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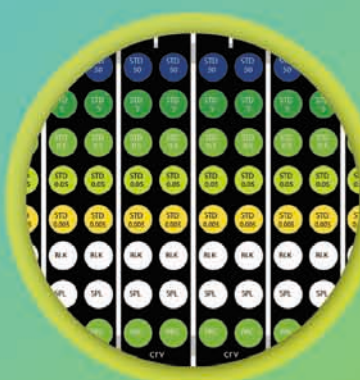
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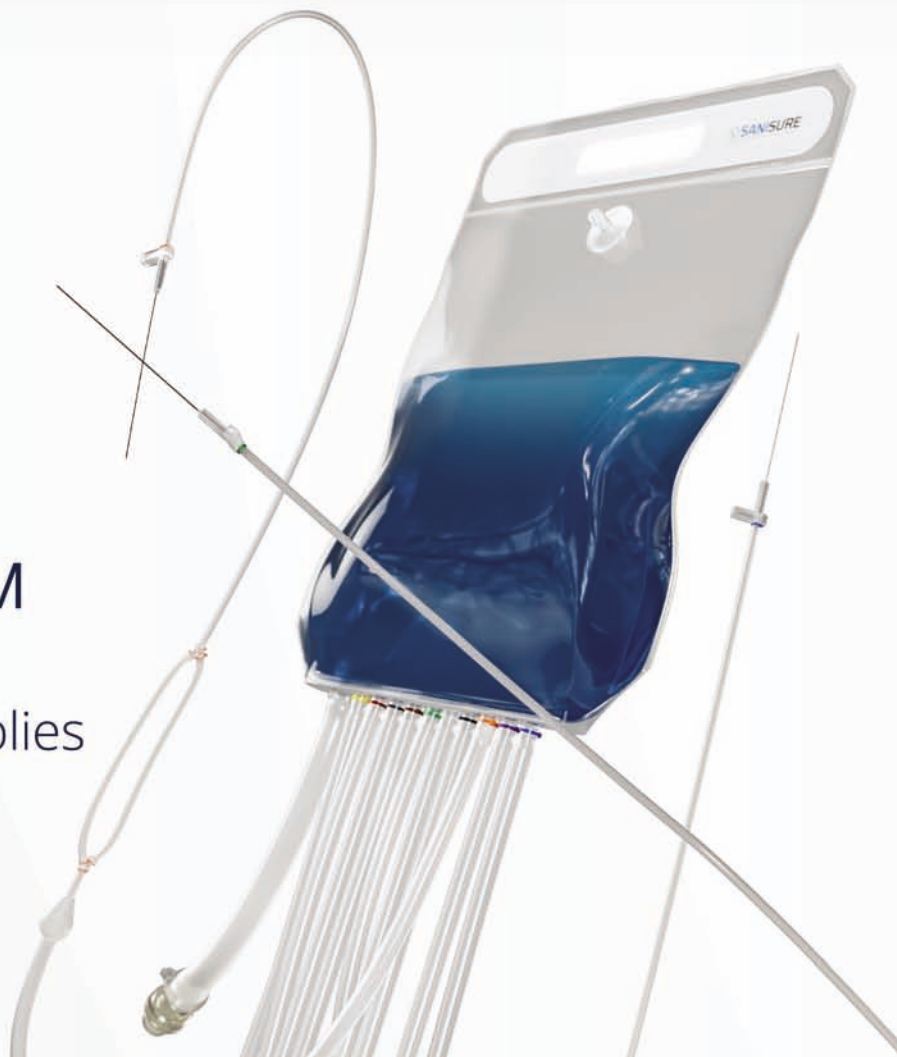


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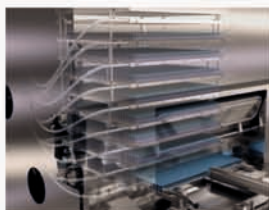
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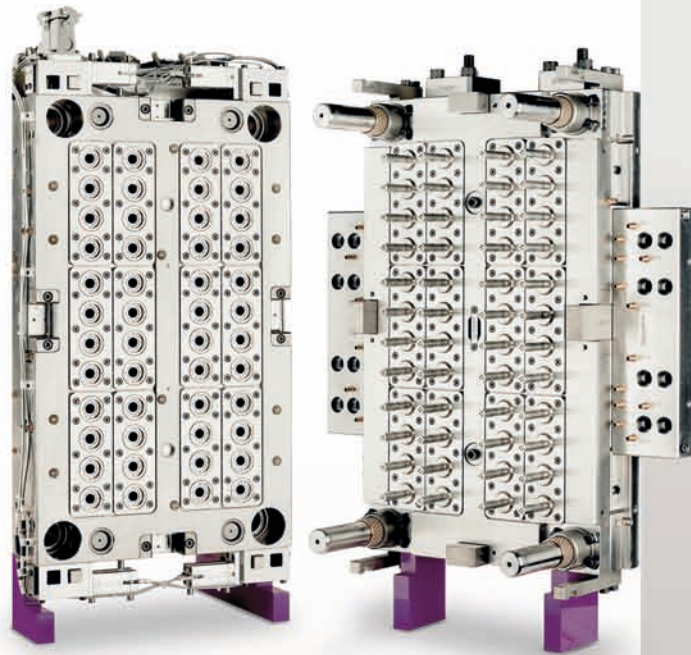
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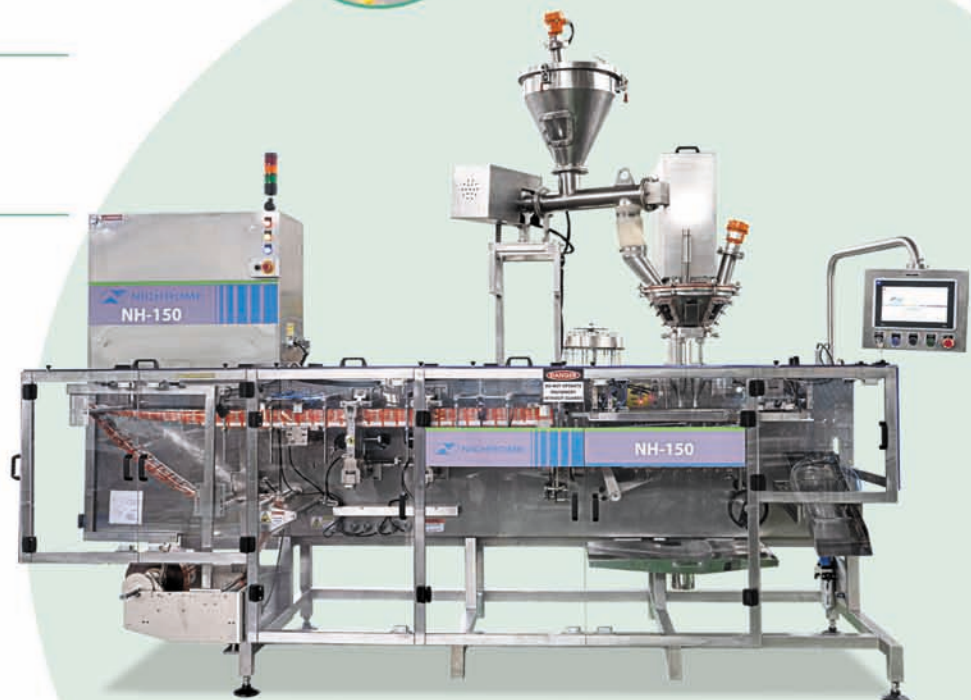
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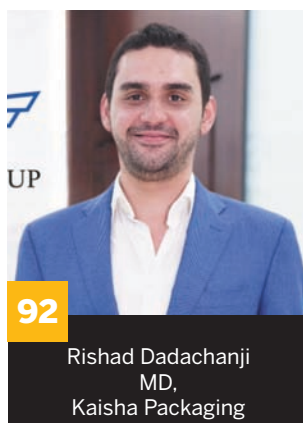
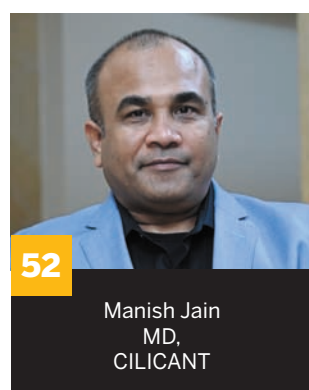
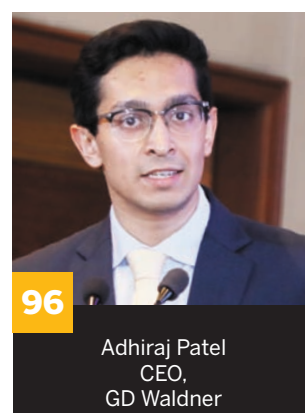
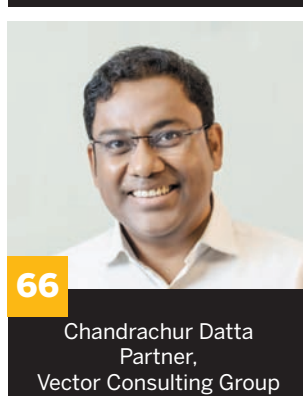
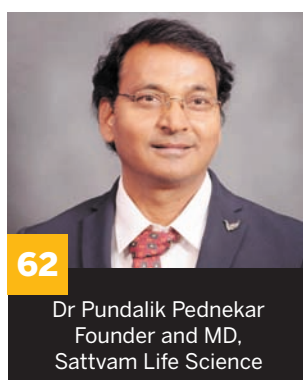
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A biosimilar boost amid trade barriers

