongoing regulatory engagement throughout development, particularly when existing guidance does not adequately address the circumstances of a program. This line of communication and alignment helps ensure that evidence generated can answer any regulatory questions the study was designed to resolve.

Patient experience should shape trial design

Patient experience should influence more than how sponsors can recruit and retain patients.

It should be the source of truth as to whether the study can realistically be accomplished to the degree that sponsors require.

Bringing this viewpoint into the development stage gives sponsors an opportunity to pinpoint assumptions that may not withstand the realities of participation. From there, patient-centeredness becomes part of building a clinical trial that can generate meaningful evidence for regulators to confidently evaluate a therapy.

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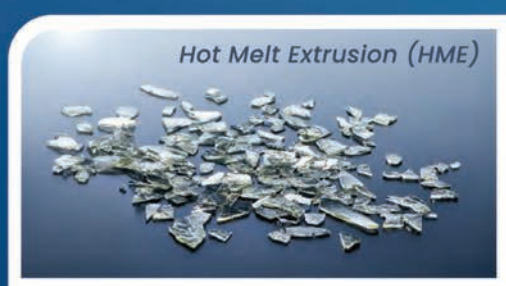

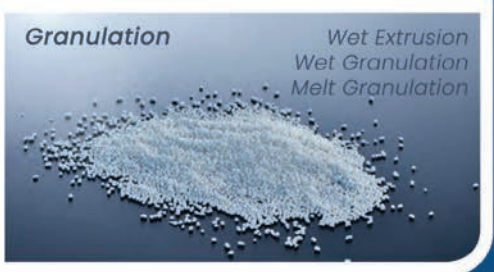

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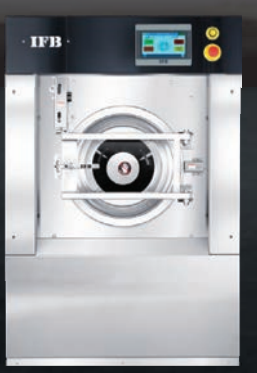

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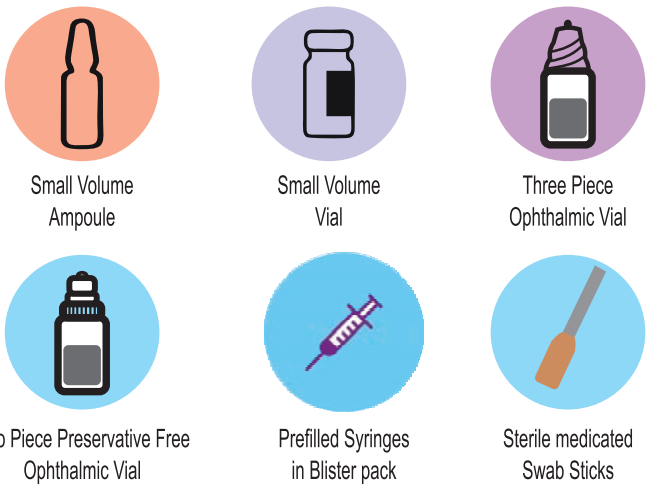

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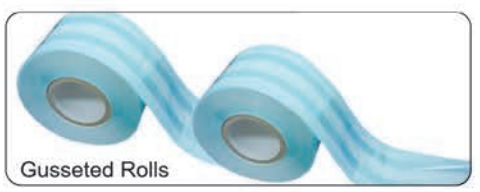

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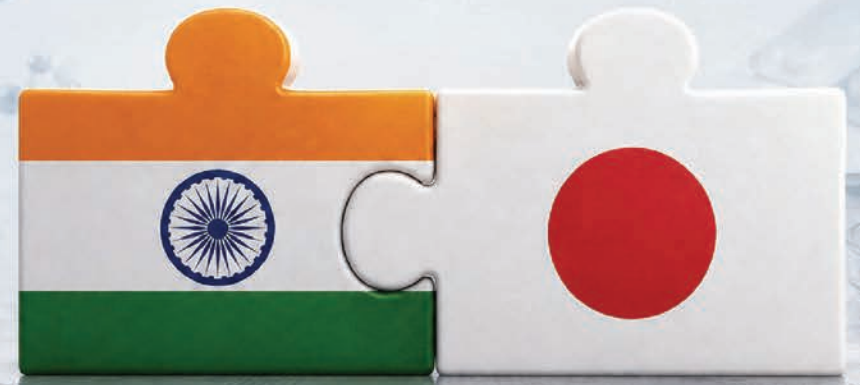

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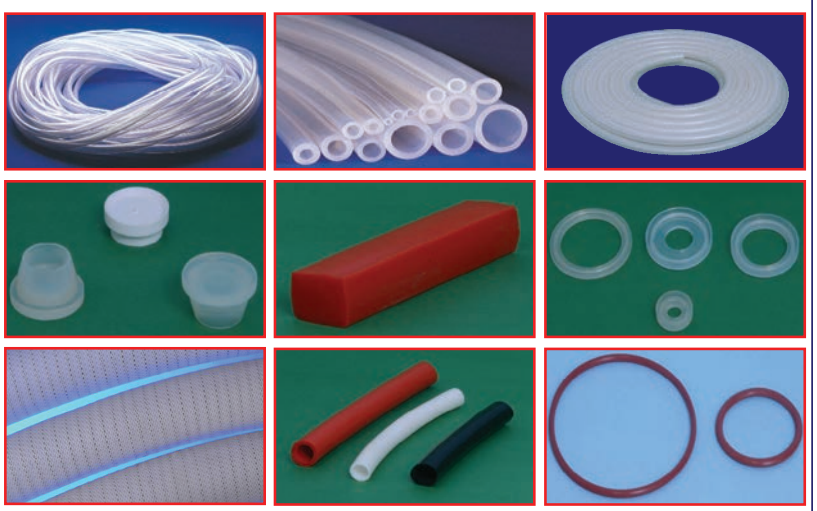

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Floor-standing ovations: Eppendorf introduces the new SpinPro® 8 R high-speed centrifuge

SpinPro 8 R combines high-speed performance with up to 6 L capacity and a selection of 35 rotors

Hamburg, Germany, September, 22, 2026: Eppendorf is expanding its centrifuge portfolio with the launch of the new SpinPro 8 R, a refrigerated, floor-standing high-speed centrifuge designed for demanding high-volume workflows. As the successor to the Centrifuge CR22N, the SpinPro 8 R combines established performance and rotor compatibility with a 7-inch user interface, sustainable CO_2 based cooling, traceable run documentation, and connectivity options.