Amidst the uncertainty of 50 per cent tariffs on India, the US FDA's October 29 draft guidance reducing the need for comparator efficacy studies for biosimilars comes as a welcome silver lining. Though the tariffs do not as yet apply to generics, the uncertainty has been a drag on the Q2FY2026 performances of most pharma companies in India.

Which is why the US FDA's new guidance got positive reviews from India Pharma Inc. As the US FDA press release points out, despite requiring one to three years and costing \$24 million on average, comparative efficacy studies generally have low sensitivity compared to many other analytical assessments. The FDA's new guidance reduces this unnecessary resource-intensive requirement for developers to conduct comparative human clinical studies, allowing them to rely instead on analytical testing to demonstrate product differences.

It's a move that will slash development costs and result in more affordable biosimilar medicines for the US market. For biopharma companies, that spells better margins and more incentive to invest in biosimilars.

The draft guidance is part of President Trump's Make America Healthy Again (MAHA) plan. The US FDA release points out that biologic medications make up only five per cent of prescriptions in the US but account for 51 per cent of total drug spending as of 2024. Market share of FDA-approved biosimilars remains below 20 per cent. While there are more than 30,000 approved generics, exceeding the number of approved brand drugs, the 76 US FDA approved biosimilars corresponded to a small fraction of approved biologics. Only about 10 per cent of biologic drugs expected to lose patent protection in the next decade currently have a biosimilar in development.

Clearly the draft guidance aims to attract more players into biosimilar development. It is expected that more of India's biopharma majors will double down on their biosimilars strategy for the US market.

Calling it a welcome step, Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance analyses, "The simplification of interchangeability guidelines and approval pathways will create a more enabling environment for the industry to diversify in large-molecule space. India already has nearly 130 approved biosimilars, and over the next seven years, more than 55 blockbuster drugs are expected to lose exclusivity in the US. India has long been a trusted partner in ensuring access to quality-assured, affordable medicines for American patients. These reforms will further strengthen the US-India partnership and our shared goal of improving healthcare access and affordability."



Even as India's biggest pharma companies pursue biosimilars, product recalls related to manufacturing defects threaten to queer the pitch

But even as India's biggest pharma companies pursue biosimilars, product recalls related to manufacturing defects threaten to queer the pitch. For instance, atorvastatin tablets made in India by Alkem Laboratories and distributed by Ascend Laboratories in the US had to be recalled as some tablets failed to dissolve. A US-based subsidiary of Sun Pharma had to recall kits of its renal imaging agent. Glenmark Pharma received market complaints about the gritty texture of azelaic acid gel tubes produced at the company's Goa plant. Both Granules India and Unichem Pharmaceuticals USA had to recall batches of medicines due to "failed impurities/degradation."

These recalls are worrisome as the resolution sucks up resources which could have been utilised to chase new opportunities, like the development and launch of biosimilars, which are more difficult to develop but promise better margins.

On the home front, Drug Controller General (India) Dr Rajeev Raghuvanshi has asked all state and Union Territory drug controllers to initiate planning to carry out inspections of manufacturing units which had applied for extension of revised Schedule M, from the effective date of January 1, 2026, to verify their compliance.

The November 7 letter also notes that "immediate inspection and action shall be initiated right now for those units who have not applied for the extension, as the revised Schedule M is already applicable for such units."

Dr Raghuvanshi has also asked all state and Union Territory drug controllers to submit monthly reports on inspections and observations made, and secondly, the actions taken pursuant to such inspections. This is a clear indication that there will be no more extensions of the January 1, 2026 deadline for complying with the revised Schedule M, especially after the deaths of 24 children after consuming cough syrups contaminated with DEG. Will the MSME pharma sector survive the upgrade to revised Schedule M norms? Or will there be a wave of consolidation and attrition?

With this December 2025 edition, *Express Pharma* completes 31 years of reporting on the pharma sector. From the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of January 1995, just a month after the inaugural *Express Pharma Pulse* edition, to President Trump's tariffs in 2025, it's been three decades of growth spurred by challenges. As we close the last edition of 2025, we look forward to continuing to serve the interests of India's pharma sector in 2026 and beyond.

VIVEKA ROYCHOWDHURY, Editor
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Overcoming oral delivery challenges: The science behind scalable enteric capsules

Lonza has reimagined enteric delivery with Capsugel® Enprotect®, a bi-layer, ready-to-use capsule that integrates enteric functionality directly into its shell without the need for post-filling coating

The pharma industry is witnessing an accelerating shift toward biologics, peptides, and other complex molecules that hold immense therapeutic promise, but their journey from lab to patient often hits a wall at the oral delivery stage.

While oral dosage forms remain the most patient-friendly route of administration, many advanced actives fail in the stomach, degraded by gastric acid or enzymes before they ever reach their target. This results in limited bioavailability, low efficacy, and the need for more invasive administration routes such as injections.