The SpinPro 8 R is the first new floor-standing centrifuge development since himac became part of the Eppendorf Group and its product portfolio. Drawing on himac's long-standing centrifugation knowledge and Eppendorf's expertise across the full range of centrifugation solutions, it marks an important step in the continued development of high-performance centrifuges for laboratories worldwide.

More workflows on one high-speed centrifuge

Large-volume centrifugation rarely follows one neat path. Cell harvest may be the main application, but the tasks around it keep changing: vessels change, speed requirements shift, multiple users share the same system, and records still need to make sense afterwards. That is where the SpinPro 8 R stands out. It brings true high-speed capability and capacities of up to 4 × 1.5 L or 6 × 1 L into one compact floor-standing system, helping laboratories keep more of their workflow on one centrifuge instead of splitting it across multiple instruments.

Designed for biotechnology, pharmaceutical and high-capacity academic research laboratories, the SpinPro 8 R supports cell harvest, large-volume processing and other demanding separation tasks – including work with temperature-sensitive samples and workflows in regulated environments.

The rotor portfolio supports changing applications and vessel formats. The SpinPro 8 R remains compatible with the more than 30 rotors available for the Centrifuge CR22N and adds two new options:

- Rotor R5SS3 swing-bucket rotor: Operates at up to 4,700 rpm and 4,830 × g. Based on the Rotor S-4x750 from our benchtop portfolio, it supports a wider range of vessel formats through available adapters, buckets, and compatible consumables.
- Rotor R5A fixed-angle harvesting rotor: Operates at up to 5,300 rpm and 6,110 × g with a capacity of 6 × 1,000 mL. It is compatible with 1,000 mL Nalgene® bottles and offers an alternative to 4 × 1.5 L configurations when established protocols or standard operating procedures require the common 1 L format.

Both rotors are backwards compatible to fit Centrifuge CR22N and Rotor R5SS3 will be available in a version fitting Centrifuge CR30NX.

This combination of high-capacity and high-speed rotor options helps laboratories align larger batches, changing vessel requirements and more workflow steps on one system.

Intuitive operation for shared laboratory environments also supporting sustainability goals

The refrigerated SpinPro 8 R uses CO_2-based cooling technology (R744) with a Global Warming Potential (GWP) of 1 and Ozone Depletion Potential (ODP) of 0. The refrigerant supports laboratories that want to combine reliable temperature control with a sustainable refrigerant. Its use is also aligned with the direction of current EU F-gas regulation.

The SpinPro 8 R features a new, larger 7-inch touch display and a modern, intuitive user interface. Thirteen onboard languages support use across international laboratory environments, while programs, favorites and user management make routine operation easier to organise.

AuditSafe Mode and clear, traceable run records help laboratories manage shared use and support documentation requirements in regulated workflows. The updated electronic architecture provides the basis for a more consistent operating experience across Eppendorf's centrifuge portfolio, as well as future software updates and connectivity options.

"The SpinPro 8 R is about more than size and speed", explains Tim Schommartz, Global Marketing Manager Eppendorf Group. "It brings high-speed performance, rotor flexibility, easier day-to-day operation, sustainable CO_2 cooling and connectivity options together in one refrigerated floor-standing centrifuge."

Product highlights at a glance

- Refrigerated, floor-standing high-speed centrifuge for large-volume separation workflows.
- CO_2-based cooling technology using R744, with a GWP of 1 and ODP of 0.
- Capacity of up to 4 × 1.5 L or 6 × 1 L per run.
- Temperature control from -20 °C to 40 °C to protect temperature-sensitive samples.
- Two new rotor options and compatibility with more than 30 existing rotors.
- 7-inch touch display with intuitive user interface incl. 13 onboard interface languages.
- Light line and distance screen provide device status at a glance.
- AuditSafe Mode and traceable run records for shared and regulated environments.
- Supports VisioNize® connectivity and monitoring
- Direct connections to laboratory information management systems and electronic laboratory notebooks via standard protocols, including JSON-RPC.
- Software features and services designed to support 21 CFR Part 11 compliance.

For laboratories processing large-volume and temperature-sensitive samples, the result is a step forward: bigger batches without making the workflow harder to manage, more workflow steps kept on one centrifuge, broader vessel choice and clearer records for shared use. It is performance, flexibility and ease of use that deserve floor-standing ovations.

Get a preview of the new SpinPro 8 R at World of Industry, Technology & Science (WoTS) 2026 in Utrecht, Netherlands.

The SpinPro 8 R will be available for purchase at the end of September 2026.

A live launch webinar will take place on 1 October 2026, with the recording available on demand afterwards: https://www.eppendorf.link/spinpro8r-launch

For more information on SpinPro 8 R, visit: https://www.eppendorf.link/spinpro8r-launch or contact your local Eppendorf representative.

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Gandhi Automation's PRIME NEO high speed doors for cleanroom environments

Designed for pharmaceutical facilities and laboratories, PRIME NEO combines washability, effective sealing, pressure resistance and contamination control

When it comes to pharmaceutical facilities and laboratories, clean rooms' hygiene and protection from environmental contamination are the most important factors to consider. Gandhi Automation's PRIME NEO High Speed Doors are designed to provide superior sealing and resistance to pressure differences for clean rooms. And the added advantage is that it is absolutely washable.

PRIME NEO High Speed Doors assures:

Minimised contamination:

The reinforced polymer material is smooth-surfaced and joint-free. The door structure has been designed with full accessibility for water cleaning. Contamination risks are very minimal, making it fully compliant with the requirements of clean environments.

Just-in-time opening cycle:

Its smart design and German technology cause no delay in operation. Opening and closing in time reduces exposure time to a minimum, resulting in a reduction in energy costs and the risk of airborne contamination.

Sealing and Resistance to Pressure Differences:

The door has a flexible curtain with horizontal FRP stiffeners guided by vertical guides. Pressure is evenly distributed over the whole curtain, pushing it against the guides, giving a perfect seal. This design allows the door to operate even under pressure differences up to 50 Pa in a controlled room environment.

Safety:

PRIME NEO reduces the risk of accidents and damage. The free, flexible, and soft bottom edge minimises hitting impact. The radar detector and inbuilt photocells reopen the door at the slightest impact.