A 2022 NIH review estimates that more than 70 per cent of new drug molecules show poor oral bioavailability, especially peptides and macromolecules. This not only increases R&D cost but also limits patient accessibility, particularly in chronic and large-scale therapies.

So the challenge is clear: how can pharma innovators make sensitive molecules orally viable, without adding layers of complexity, time, and cost?

Why traditional enteric coatings fall short

Conventional enteric coatings were designed to protect APIs from the gastric acid environment and release them in the intestine. While effective in principle, the process introduces several bottlenecks:

- Exposure to solvents, heat, or mechanical stress during coating can degrade sensitive APIs.
- Maintaining consistent coating thickness and release profiles adds complexity to scale-up.
- Additional equipment, formulation steps, and regulatory

>70% of new drug molecules show poor oral bioavailability, especially peptides and macromolecules limiting patient accessibility. The challenge for pharma innovators is to make sensitive molecules orally viable

documentation prolong development timelines.

Each of these challenges compounds as drugs move from the R&D bench to commercial scale. In fast-paced development environments, formulators are looking for enteric solutions that are both scientifically robust and operationally simple.

The new generation of enteric delivery: built for science and scale

To address this, Lonza has reimagined enteric delivery with Capsugel® Enprotect®, a bi-layer, ready-to-use capsule that integrates enteric functionality directly into its shell.

Rather than coating a filled capsule, Capsugel® Enprotect® is engineered from two specialised polymers, hydroxypropyl methylcellulose (HPMC) and HPMC acetate succinate (HPMC-AS), that provide built-in acid resistance and targeted intestinal release.

This design eliminates the need for coating altogether, simplifying formulation and accelerating the transition from clinical trials to market. The capsule meets compendial enteric requirements, is compatible with standard capsule-filling equipment, and supports both powder and liquid fills.

For drug developers, this translates to fewer process steps, lower risk, and faster time to first-in-human studies.

Real-world proof: Predictable enteric release

The question any scientist would ask: Does it perform consistently inside the body?

To answer that, Lonza conducted in-vivo studies under both fasted and fed conditions using capsules filled with iron oxide and caffeine to evaluate disintegration time of capsules by a combination of 2 methods: MRI and caffeine quantification in volunteers' saliva

Key findings:

- In fasted volunteers, Enprotect® capsules disintegrated after gastric emptying in about 45 ± 14 minutes (MRI) and -36 ± 18 minutes (caffeine).
- In fed volunteers, despite longer gastric residence, disintegration occurred within -39 ± 21 minutes (MRI) and -32 ± 17 minutes (caffeine), confirming that the capsule resists mechanical and pH changes after gastric emptying.

This evidence demonstrates reliable enteric performance regardless of meal state: a crucial factor for clinical predictability and regulatory confidence.

From lab to line: A scalable, stress-free solution

The bi-layer manufacturing process enables fine-tuning for desired release profiles, pH-triggered, microbiome-sensitive, or targeted to specific intestinal regions.

Capsugel® Enprotect® capsules are supported by Drug Master File (DMF 038694) and can be filled on standard machines, allowing seamless progression from lab-scale studies to commercial batches.

By integrating enteric protection directly into the capsule material, developers can eliminate a complete unit operation — coating — saving weeks in production and avoiding the risks of scale-up variability.

In essence, it's an enteric solution that's both scientific and scalable.

Beyond the capsule: A complete molecule-to-market framework

Enprotect® capsules are part of Lonza's broader "Molecule to Market" framework, combining capsule innovation with integrated CDMO support.

Through the Innovaform® Accelerator, fill formulation and capsule composition can be optimised for release kinetics, compatibility, and manufacturability, while Lonza's global cGMP network handles scale-up, analytical validation, packaging, and regulatory submissions.

This full-service approach de-risks development and ensures that what works in the lab can be produced at commercial scale: efficiently and compliantly.

Choosing the right enteric strategy: What to ask

Formulation teams evaluating enteric technologies should consider:

1. **Is the API heat- or solvent-sensitive?** Opt for low-stress, integrated capsule systems that protect fragile molecules during processing.
2. **What's the fill compatibility?** Assess whether powders, liquids, or devices interact with the capsule polymer system.
3. **What's the path to scale-up?** Select solutions compatible with existing capsule-filling lines to reduce transfer risks and speed up commercialisation.
4. **Is there clinical proof or validation?** Human data across both fed and fasted states ensures predictable and reliable performance.
5. **Are regulatory pathways available?** Established DMFs and validated processes simplify submissions and accelerate approvals.

The right enteric strategy combines robustness, scalability, and regulatory confidence, helping bring patient-friendly oral therapies to market faster.

The future of oral drug delivery

As patient-centric innovation continues to shape the pharma landscape, oral delivery remains a cornerstone not just for convenience, but for accessibility and adherence.

Technologies like Capsugel® Enprotect® are redefining what's possible—combining scientific rigor with manufacturing simplicity to bring sensitive APIs safely to the intestine and onward to patients who need them most. By bridging science and scalability, Lonza is enabling a new era of enteric solutions: faster to develop, easier to manufacture, and built for real-world performance.

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INTERVIEW

Pharmacists can be true change-makers in population health

Manjiri Gharat, FIP India Envoy; VP, SEARPharm Forum of FIP; I/C Principal, K.M. Kundnani Pharmacy Polytechnic, Ulhasnagar; Former VP, International Pharmaceutical Federation (FIP) and Indian Pharmaceutical Association (IPA) gives some suggestions on how pharmacists can be made a more integral part of the India's health system, in an interview with **Viveka Roychowdhury**

You've trained pharmacists for over three decades as a community pharmacy leader at local, regional, and global levels. You have also led public health initiatives, such as the DOTS TB pharmacists project of IPA. What has been the impact of such initiatives in terms of disease detection rates, compliance with medicine regimens, etc?

Pharmacists have long remained a missing link in our health system, with their true potential yet to be fully tapped. However, I have always strongly believed that pharmacists are — and must be — an integral component of the healthcare team. With this conviction, I have continued my efforts to involve community pharmacists in people-centered care through various initiatives.

One of the key milestones in this journey was engaging pharmacists in the Revised National Tuberculosis Control Program (RNTCP). This was a pioneering example of a public-private partnership implemented from the local to the national level.

In Maharashtra alone, during 2010-2012, 525 pharmacists from six municipal corporation areas were trained in TB care and control and almost 100 served as DOTS providers. This was a historic development — more than 500 patients were treated at pharmacies, and trained pharmacists referred several TB suspects. Just to give an



example: In the Bhivandi corporation area, 37 pharmacists referred 476 suspects, of whom about 14 per cent were confirmed positive cases. These were patients who might otherwise have been missed, and by identifying them, pharmacists played a significant role in breaking the chain of TB transmission.

The success of this PPP model had a multiplier effect — it was replicated by NGOs in different parts of the country. The training module developed

by the Indian Pharmaceutical Association (IPA), in collaboration with the Ministry of Health and Family Welfare (MoHFW), was translated by NGOs into several regional languages to facilitate wider implementation.

Perhaps the most significant outcome of this initiative was that policymakers and communities began to recognise pharmacists as a new pool of human resources for public health. This experience reaffirmed my belief that when

pharmacists are appropriately trained and supported within the right ecosystem, they can indeed become powerful change agents in public health.