Windows:

The transparent material allows people to see coming traffic. Long-term transparency is assured, as the material is anti-fatigue PVC fabric.

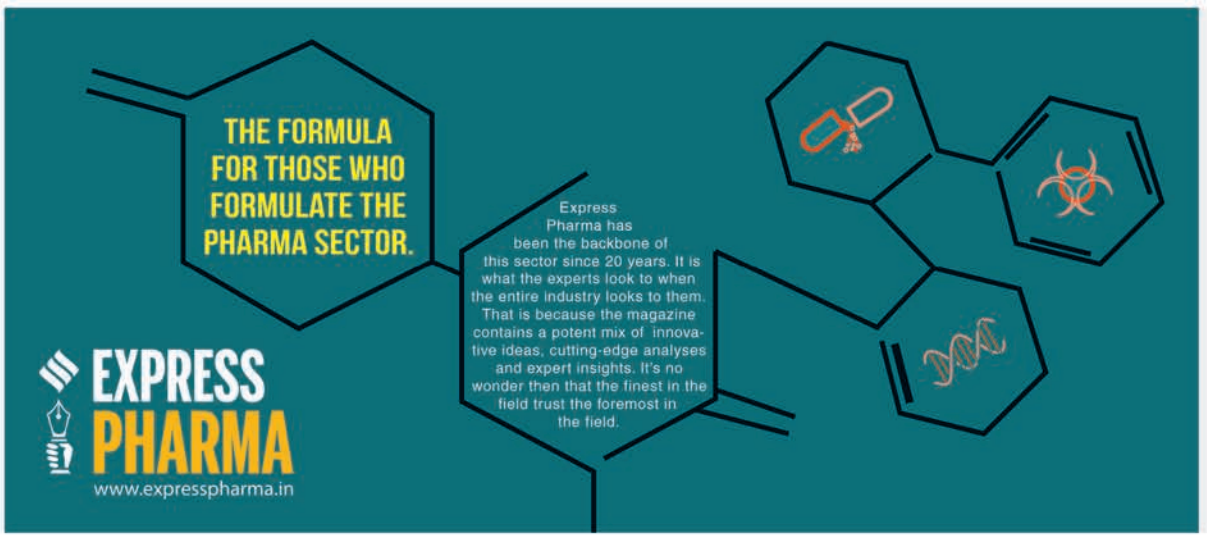
Multi-composite structure:

The toughness of the side guides and their ability to absorb an impact avoid high repair costs. PRIME NEO is anti-corrosion and paint-free, which ensures durability in corrosive and aggressive environments.

Auto-reset:

The door is equipped with auto-reset technology. In the event of an accidental crash, the curtain sets itself again. This unique system avoids time loss and reduces the risk of high repair costs.

To know more about PRIME NEO, write us at sales@geapl.com or call 022 6672 0200/0300



Building resilience in Indian pharma through technology and local networks

Nicola Magriotis, CSO, Romaco Group, and **Sanjeev Nimkar,** Managing Director, Romaco India, explain how energy-efficient equipment, local production, digital services and flexible machinery can help Indian pharmaceutical companies manage supply chain disruptions and strengthen operational resilience

By Nicola Magriotis, CSO Romaco Group and Sanjeev Nimkar, Managing Director Romaco India

Geopolitical volatility has become a defining factor for industrial decision-making. International conflicts, tariffs, sanctions, and shifting trade relations are reshaping markets worldwide. This manifests itself, for example, in unstable energy prices, limited transport routes, and import and export restrictions that hinder cross-border trade. The pharmaceutical industry and its suppliers are experiencing this dynamic: Manufacturers face growing pressure to secure supply, protect margins, and maintain stable operations under increasingly uncertain conditions.

This environment changes the demands placed on technical solutions for the Indian pharmaceutical industry. Whereas the focus used to be primarily on performance and investment, they must now also help pharmaceutical companies lower exposure to external shocks, stabilise costs, and improve their adaptability. They must build resilience and, in doing so, also support competitiveness and long-term viability.

In this regard, technological solutions and associated services must address five aspects in particular:

Inauguration of Romaco India's new spare parts centre in Chennai, Sri City

Tableting lab at the Romaco India Experience Centre in Hyderabad

Local format part production and blister packaging tests at the Romaco Experience Centre in Hyderabad

Romaco heat recovery system for fluid bed processing

Highly automated tablet coater OPT PRO by Romaco Tecpharm

Reducing energy demand: lower consumption, lower exposure

Rising energy costs are one of the greatest challenges of our time. In pharmaceutical production, many core processes require large amounts of thermal energy, conditioned air, and mechanical power. Drying, granulation, coating and packaging all contribute. When energy becomes more expensive, for example through tariffs or wars that restrict access to affordable energy resources, production costs rise quickly. That is why energy reduction deserves attention not only as an environmental measure, but as a risk management strategy. Lower consumption reduces exposure to volatile energy markets and improves planning security.

A good example comes from fluid-bed processing, one of the most energy-intensive procedures in solid dose manufacturing. Granulate and micropellet production require substantial drying energy, which makes waste heat recovery especially valuable. Our Heat Recovery System (HRS) developed by Romaco Innojet for its VENTILUS® product family integrates a high-temperature heat pump directly into the air handling system. Instead of allowing the thermal energy in the exhaust air to dissipate unused, the HRS recovers it and feeds it back into the running process. Even the friction heat generated by the exhaust fan is reused. The effect is significant. Depending on process conditions and machine size, thermal energy savings of up to 60 per cent are possible. From a resilience perspective, that means more than lower utility bills. It means lower sensitivity to sudden price increases and reduced dependence on external energy supply conditions. If a production line requires less heating energy per batch, it becomes easier to protect margins in turbulent markets.

Tablet coating offers a similar example. Coating remains energy-intensive because tablets must be sprayed with suspension and dried simultaneously with large volumes of hot, dry air. Traditionally, much of this energy leaves the machine with the warm exhaust stream. Our highly automated Tecpharm tablet coaters work differently. They can be equipped with an energy recovery system (ERS) with cross-flow plate heat exchangers that can transfer heat from outgoing to incoming air by letting the streams flow in opposite directions without mixing them. This reduces the thermal gap that the heating system must cover and can cut thermal energy demand in coating applications by up to 50 per cent. The business case is particularly strong in high-throughput environments and for products with tighter margins. In such settings, lower energy input directly reduces manufacturing costs per batch.

Measurement is equally important. Our integrated energy monitoring tools, available on all Romaco machines integrated into the HMI, allow manufacturers to track consumption in real time at machine and component level. These systems quantify total energy use, identify the contribution of specific functions, and document the actual effect of recovery measures. The resulting data supports both operational improvement and reliable sustainability reporting. That matters in an unstable market. Companies need facts, not assumptions. Machine-level energy data helps them compare operating modes, identify inefficiencies, and make better investment decisions.

Local production and regional networks in India: shorter routes, stronger control

Global supply chains have delivered cost advantages and specialisation for years. But they also create vulnerability. When machine parts, production materials or technical expertise have to cross several borders to get to India, every customs process, freight route and political decision becomes a risk factor. This has become increasingly clear as transport costs climbed, lead times stretched and trade restrictions multiplied.

For Indian pharmaceutical manufacturers, local parts production and regional networks offer a practical counterweight. From an environmental perspective, shorter transport distances reduce logistics-related emissions. From an operational perspective, they reduce dependency on fragile international flows.

One good example is our localisation of format part production for blister packaging and cartoning machines and lines in India. Format parts are

essential for multi-product production concepts. If they are sourced from distant manufacturing centres, delivery times can become lengthy and vulnerable to disruption. As we produce them locally, our response times shrink. Manufacturers gain speed, flexibility, and a more reliable route to output.

The benefit does not stop at transport time. Our local format part production also reduces the administrative burden associated with cross-border shipments. It is standard practice that qualification work for new formats requires test materials or placebo tablets to be sent abroad, often under strict customs and import rules. That process drives up air freight costs, delays projects, and increases documentation effort. Once production and qualification move closer to the user, much of that complexity disappears. This directly supports resilience, as pharmaceutical companies become less dependent on the smooth functioning of a global logistics system that has become less predictable.

Regional service structures also amplify this effect. We offer local training and an Experience Centre equipped with a laboratory, representative equipment and process expertise that can handle film tests, operator training, format approvals and technical adjustments. When local technicians are trained to the same standard as global specialists, customers gain access to qualified support without waiting for long-distance deployment. And this benefit extends beyond India's borders. Romaco India's service team is also deployed to assist international customers in countries to which other Romaco technicians are unable to travel due to travel bans or restrictions.

What emerges from all of this is a "local for local" model. It does not replace global collaboration; it rebalances it. Global know-how like we offer through the Romaco Group still matters, but execution moves closer to the point of use. For pharmaceutical manufacturers operating under geopolitical uncertainty, this can make the difference between stable operations and repeated disruption.

Regionalisation also improves cost control. Freight charges, customs duties and compliance-related logistics expenses can erode the economics of machine support faster than expected. Local and regional structures cushion these effects. They reduce hidden costs, simplify planning, and create more predictable service conditions.

Spare parts warehouse operating as a customs warehouse: faster processing, avoidance of unnecessary costs

Despite all the advantages offered by regional offerings, it would be a major disadvantage for globally operating companies with production facilities around the world if they were unable to draw on these resources in a particular market. This is where an approach comes into play that builds resilience by linking local resources with international supplies: We have just opened a spare parts and logistics centre for tableting parts in India (Chennai, Sri City), operating as a customs warehouse. The functionality behind this is as follows: into such a warehouse, which is subject to customs supervision, we can import spare parts for pharmaceutical machinery and technologies from abroad without the goods having to clear customs first, and without import taxes being payable immediately afterwards. This offers two enormous advantages: firstly, if the final destination of our spare parts is not India, the goods can simply be forwarded from there without customs formalities. This saves time and avoids unnecessary costs. The second advantage is that, when the parts are required in India, the actual customs clearance process is handled locally by a well coordinated team and is therefore considerably faster and less complex. Generally speaking, the cooperation between warehouse managers, local logistics providers and the local customs office is usually so close and streamlined that workflows are significantly faster. This can save weeks of time and, as a knock-on effect, lead to faster delivery, more satisfied customers and increased turnover.

In summary, it can be said that this model prevents or mitigates delays caused by customs formalities, which, amongst other things, can help to counteract supply bottlenecks and make a company overall more agile on the international stage.

Digital service offerings: expertise without travel dependency

A complement to local service offerings are digital solutions. They also reduce the need for travel, which leads to significant cost and time savings, and make repair and maintenance services more agile and resilient. An example for this is our remote support, that enables machine operators of our Indian customers and our technical experts to collaborate in real time without requiring immediate physical presence for every issue. Through live-stream communication and visual guidance, Romaco's specialists from India and the European business units can support Indian pharma companies by leading inspections, explaining corrective actions, or providing support for tasks such as commissioning, format changes or preparing for repairs. The impact on performance can be significant – fewer production downtimes and improved overall equipment effectiveness, which in turn contributes to economic stability.

We also conduct remote FATs from our global production sites during which our customers' respective teams are supported not only by Romaco experts from abroad but also by our Indian specialists. This enables machines to be commissioned even if our customers are unable to obtain visas at short notice or if other travel restrictions arise.

In summary, it can be said that local offerings and expertise, combined with digital capabilities, improve resilience – whether in troubleshooting, commissioning, maintenance, or operator support.

Machine flexibility: ready for changing requirements

The flexibility of the machines used in pharmaceutical manufacturing is another powerful driver for greater business continuity, especially for contract manufacturers and packagers. They must adapt quickly to dynamic market demands and new products – and this is where versatile systems come into play. For example, with wide format ranges for blister packaging lines like the Romaco Unity series, high batch variability of the Romaco RTC OPT tablet coating machines, and a general high degree of automation with advanced process control, these technologies provide a solid foundation for rapid and reliable adaptation to new formulations and quantity specifications. At the same time, such advanced processing and packaging machinery ensures energy savings, reduces cleaning efforts, and minimises the number of machines required. But it's not just contract manufacturers and packagers that benefit from flexible technology with a high degree of automation. When it comes to implementing new legal requirements and regulations – for example, in the context of sustainability guidelines – most companies need to be able to adapt as quickly, precisely, and cost-effectively as possible. Flexible equipment provides this adaptability and, consequently, future-proofing.