Building on the success and confidence gained from the DOTS TB Pharmacist Project, we have continued our efforts to engage pharmacists in national health programmes targeting noncommunicable diseases (NCDs) and vector-borne diseases. Although these initiatives have not yet yielded tangible results, sustained advocacy and collaboration with policymakers are ongoing. I remain hopeful that, with continued commitment and recognition of pharmacists' value in the health system, their integration into these broader public health programmes will soon become a reality.

In an era where online pharmacy chains are outnumbering the corner chemist shop, at least in metros, you have a faceless doctor calling you up to verify your prescription. How can we enhance the role of pharmacists as gatekeepers of public health in India?

As stated earlier, I strongly believe that pharmacists can be true changemakers in population health. The interaction between pharmacists and patients is the most defining and valuable feature of pharmacy practice. While people increasingly turn to online platforms for purchasing medicines due to

discounts and convenience, no technology can replace the human interaction and personal touch that occur in a pharmacy. Neither phone calls nor chatbots can replicate the empathy, reassurance and trust that come from face-to-face engagement with a pharmacist.

Although online medicine purchases cannot be completely prevented, the focus should be on strengthening the patient-centered role of pharmacists. By demonstrating their true value through personalised care, pharmacists can encourage patients to prefer in-person pharmacy visits over virtual transactions. Pharmacists must truly act as a vital link between the patient and the doctor, serving as approachable and knowledgeable medication counsellors.

Even small, consistent efforts — such as offering practical tips for responsible medicine use — can significantly enhance the pharmacist's perceived value in the eyes of patients. Simple clinical services like blood pressure measurement or BMI calculation are easy to implement and can help position community pharmacies as accessible health hubs. Gradually, the vision should evolve towards a culture of "Think Health – Think Pharmacy."

Pharmacists can also play an essential role in connecting patients with community resources such as de-addiction

centers, old-age homes, and nursing bureaus. Beyond medicine-related advice, pharmacists across the world are establishing themselves as key contributors to social prescribing — helping people access non-medical interventions that improve their overall well-being.

Pharmacists, often the most accessible healthcare professionals, are uniquely positioned to contribute to social prescribing and community health promotion. Their role extends far beyond dispensing medications; it encompasses empathy, communication and proactive engagement. Even small gestures of kindness and curiosity can foster trust and strengthen relationships.

Issues such as loneliness and ageing populations are emerging as major social health challenges across the globe. Pharmacists, with their accessibility, empathy and clinical insight, can and should be part of the solution. While artificial intelligence and digital tools can support and complement pharmacy services, they can never replace the human connection that defines the essence of the pharmacist's role.

How has the role of a pharmacist evolved globally? Are there any models that India can adapt/adopt to address the realities of our socio-economic status and health burdens?

Globally, the role of community pharmacists has expanded to such an extent that communities can confidently relate to the phrase, "Think Health – Think Pharmacist." coined by the International Pharmaceutical Federation (FIP) In most countries, pharmacists are recognised as essential healthcare professionals who serve as a bridge between patients and doctors, contributing significantly to accessible, safe, and people-centered healthcare.

Community pharmacies across the world now provide a broad spectrum of services — including drug-use reviews,

clinical assessments, medication counselling, adverse drug reaction (ADR) monitoring, de-addiction support, health promotion, and vaccination services. In fact, in more than 56 countries, pharmacists are authorised to administer adult vaccines, reflecting their vital contribution to public health.

Pharmacists are regarded as an integral part of the health system, sharing its responsibilities and strengthening the foundation of primary healthcare. In countries such as the UK and Canada, governments have actively encouraged the public to utilise pharmacists' services for the management of minor ailments, thereby reducing the burden on general practitioners (GPs).

Pharmacists in many countries now specialise in areas such as diabetes management, anticoagulant therapy, harm reduction services, allergy testing, and even specific women's health conditions such as menopause — underscoring their expanding clinical roles and expertise. Indeed, community pharmacies have become the cornerstone of primary healthcare in many developed nations.

This transformation has been enabled by strong education, regulatory and policy frameworks that align to support pharmacy practice advancement. There is much that can be learned from these global experiences. However, as the saying goes, "Think global, act local." Practice models from other countries cannot be replicated in their entirety in India due to differences in healthcare infrastructure, policy environments, and social contexts.

Nevertheless, India can adapt and contextualise successful international models, particularly those related to the management of common ailments as developed in the UK and Canada. It is also essential to develop supportive resources for training, mentorship, and continuing professional development (CPD) of pharmacists, ensuring

they are well-equipped to deliver high-quality, patient-centered care in the Indian context. FIP has developed wonderful resources and we should take benefit of the same.

In the National Health Survey, it has been brought out that when a member of a family falls sick in India, 14.4 per cent of the people surveyed preferred to go to a pharmacy for advice. How can we enhance this role through technology, digital strategies, etc?

Digitisation and the adoption of new technologies will play a transformative role in



advancing pharmacists' contributions to healthcare and enhancing patient care services. The use of digital tools for clinical decision support and medication adherence monitoring can greatly improve the quality, safety, and efficiency of pharmaceutical care.

Developing an easy-to-use drug information database that provides ready-to-deliver medication instructions is an urgent need to support pharmacists in daily practice. Similarly, digital inventory management systems can streamline operations, minimise wastage, and ensure the timely availability of medicines.

The use of artificial intelligence (AI)-driven communication tools can strengthen patient engagement and follow-up, enabling pharmacists to maintain meaningful connections with patients even beyond the

physical pharmacy setting. I see this as most useful and easy to use application of the technology which will really improve the patient connect.

To fully leverage these opportunities, digital literacy and practical technology applications must be integrated into undergraduate pharmacy education. Teaching students to use these tools effectively — through hands-on, practice-oriented training — will prepare future pharmacists to thrive in an increasingly digital healthcare environment and to deliver innovative, patient-centered services. To do this, teachers also need to be trained in newer technologies and its real world applications

What are your recommendations for policymakers and governments to make pharmacists the gatekeepers of community health?

In India, the transformation of pharmacy practice is an urgent and essential need. Expanding the scope of pharmacists' practice — supported by appropriate education, training, legal reforms, and a conducive policy framework — is critical to realising this change. Equally important is the awareness among consumers about the range of services they can rightfully expect from their pharmacies.

India faces multiple public health challenges: an ageing population, a rising burden of noncommunicable diseases (NCDs), widespread self-medication, irrational use of medicines, antimicrobial resistance (AMR), and low health literacy. In this context, strengthening the pharmacist workforce and modernising pharmacy practice are vital steps toward improving public health outcomes. This will strengthen primary healthcare. To achieve Universal Health Coverage (UHC) and last-mile healthcare delivery, pharmacists are must.

World Health Organisation (WHO), the Organisation for Economic Co-operation and Development (OECD), and FIP emphasise the critical role of pharmacists as healthcare

professionals. The United Nations also recognises pharmacists as an important pillar of the healthcare system.

I therefore urge policymakers and all stakeholders to give urgent and focused attention to the pharmacy sector. It is time to acknowledge that while India leads globally in the pharmaceutical industry, pharmacy practice — the patient-facing arm of the profession — still lags behind many other countries.