Conclusion: Resilient technology from Romaco as a practical business strategy for Indian pharma companies

The lesson from recent years is clear. Resilience does not arise from reacting faster after a disruption. It grows from building production systems that absorb shocks more effectively from the outset. The five exemplary levers outlined here provide approaches that can contribute to this end: Lower energy demand reduces exposure to utility price shocks. Local production and regional networks reduce vulnerability to transport disruption and trade restrictions. Local spare parts warehouses operating as customs warehouses enable faster processing and avoid unnecessary costs. Machine flexibility allows for faster adaptation in dynamic environments. And digital solutions provide independence from travel restrictions. All this shows why resilience deserves to be understood as an operating model rather than an add-on. In pharmaceutical manufacturing, it increasingly defines how robustly a company can perform under pressure. For decision-makers in the pharmaceutical industry, this has strategic implications. Investments in equipment, production architecture, and service tools should not be evaluated only by throughput or purchase price. They should also be judged by how effectively they reduce structural exposure to volatility.

Romaco at PMEC India

At this year's PMEC India in Delhi, Romaco will present selected processing, tableting and packaging solutions. One of them is the VENTILUS® Lab, a versatile laboratory system for fluid bed processes such as granulation, drying and micro-pellet coating.

Also on display will be the S 710 Prime double-sided rotary tablet press. This high-speed technology for the production of mono- and bi-layer tablets achieves a maximum output of up to 1,020,000 tablets per hour and is particularly suitable for high volume production capacity.

From its packaging portfolio, Romaco will showcase the N 950E blister packaging machine which is equipped with an AI-based vision inspection and pinhole detection system for blister packs. The 3D image analysis checks the tablets for various parameters, including presence, color, shape, breakage, etc. Moreover, this intelligent system inspects the packaging film for defects. **Booth 9A32**

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Polymer Chemistry Takes Centre Stage at BASF–Trans-Chem Formulator's Forum

More than 125 formulation scientists and industry professionals gathered in Navi Mumbai for a day of technical insights on solubility, hot melt extrusion, poloxamers and coating

Navi Mumbai, 16 October 2026. The Formulator's Forum, presented by BASF Pharma Solutions in collaboration with Trans-Chem Corporation Pharma Pvt Ltd, brought together more than 125 participants at Athiva Pulse, Vashi, on 16 October 2026. Under the theme "Polymer Chemistry Driving Solutions for Your Formulation Needs", the one-day programme combined expert technical sessions, the release of a new reference publication, and ample time for networking among formulation scientists, BASF's technical and sales teams, and the Trans-Chem team.

The first session, "Soluplus® – Market proven solution for unique formulation challenges", was presented by Dr Felicitas Guth, Head of R&D, BASF Pharma Solutions. It addressed how the polymer is used to tackle difficult formulation problems, a subject close to the daily work of the scientists in the room.

> The engaged participation through the day underlined the value of bringing technical experts and practitioners together on one platform

Dr Vijay Kulkarni, Co-Founder and Director of Swalava Enterprises Pvt Ltd, followed with "Understanding HME Parameters – Dependent and independent factors which impact on product development". His session examined the process variables that shape outcomes in hot melt extrusion and how formulators can approach them in development.

The programme also marked the release of the BASF Poloxamer Compendium, followed by session on on BASF Poloxamers as a platform for formulation development and processing by Dr Aditi Poddar of Technical Services, South Asia, Pharma Solutions. Ms Tanvi Raorane, Application Scientist at the Global Application Lab, Mumbai, spoke on faster enteric coating with advanced BASF Kollicoat® coating formulations.

Mr Umakanth Kanna, Head of Technical Services, Asia Pacific, then presented the "BASF Pharma Portfolio Pulse Check". Drawing the technical programme together, his session gave participants an overview of where the BASF Pharma Solutions portfolio stands today, placing the day's topics of solubilisation, extrusion, poloxamers and coating within the wider range of solutions available to formulators in the region. For the scientists present, it offered a view of how these products connect across the development process, and for the BASF and Trans-Chem teams, a shared picture of the portfolio as they continue to work with customers.

With more than 125 participants in attendance, the forum drew a strong turnout of formulation scientists, Transchem and BASF technical and sales teams and industry professionals, reflecting the continued interest in polymer-based solutions for formulation challenges. The engaged participation through the day underlined the value of bringing technical experts and practitioners together on one platform. The event's success was driven by the strategic vision and leadership of Mr. Zubin Zaveri and Mr. Shivang Zaveri, Managing Directors of TransChem Corporation Pharma Pvt. Ltd.

This collaboration between BASF Pharma Solutions and TransChem Corporation Pharma Pvt. Ltd. exemplifies a shared commitment to innovation and excellence in pharmaceutical formulation science. As the industry advances, such forums will continue to act as vital platforms for knowledge exchange and collaborative progress.

Why EVA is preferred as a primary fluid-contact layer in bioprocessing bags

Dr Priyabrata Pattnaik, Chief Executive Officer, Ami Polymer highlights EVA films' benefits and challenges in biopharmaceutical manufacturing, emphasising material safety, quality and performance

Single-use bioprocessing bags have become important in biopharmaceutical manufacturing because they reduce cleaning requirements, simplify changeovers, and support flexible production. Their performance depends significantly on the polymer film in contact with the process fluid. Ethylene-vinyl acetate (EVA) is an attractive material for selected applications because it combines flexibility, sealability, and practical manufacturing characteristics. However, its suitability depends on polymer formulation, processing conditions, sterilization, and extractables and leachables (E&L) performance. EVA should therefore be considered a potentially suitable engineering choice rather than a universally superior or inherently inert material[1,2].

Polymer chemistry and physical properties

EVA is a copolymer of ethylene and vinyl acetate. Ethylene-derived segments provide polyethylene-like characteristics, while vinyl acetate groups disrupt regular chain packing and influence crystallinity, flexibility, and polarity. Generally, increasing vinyl acetate content reduces crystallinity and increases flexibility, although the actual properties also depend on molecular weight, branching, and processing history. These characteristics can make EVA suitable for flexible films that must tolerate folding, handling, and deformation.

EVA can offer useful low-temperature flexibility and heat-sealing behaviour. These properties support bag fabrication and the formation of fluid-tight seams. Nevertheless, flexibility does not guarantee resistance to puncture, creep, fatigue, or mechanical damage. Similarly, sealability depends on temperature, pressure, dwell time, and film thickness. The finished bag, including its welds, ports, and tubing connections, must therefore be evaluated under representative operating conditions.