To bridge this gap and unlock the full potential of pharmacists, the following key actions are imperative:

- Develop a national competency framework for pharmacists, aligned with the needs and priorities of public health.
- Expand the scope of practice for trained community pharmacists, enabling them to clinically manage a defined set of minor ailments (e.g., sore throat, diarrhea, skin infections, hyperacidity, etc.).
- Involve pharmacists in the planning and implementation of national health programmes and public health initiatives.
- Ensure strict enforcement of the Drugs and Cosmetics Act and Rules, mandating the presence of qualified pharmacists in all pharmacies across India.
- Implement Good Pharmacy Practice (GPP) standards in every pharmacy to ensure quality and consistency of care.
- Introduce a remuneration system for pharmacists' professional services — even if modest initially — to acknowledge and incentivise their contribution to healthcare.
- Reform and strengthen pharmacy education, which currently requires urgent attention to align with global standards and contemporary healthcare needs.

Together, let us unlock the full potential of pharmacists and bridge this missing link in India's healthcare system — for the benefit of society and the health of our nation.

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India's next leap: From batch dependency to continuous quality leadership

Dr Vinay Rao, Head - Research & Development – STEERLife, highlights the transition to continuous processes is not a distant aspiration; it is a strategic necessity that will define India's competitiveness, credibility, and contribution to global healthcare

For decades, the Indian pharmaceutical industry has successfully operated as the 'Pharmacy of the World,' built on the backbone of efficient, high-volume batch manufacturing. This traditional process has ensured reliability and scale, supplying nearly 40 per cent of US generics and 25 per cent of UK medicines. But let's be honest, the global game is changing. Increased regulatory precision, intense post-

COVID scrutiny, and the demand for absolute supply-chain resilience now require something better. We have to move beyond the inherent limits of batch processing toward the certainty and efficiency of continuous manufacturing.

This isn't a distant, theoretical goal; it's an absolute necessity. If India wants to maintain and strengthen its dominant position, we have to act now. And the most decisive and im-



mediate first step in this modernisation is the widespread adoption of continuous granulation.

The limits of a legacy workforce

Granulation is arguably the most critical step in making tablets and capsules. It's where raw powders turn into uniform, compressible granules. In our traditional batch operations, this process is sequential and

segmented: wet massing, drying, milling, and blending. They often happen across multiple pieces of equipment, with manual transfers and hold points in between.

While it has served us well, this approach introduces some fundamental headaches:

● **Variability is inevitable:** When you expose a bulk wet mass to short, intense shear cycles or dry a huge bed of material in a fluid-bed dryer, you get

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inconsistent heat and mass transfer. The result? Inconsistencies between one batch and the next, or even within a single batch. Not every particle gets the same treatment.

● **Slow and clunky:** All those stop-start cycles, multiple hold points, and reliance on operator judgment create long cycle times. Agility is limited.

● **Compliance burden:** Trying to achieve Quality-by-Design (QbD) and real-time release becomes an uphill battle when quality is assessed only after the product is finished, not while it's being made.

When the world demands predictable, zero-defect quality, trying to solve tomorrow's complex formulation challenges with yesterday's technology simply won't cut it anymore.

Continuous Granulation: Same Science, Smarter Engineering

The beauty of Continuous Granulation is that it keeps the fundamental scientific principles (wetting, nucleation, growth, and consolidation) but completely transforms the execution. It integrates every single step: feeding, wetting, mixing, drying, sizing, and discharge, into one single, closed, and uninterrupted flow.

The difference comes down to the core concept: we move from a stop-start cyclic process to a thin-stream, steady-state flow. Only a small amount of material (often a 2.5 kg/min thin-stream flow) is in process at any given moment, instead of

a large 100–200 kg bulk load.

This shift gives us game-changing control:

1. Uniformity built in: Every particle is exposed to the identical process history because the flow is steady-state. Uniformity isn't something we test for; it's something that happens automatically.

2. Real-time control: Sensors are constantly monitoring Critical Process Parameters (CPPs) like torque, temperature, and feed rates. If something drifts, the system corrects itself immediately. This is how we move from post-production quality control to in-line quality assurance.

3. Operational efficiency: We eliminate multiple hold points and material handling steps. The conductive-convective thin-stream drying is much more energy efficient, contributing to lower specific energy utilisation.

This isn't an incremental upgrade; it's a structural modernisation of our manufacturing economics.

The regulatory and economic imperative

The reasons we need to make this jump are compelling and immediate.

First, there's Global Regulatory Alignment and Credibility. The US FDA, EMA, and other major regulators are actively encouraging continuous manufacturing under the ICH Q8–Q13 framework. For Indian manufacturers exporting to these markets, this is the direc-

tion of travel. Crucially, the consistency of continuous processes allows us to reproduce granule attributes identical to the batch process, which means we can achieve Q1/Q2 equivalence with existing batch products. This translates to faster approvals (often minor variations) because the drug composition is unchanged, and the process control is superior. Continuous manufacturing isn't a regulatory headache; it's a regulatory advantage.

Second, there is the undeniable benefit of superior economics and cost of quality (CoQ). While the initial investment requires capital, the long-term economic advantages are undeniable. One integrated continuous line often replaces four or five sequential unit operations and can be supervised by a single operator. This streamlined approach delivers significant lower utilities due to efficient heat transfer, reduced waste via seamless, enclosed conveyance, and faster returns because reduced cycle times, less inventory tied up, and in-line release confidence all accelerate our cash flow and time to market. As we shift toward high-value, complex, and highly potent molecules, every incremental efficiency compounds our competitiveness.

Bridging the adoption gap: Our call to action

The good news is that the technology is here. Commercial-ready systems are being designed, built, and demonstrated

within India. The barrier today is not technical; it's mindset, preparedness, and coordinated action. To unlock India's leadership in continuous quality manufacturing, three strategic enablers will make all the difference.

We need Demonstration Facilities. India requires a network of dedicated application centres where engineers and decision-makers can see continuous systems in live operation, validating performance and assessing scalability before full-scale adoption. Platforms such as the Integraal Gamma Line are already proving this model's feasibility, delivering industrial-scale throughput of 150–250 kg/h within a compact footprint. The Integraal Gamma Plus configuration, scalable up to 500 kg/h with minimal additions, demonstrates how locally accessible, high-throughput systems can future-proof Indian facilities. Just as importantly, their flexibility to handle wet, melt, or dry granulation reflects the adaptive, world-class manufacturing that India must now champion.

Next, we must have Policy & Fiscal Incentives. Government and industry must work hand-in-hand to design targeted fiscal and regulatory mechanisms that reward modernisation. This includes tax benefits or accelerated approval pathways for facilities transitioning to continuous manufacturing, which will de-risk investment and signal India's strategic intent to lead.

Finally, we need Talent Transformation. Technology adoption alone won't deliver transformation without a skilled workforce. India must invest in developing a new cadre of engineers and process scientists trained to operate, troubleshoot, and optimise highly automated, data-driven continuous systems. Building this future-ready talent pool will ensure technological progress translates into sustained operational excellence and global leadership.

The way forward

These three enablers - demonstration, policy, and talent, form the foundation of India's next leap in pharmaceutical manufacturing. The transition to continuous processes is not a distant aspiration; it is a strategic necessity that will define India's competitiveness, credibility, and contribution to global healthcare. The technology is proven, regulators are supportive, and the economics are compelling. What remains is collective resolve from industry leaders, policymakers, and innovators to turn intent into implementation. India has the scale, scientific depth, and entrepreneurial energy to lead this transformation. By embracing continuity in process, precision in quality, and sustainability in practice, we can redefine what it means to be the world's pharmacy, not just in volume, but in value. The future of medicine-making is continuous. It is time for India to lead it.



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Booth: 14.A58

Cilicant: Advancing drug stability through active packaging science

Manish Jain, MD, CILICANT elaborates how his company is pioneering the shift from passive to active pharma packaging, combining innovation and sustainability to enhance drug stability and patient safety. With a mission rooted in purposeful protection, the company is shaping the future of packaging through science, collaboration, and responsible design

Packaging's new role in pharma

In my experience in the pharmaceutical packaging industry, one thing has become increasingly clear: packaging is no longer a passive layer. It is an active participant in ensuring product integrity. The medicines we make today are more sensitive, the supply chains more complex, and the expectations for patient safety higher than ever.

At CILICANT, our focus has always been on one idea—protection. Protecting the stability of formulations, protecting the trust of patients, and protecting the promise that every dose delivers. This belief shapes the way we innovate, how we collaborate, and the way we see our role in the larger healthcare ecosystem.

The industry we serve operates in a space where even a minor lapse can alter outcomes. That is why our pursuit of excellence is constant and deliberate. Active packaging, when done right, bridges science and assurance — it is the invisible layer that safeguards efficacy, consistency, and confidence.

Innovation with purpose

The pace of pharmaceutical innovation is relentless. As formulations evolve, so must packaging. Our R&D team spends a lot of time not just creating new products, but understanding what challenges our partners are facing at various stages - on the manufacturing floor, during stability testing, and across distribution chains that span varied climates.

Moisture ingress, oxidation, odour migration, and humidity sensitivity are everyday realities in pharmaceutical manufacturing. These factors determine whether a formulation performs as intended, so our innovation begins by address-



ing them at the source.

When we innovate, we start with the problem, not the product. That's how solutions like Accuflip®, Frexil®, and Oxabide® came to life. Each was developed to answer a specific challenge, and refined with feedback from the people who actually use them. Accuflip regulates humidity levels with precision, ensuring formulations remain within their optimal stability window. Frexil, a dust-free activated carbon canister, improves both safety and performance by addressing odour and moisture simultaneously. Oxabide provides advanced oxygen absorption to protect oxidation-sensitive formulations.

Innovation for us, at Cilicant, also means responsibility. Every new material or process

is reviewed for its environmental impact. Sustainability is not a separate initiative; it is a part of how we design, manufacture, and operate. Our recent EcoVadis Bronze certification is one step forward in that direction. It reflects our ongoing commitment to ethical and sustainable practices—something that matters deeply, especially for our partners who export to regulated markets like Europe.

Partnerships that go beyond supply

In packaging, the smallest detail can make a big difference. A small variance in moisture transmission or oxygen absorption can alter a product's stability profile. That is why we work closely with pharmaceutical formulation and packaging teams from the early stages of

product development. Our team engages with customer teams to identify the right desiccant type, define target equilibrium relative humidity, and optimize protection based on real-world stability data. This level of partnership transforms what could be a simple material supply into a tailored, science-driven solution.

Our goal is to be more than just a vendor. We want to be the partner who helps our clients anticipate risks before they become problems. Many of our

and collaborate more closely with manufacturers worldwide.

Beyond pharmaceuticals, we are extending our expertise into sectors such as food, agriculture, textiles, and electronics. These industries may differ in output, but the core challenge remains the same — preserving product integrity against moisture, odour, and oxygen. Applying active packaging science to these areas allows us to protect value across more points in the global supply chain.



long-standing relationships began with one small pilot and grew into strategic collaborations built on reliability and shared purpose.

Building for the future

The industry is entering a new phase. Biologics, complex molecules, and temperature-sensitive products are rewriting the rules of packaging. To meet this evolving landscape, we are investing in both infrastructure and proximity to our customers. Expanding our presence in the United States, Europe, and the UAE allows us to respond faster, understand local regulatory requirements,

Purpose that guides everything

CILICANT was built on a simple idea—that protection is not passive, it's purposeful. Every material we develop, every partnership we form, and every improvement we make serves one mission: to preserve the efficacy of what heals.

As I look at the road ahead, I see immense opportunity in how packaging can contribute to safer, more sustainable healthcare. It's a journey that demands precision, empathy, and courage to think differently. At CILICANT, that is the journey we are proud to lead.

INTERVIEW

Learning agility is the name of the game

Sadhna Joglekar, Sr VP and Head of Global Drug Development, Novartis shares her views on the evolving opportunities for women in R&D and clinical development, the importance of mentorship and sponsorship in leadership journeys, and why adaptability and continuous learning are key to thriving in the age of digital transformation, in an interaction with **Kalyani Sharma**

You lead global drug development in a highly scientific and regulated environment. What do you see as the biggest opportunities for women in R&D and clinical development to step into strategic leadership roles? That's an interesting question. If you look at the evolution of the field, you'll notice that more and more women are stepping into strategic roles even in India. For instance, in Mauritius, around 40 per cent of the workforce in R&D is women. And even at leadership levels, more than 30 per cent of leaders are women.

We have a very conscious focus on diversity and inclusion. As part of that, we ensure that our emerging and senior leaders receive the training they need to take on executive roles. It's a concerted effort to help them move to that next level. Scientifically, women are as capable as anyone else, but what often makes the difference is mentorship and sponsorship—these are crucial in helping women navigate complex leadership paths.

Women are well represented in scientific and medical functions early in their careers, but fewer transition into senior decision-making positions. What structural or cultural shifts are needed within pharma organisations to bridge this leadership gap?

I like to explain this using what I call the "three Cs": Culture, Compensation, and Career.

When someone decides to join a company, they look at these three factors. First, Culture: does this company



A true leader must be strategic and think at the enterprise level. Once you claim that seat, it's crucial to have a vision—a North Star that gives direction to your team. Without that, people can easily move in different directions. A clear vision inspires alignment and ambition

care about its people? Second, Compensation: does it have an equitable pay structure that is gender-agnostic? And third, Career: does it provide equal opportunities for growth?

Many companies, including Novartis, have adopted what we call a lattice career approach instead of a ladder

career. Earlier, everyone thought only about the next promotion, but that model builds depth in one function and limits cross-functional mobility. With a lattice career, you move across functions early on, building breadth of experience that later enables you to grow into diverse

leadership roles.

I always advise young professionals to use their first ten years to gain experience across different pillars and functions. This broad exposure helps you leapfrog into leadership positions later. At Novartis, we also run several training programmes for women at various leadership levels, focusing on mentorship, sponsorship, and providing every opportunity to help them realise their potential.

Visibility and sponsorship are often critical for advancement in pharma leadership. What practical steps can women take to ensure their scientific contributions are recognised, and how can leaders like yourself foster sponsorship more intentionally?

The first step is to claim and earn your seat at the table. Having a seat is one thing, but why should people listen to you? It's not only about your scientific expertise—your voice must carry weight. That happens when you think beyond your function and wear an enterprise hat.