Gas and water-vapour permeability also require attention. Changes in crystallinity and film construction can influence molecular diffusion through the polymer. Consequently, EVA may not provide sufficient barrier performance for every oxygen-sensitive formulation or extended-storage application. Where barrier properties are critical, the complete film structure must be tested rather than relying on the polymer designation alone.

Manufacturing feasibility

EVA can be processed using established thermoplastic film-manufacturing methods, including blown-film and cast-film extrusion, depending on the selected grade and design. Its processing and sealing characteristics can support scalable production of flexible bags. However, pharmaceutical-grade manufacturing requires considerably more control than producing a conventional packaging film.

Melt temperature, residence time, cooling rate, and extrusion conditions can influence film thickness, morphology, mechanical properties, and chemical composition. Inconsistent processing may contribute to defects or variability in the finished product. Heat-sealing conditions must likewise be controlled to prevent incomplete bonding, local thinning, or weak seal interfaces. Sterilization and ageing may subsequently alter mechanical integrity or chemical profiles.

Manufacturers should establish specifications for raw materials, film thickness, seal strength, integrity, particulate contamination, and traceability. Changes in resin supplier, additives, processing conditions, or sterilization parameters should undergo documented change assessment. Manufacturing economics should consider production yield, rejected batches, qualification costs, and lifecycle reliability, rather than resin price alone.

Extractables and leachables – the qualification factor

Extractables are substances released from materials under defined laboratory extraction conditions. Leachables are substances that migrate into process fluids or products under actual or simulated conditions of use. Extractables studies help identify potential migrating compounds, while leachables studies establish their relevance under application-specific conditions [2,3].

EVA's E&L profile depends on its formulation and manufacturing history. Potential contributors include residual low-molecular-weight compounds, additives, impurities, and degradation products, where present. Oxidation or sterilization may also alter the chemical profile. These substances should not be presumed to occur in every EVA film; their presence and significance require analytical evidence.

A finished bag may contain additional materials, including tubing, connectors, weld interfaces, adhesives, and other polymer layers. Consequently, testing the base resin alone cannot establish the chemical suitability of the complete assembly. Research examining multiple single-use bag films has demonstrated substantial chemical diversity and the importance of identifying compounds under appropriate extraction and use conditions [3,4].

A risk-based assessment should consider the intended fluid, contact duration, temperature, surface-area-to-volume ratio, sterilization history, and storage conditions. Analytical methods may include gas chromatography–mass spectrometry for volatile and semivolatile compounds, liquid chromatography–mass spectrometry for less volatile substances, and ICP-MS for relevant elemental impurities. No single analytical technique captures every possible substance.

Detection alone does not establish unacceptable risk. Each relevant leachable must be assessed according to its identity, concentration, potential patient exposure, toxicological characteristics, and possible effects on product quality. For biologics, cell therapies, and other sensitive products, investigations may also need to consider effects on stability, viability, or biological activity. Generic supplier data are useful, but their applicability to the intended process must be justified [2,4,5].

Conclusion

EVA can be a suitable primary fluid-contact material for bioprocessing bags because its copolymer chemistry supports flexibility, practical sealing, and established film-conversion processes. Its suitability, however, cannot be established from material identity alone. Mechanical integrity, permeability, sterilization stability, manufacturing consistency, and formulation-specific E&L characteristics must be demonstrated for the finished assembly.

For bioprocessing manufacturers, the appropriate strategy is to combine controlled material selection with process qualification, analytical characterization, and lifecycle change management. EVA is most defensible as a material choice when its measured performance and chemical profile meet the requirements of the intended application. The decisive factor is not whether EVA is generally preferred, but whether the selected EVA formulation consistently protects product quality and patient safety under defined conditions of use.

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PROSOLV® SMCC 50 - A high-functional excipient from JRS Pharma

The development of co-processed, multi-functional excipients has enabled formulators to address multiple challenges with a single excipient, resulting in enhanced production and better finished product quality.

Why PROSOLV® SMCC?

Attaining good hardness at low compaction forces is quite essential while considering suitability of excipient for tablet formulation. Microcrystalline cellulose is one of the widely used and accepted excipients in tablet dosage form. Compactability of microcrystalline cellulose (MCC) is of prime importance during compression.PROSOLV® SMCC is a novel high-functionality tableting excipient. The material is manufactured by co-processing MCC with colloidal silicon dioxide (CSD) and can be used to improve flow, lubricant sensitivity and tablet strength. The addition of CSD in MCC helps to improve compactability [1][2].

It has been reported that silicification appears to have no apparent effect on the primary chemical and polymorphic characteristics of MCC. This suggests that bulk modification of MCC does not occur during silicification and that the CSD, either by providing surface modification or by modifying strengthening interactions, is primarily responsible for the improvements in functionality, in particular tablet strength. This may be solely due to a morphological property or some other silicon dioxide MCC interfacial interaction. Based on scanning electron microscopy studies together with electron microprobe analysis, it was stated that silicon dioxide is primarily located at the surface of the SMCC particles. While certain amounts of silicon dioxide were detected in the internal regions of some particles, the colloidal silicon dioxide particles present at the surfaces of the SMCC particles are shown to be uniformly distributed[2][4].

PROSOLV® SMCC is available in following grades[3]

Grade	Functionality
PROSOLV® SMCC 50 LD	Best in class binder (improves tabletability)
PROSOLV® SMCC 50	Formulas in which optimal compaction and decent flow are required
PROSOLV® SMCC 90	Formulas in which a balance of flow and compaction are required
PROSOLV® SMCC HD 90	Formulas in which optimal flow and consolidation are required
PROSOLV® SMCC 90 LM	Equivalent to PROSOLV® SMCC 90, with lower moisture content

PROSOLV® SMCC provides solutions to the problems often encountered by formulation scientists while using conventional diluents having low bulk density (BD), poor flow, low compactability or loss of compactability during processing, sticking and sensitivity to lubricant(s). This article will focus on physico-chemical properties, applications and advantages of PROSOLV® SMCC 50 & PROSOLV® SMCC 50 LD on tablet dosage form.