A true leader must be strategic and think at the enterprise level. Once you claim that seat, it's crucial to have a vision—a North Star that gives direction to your team. Without that, people can easily move in different directions. A clear vision inspires alignment and ambition.

I also believe in authenticity and courage. Women often hesitate to voice their opinions even when they have valuable insights. It's time to change that mindset. Your voice

carries as much weight as anyone else's. Traditionally, boardrooms have been male-dominated, but that's changing.

I always tell women to look up to successful female leaders—observe them, reach out to them if possible, learn about their journeys, and understand the challenges they faced. Their stories can be valuable blueprints for your own growth.

The future of pharma is being reshaped by digital technologies. What skills should women in pharma start building now to prepare for leadership in this changing landscape?

This isn't gender-specific—these skills are important for everyone. The world five years from now will look very different. As Mahatma Gandhi said, "*Change is the only constant.*" We need to anticipate where the world—and our industry—is heading and prepare ourselves accordingly.

Digital and artificial intelligence are here to stay. People often ask me whether AI will replace humans. My answer is no—AI won't replace humans, but humans who use AI will replace those who don't. We should see AI as augmenting intelligence rather than artificial intelligence. Use it to enhance decision-making, improve quality, and increase efficiency. Whether you're 20, 30, or 50, success today and tomorrow depends on one thing—learning agility. Keep learning, stay curious, and be open to new ideas. That's how you stay ahead of the curve.

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Beyond the machine: How intelligent packaging design elevates parenteral delivery

For sensitive parenteral products, the packaging is as critical as the drug itself. Uhlmann demonstrates how deep design competence turns packaging challenges into patient-centric solutions



The pharmaceutical market is witnessing unprecedented growth in parenteral drugs, especially as devices for self-administration like injector pens are becoming more popular among patients. This trend presents a critical challenge: how to safeguard these highly sensitive, often fragile products while ensuring they are perfectly safe and easy for both healthcare professionals and patients to handle. Manufacturers that want to stay successful in the market require sophisticated packaging design, where deep expertise is the most valuable asset.

This expertise is centralised in the Uhlmann Packaging Competence Center. Here, custom packaging concepts are prototyped, tested, and validated on production-level machinery, guaranteeing a seamless and efficient transition

from initial design to full-scale manufacturing.

The core challenge: A multifaceted design puzzle

Packaging for parenteral products must first guarantee product integrity. This involves securing fragile glass vials, pre-filled syringes, and complex pen devices against shock and vibration. But the challenges run far deeper. Material selection, for instance, is a critical balancing act. The clarity and formability of plastic materials like PET and PP are valuable, but materials must also perform flawlessly under challenging conditions, such as maintaining sterility during cold chain storage without becoming brittle.

Simultaneously, the industry is increasingly focused on sustainability, driving a shift toward recyclable mono-materials or

even fiber-based trays to reduce the environmental footprint.

In terms of product safety and cost-efficiency, the structural engineering of the package, particularly the inner tray, is a task of immense precision. A tray is not a simple holder; it is a custom-engineered component. Its design must accommodate everything from a single vial to a complex, multi-component kit containing a pen, several cartridges, and literature. The density and layout of these components impact not only material usage but also the stability of the final package and the efficiency of its assembly.

The solution: Integrating design and automation

Addressing these complexities requires a holistic approach that seamlessly integrates package design with machine

performance. The most effective solutions emerge when pharmaceutical manufacturers partner with packaging experts who possess both design acumen and deep engineering knowledge.

This expertise enables the development of highly flexible packaging lines capable of handling a vast range of materials and complex formats – from traditional blisters to innovative paper-based trays – without compromising speed or reliability. This capability is paired with a sharp focus on the end-user. Through collaborative design, features like intuitive thumb-push openings, clear perforations, and tamper-evident cartons become integral to the package, enhancing safety and accessibility for everyone.

To de-risk the process, solution providers such as

Uhlmann offer access to specialized competence centers. In these collaborative environments, custom packaging concepts can be prototyped, tested, and validated on production-level machinery, guaranteeing a seamless transition from an initial idea to full-scale manufacturing.

Conclusion: A partner in packaging excellence

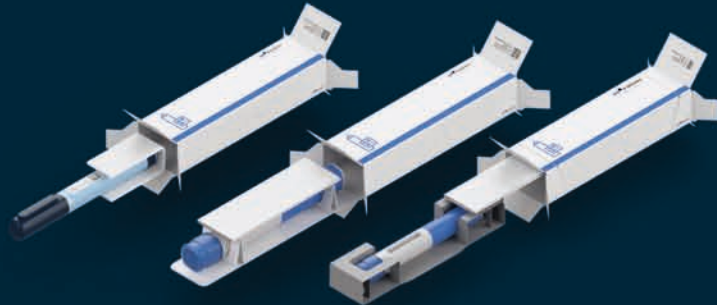
In the demanding parenteral sector, the packaging solution is a critical component of a product's success. The challenges are significant, but partners like Uhlmann demonstrate that by merging automation with profound design expertise, the industry can deliver solutions that are secure, efficient, and user-friendly, ultimately bringing vital medicines to patients safely and reliably.

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Discover a selection of our countless parenteral packaging solutions.

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Tray and trayless designs



New slim tray design



Custom combi packs



Upright or horizontal



Stackable and non-stackable



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Amount of packaged products



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parenteral packaging now

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- ◆ **Flexible cartoner**
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E-pharmacies: Fueling India's digital health revolution

Pradeep S Mehta, Secretary General, CUTS International, E-pharmacies are transforming India's healthcare landscape by making medicines and services more accessible, affordable, and efficient. Their rapid growth reflects a larger digital shift aligned with the country's vision for universal and inclusive healthcare

The healthcare sector in India has seen sweeping changes in the last few years. The sector has benefited greatly from quick technical breakthroughs, increasing investor interest, government concentration, and public awareness, even if the pandemic's effects are still being felt. Despite the long-standing dominance of traditional retail pharmacies in the market, e-pharmacies are becoming strong substitutes that are transforming the Indian healthcare sector. Valued at \$3.18 billion in 2024, the sector is projected to grow at a compound annual growth rate of 16.6 per cent, reaching \$12.7 billion by 2033. These are a case-in-point towards changing consumer behaviours and industry attitudes.

Bridging the accessibility gap

The World Health Organisation prescribes one pharmacy for every 2,000 people. The reality in India, particularly rural India, is one pharmacy for every 8,000 people. Geographic disparities in healthcare accessibility across Tier I, Tier II cities and rural areas are key challenges to overcome in India's goal of achieving Universal Health Coverage. Today, leveraging technology and access to large inventories from multiple stores, e-pharmacies are already serving more than 15,000 pin codes across India, ensuring access even in regions where physical pharmacies are scarce. By offering 24/7 availability through apps and websites, they bridge critical gaps in healthcare delivery, making medicines and consultations accessible round the clock.

Beyond this, at-home delivery is equally appreciated by senior citizens and those with mobility issues, as well as metro city dwellers with a



E-pharmacies are not just digital storefronts but catalysts of structural transformation in Indian healthcare. By bridging accessibility gaps, driving affordability, and aligning with government-led digital health initiatives, they are steadily becoming an integral part of the system

paucity of time. Larger inventories mean e-pharmacies carry more medicines than traditional retailers, helping consumers avoid multiple trips to different pharmacies in search of medicines.