PROSOLV® SMCC 50 LD is the Low density grade from PROSOLV® family of excipients having below characteristics –

Particle size (d50)	Bulk density
Around 50 µm	0.20-0.30 g/cc

PROSOLV® SMCC 50 is the grade from PROSOLV® family of excipients having below characteristics –

Particle size (d50)	Bulk density
Around 65 µm	0.25-0.37 g/cc

PROSOLV® SMCC 50 LD.

These grades offers several benefits to formulation development scientist(s) during development and production at later stage. These benefits along with a few case studies will be elaborated in next section of this article –

Benefits of PROSOLV® SMCC 50 and PROSOLV® SMCC 50 LD in Roller Compaction Applications [3][4]:

As stated above,Silicification of Microcrystalline cellulose results in an increase in surface area. This increase in surface area increases binding interaction between the individual particles by reducing the interparticulate cohesion. As a result, silicification improves both the flowability and re-compaction properties of compacts.

PROSOLV® SMCC 50 LD is a low-density PROSOLV® SMCC grade, it is having benefits like it improves the tablet hardness and re-compactability issues after roller compaction. PROSOLV® SMCC 50 LD can be first choice.

PROSOLV® SMCC 50 can be useful when both tablet hardness and powder flow are required.

Following are the case studies to evaluate the effect of physiochemical properties of PROSOLV® SMCC 50 and PROSOLV® SMCC 50 LD on tablet dosage form.

Roll compaction is necessary to improve bulk density, flowability, compactability & to improve content uniformity in the tablet dosage form.

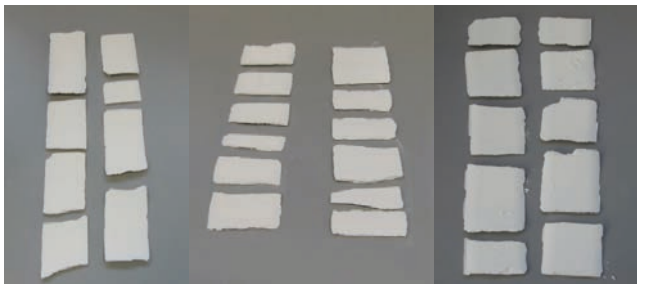
In this study the comparison of MCC 101, PROSOLV SMCC 50 & PROSOLV SMCC 50 LD was studied & evaluated in roller compaction. The Powder blends used consisted of 75% of the Cellulosic compound (either MCC or SMCC) and 25% Dicalcium phosphate dihydrate.Material were blended for 10 mins.Different roller compaction forces were adjusted and the compacts were milled. The resulting powder was tested for particle size distribution and flowability. Furthermore, placebo tablets containing 0.5% of the lubricant, Sodium Stearyl fumarate (PRUV®), were compressed (Tablet weight- 400 mg, round, 13mm diameter) and hardness as well as disintegration time of compressed tablets was analyzed.

Ingredients	Percentage
PROSOLV® SMCC or MCC	75 %
DCP (EMCOMPRESS®)	25 %
PRUV® (Extra granular)	0.5 %

Compacts comparison:

In this study, the comparison of compacts at 25 KN was evaluated. After roller compaction compacts density plays an important role to get desired Granules: Fines ratio. This is important step for the flow & content uniformity point of view.

Conclusion:

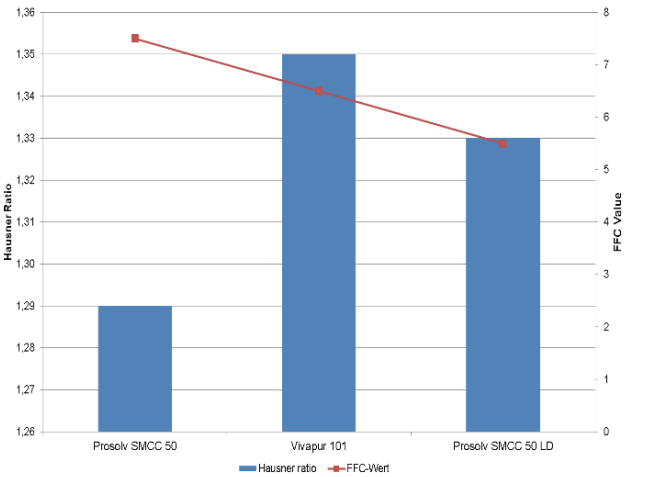


MCC 101 PROSOLV® SMCC 50 PROSOLV® SMCC 50 LD

Observation: MCC 101, PROSOLV® SMCC 50 and PROSOLV® SMCC 50 LD yield nicely shaped hard compacts at 25kN compaction force. From above picture we can conclude that PROSOLV® SMCC 50 LD yields dense compacts compare to Microcrystalline cellulose.

Flowability

In this study the flow of milled compacts was evaluated.

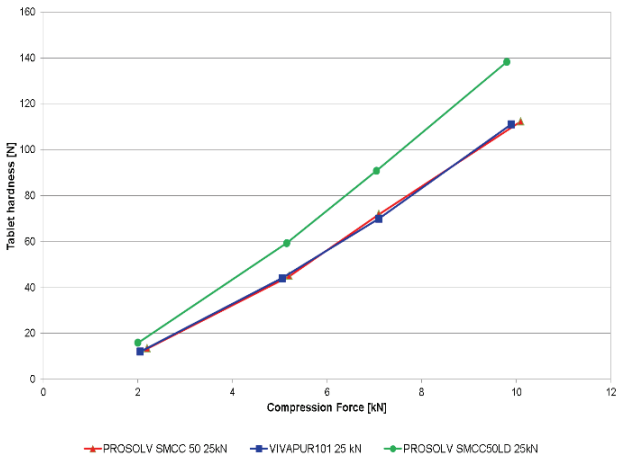


Observation:
Compacts were milled. It was found that PROSOLV® SMCC 50 exhibit best flowability followed by PROSOLV® SMCC 50 LD and MCC 101.

The silicification of MCC has been shown to significantly influence the hardness and the flowability of compacts in roll compaction process, as well as the hardness of tablets made from granules obtained from the milled compacts. If the over-

Tablet Hardness

In this study the effect on Tablet harness of roller compacted granules was evaluated.



Observation: Tablets were manufactured by using lubricant sodium stearyl fumarate (PRUV®) & compressed in to tablets.
Compacts based on PROSOLV® SMCC 50L D yield 30% harder tablets. Compacts based on MCC 101 and PROSOLV® SMCC 50 have nearly identical tablet hardness profiles over the entire range of compression forces.

all target in tablet production is the highest possible tablet hardness, the use of PROSOLV® SMCC 50 LD recommended [3][5][6].

If both, the particle flow and the tablet hardness is the target PROSOLV® SMCC 50 is the best choice [3].

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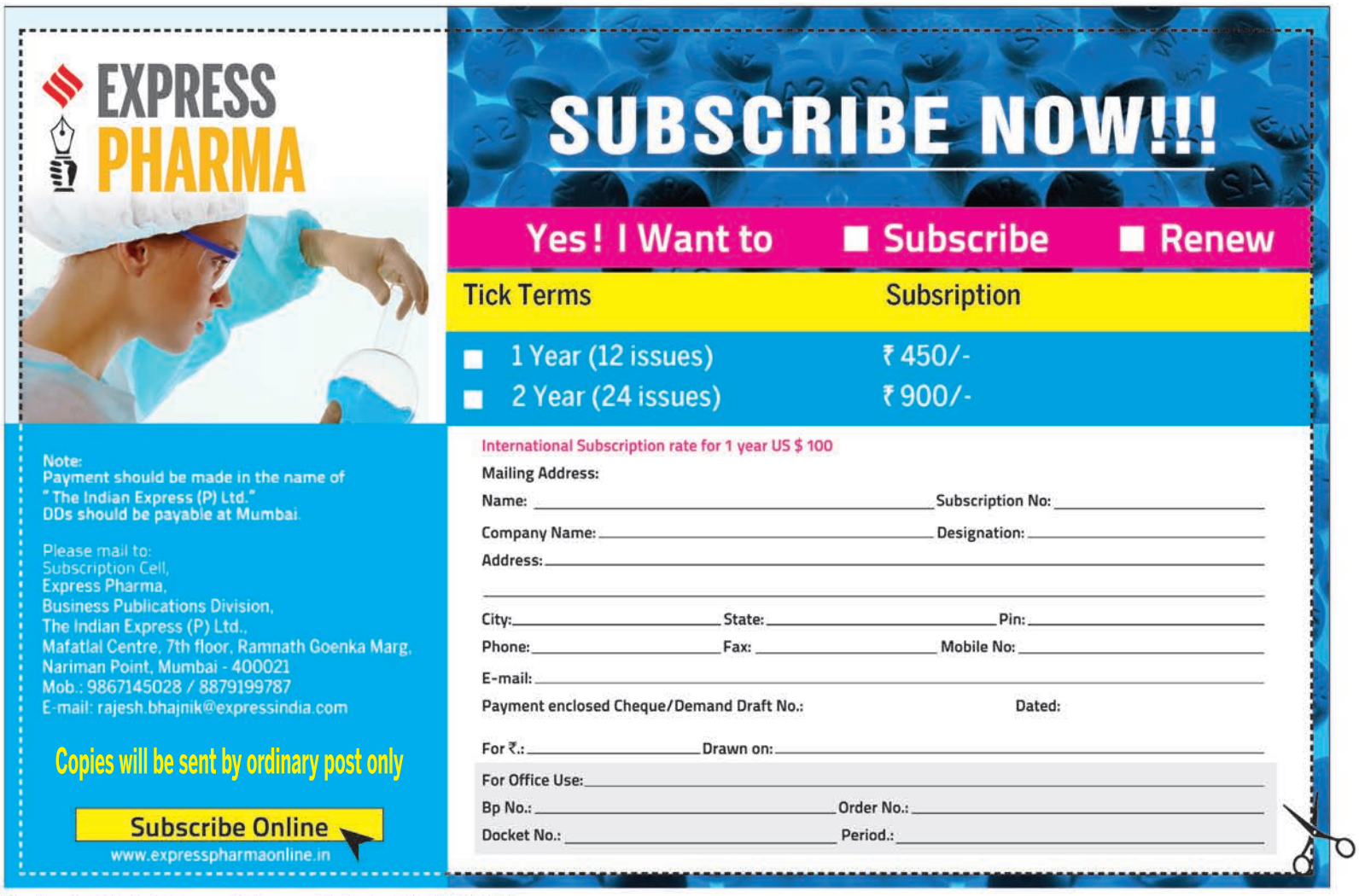

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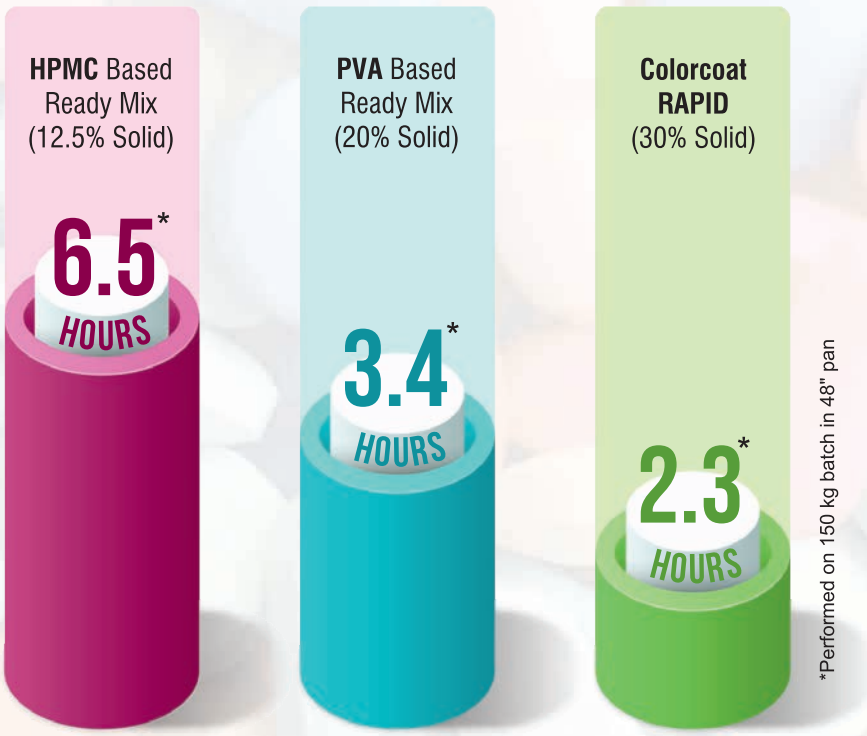

*Performed on 150 kg batch in 48" pan

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