Driving affordability

Efficiency in procurement and operation processes combined with reduced working capital and overhead costs ensure e-pharmacies can offer significant cost advantages to con-

sumers, with medicines being offered at 15 to 25 percent cheaper than traditional retailers. This ensures medicines, especially crucial, life-saving ones, become affordable for larger sections of society. It also reduces the financial burden on families dealing with long-term treatments.

E-pharmacy platforms have now evolved to provide a comprehensive and seamless healthcare experience that caters to larger medical re-

quirements beyond medicine delivery, like connecting with healthcare professionals for consultations, medical testing and diagnostics, and keeping track of prescription refills. Improved digital infrastructure and internet penetration owing to government initiatives like Digital India have empowered citizens in smaller towns and rural areas to access these services.

Building trust through regulation

While e-pharmacy platforms witness steady growth in users, some concerns surrounding quality and authenticity of medicines have been raised by the traditional retail community. However, e-pharmacy platforms are regulated by state drug regulators under the Drugs and Cosmetics Act, 1940, operating under the same licensing requirements as traditional pharmacies and can only dispense medicines against valid prescriptions through registered pharmacists. Meanwhile, the E-Pharmacy Draft Rules, 2018 are in the pipeline to be finalised by the central government.

Technology-enabled features like robust prescription validation, drug authentication, and end-to-end traceability make e-pharmacy safeguards often stronger than those in the offline sector. Centralised warehouses also enable better storage practices such as temperature control and cold chain compliance, offering regulators a chance to enforce higher and more uniform standards. The very nature of operation for these platforms creates a digital paper trail of prescriptions, bills and delivery details that make tracing and accountability easy and effortless.

Government e-healthcare initiatives like Ayushman Bharat Digital Mission and

eSanjeevani signal structural changes in healthcare policy. The rising popularity of e-pharmacy platforms is in line with the government's aim to digitise the sector for better accessibility, transparency, and efficiency in healthcare delivery.

Towards a collaborative future

The growth of e-pharmacy platforms need not come at the expense of traditional retailers. E-pharmacy platforms have the capacity to manage larger inventories with smaller working capital, thereby enabling traditional retailers to cater to a broader range of consumers with a larger margin. There are already examples of small pharmacies that expanded their reach nationwide by integrating with online platforms. Such hybrid models demonstrate that local chemists need not lose out; instead, they can use digital tools for inventory management, storage compliance, and last-mile delivery. Much like other sectors that evolved into omnichannel models, the future of pharma will likely see coexisting models: local retailers for certain products, branded chains for integrated stores, and online platforms for wider distribution.

E-pharmacies are not just digital storefronts but catalysts of structural transformation in Indian healthcare. By bridging accessibility gaps, driving affordability, and aligning with government-led digital health initiatives, they are steadily becoming an integral part of the system. When supported by robust regulations and collaborative models with traditional pharmacies, e-pharmacies have the potential to redefine healthcare delivery in India, making it more accessible, affordable, and accountable for every citizen.

INTERVIEW

Great ideas and innovation always come from startups

Sattvam Life Science is a company pioneering advancements in green chemistry, biomanufacturing and AI-driven process development. **Dr Pundalik Pednekar**, Founder and MD, Sattvam Life Science shares his insights on the company's journey, its innovation-led growth, and its mission to make Indian science a global benchmark for quality and responsibility, in conversation with **Swati Rana**

Can you share the thought behind the establishment of Sattvam Life Science and what inspired its foundation?

Sattvam Life Science was founded with a vision to build a science-driven, innovation-led pharma company rooted in integrity, quality, and sustainability — offering end-to-end solutions from drug substance to drug products. Our expertise spans advanced chemistry disciplines, including synthetic chemistry, biopharmaceuticals, nutraceuticals, and bioenzymatic catalyst-based chemistry. We also focus on developing continuous processes, such as flow chemistry, to reduce waste and carbon footprint.

After years of experience in the life sciences and specialty chemicals sector, I recognised a clear gap — the need for an agile Indian company focused on value creation through advanced chemistry and responsible manufacturing.

The idea behind Sattvam was not merely to produce pharmaceuticals, but to redefine how science can serve humanity — by integrating green chemistry, digital technology, and scalable innovation. “Sattvam,” derived from Sanskrit, symbolises purity, balance, and knowledge — the very principles that guide our organisation.

Great ideas and innovations often originate



from startups, and Sattvam embodies that spirit.

What are the key growth drivers for the company since its inception?

Our growth has been driven by three major pillars:

- Innovation at the core – focusing on process development, biotransformation, and technology-enabled manufacturing.
- Commitment to quality – aligning systems with global

standards such as WHO, USFDA, and EU-GMP.

- Customer-centric approach – building long-term partnerships and customized solutions rather than transactional engagements.

Additionally, our emphasis on cost-effective and sustainable manufacturing has made us competitive both in India and globally.

How does Sattvam differentiate itself in the Indian and global pharma

landscape?

Sattvam stands out for its fusion of scientific depth and operational excellence. We integrate chemical synthesis, biomanufacturing, and analytical science to develop high-value intermediates, APIs, and formulations.

Our differentiation lies in:

- Cultivating a research-first culture and adopting sustainability-driven change.
- Developing molecules not currently manufactured in India and reducing dependency on imports from China and other countries.
- Creating eco-efficient, high-yield processes.
- Building a strong foundation in intellectual property and regulatory compliance.

Globally, we aim to position Sattvam as a trusted partner for sustainable, high-quality pharmaceutical manufacturing.

Could you highlight any new therapeutic areas, technologies, or innovations in the company's pipeline?

We are currently developing Rifampicin and other anti-infective APIs, emphasising process optimisation and cost reduction for global markets. In parallel, our R&D team is exploring vitamin biomanufacturing from agro-waste such as rice bran and husk — aligning with India's BioE3 policy and circular economy principles.

We are also working on technology platforms for green chemistry, process

intensification, and AI-assisted analytical modeling to accelerate innovation and ensure quality by design.

What role does research and innovation play in Sattvam's growth strategy?

Research and innovation are at the heart of Sattvam's growth. Every initiative begins with scientific curiosity and is driven by innovation-led execution.

Our R&D team focuses on developing scalable, IP-compliant, and environmentally responsible processes that create long-term value. Innovation extends beyond products — into data analytics, digital quality management, and predictive maintenance — enabling us to operate smarter and more efficiently.

How is the company leveraging technology, data science, or AI to enhance product development and quality?

We are actively embedding data science and AI into process development and quality control.

By implementing digital twins and predictive analytics, we optimise reaction pathways, reduce variability, and improve yield. AI tools are also being explored for spectral data interpretation, stability prediction, and risk-based quality assurance.

Our goal is to create a digitally intelligent manufacturing ecosystem

that integrates chemistry, engineering, and data in real time.

How do you see the Indian life sciences and pharma sector evolving over the next decade?

India's life sciences sector is on the verge of transformation — transitioning from a generic manufacturing hub to a global innovation powerhouse. Over the next decade, we anticipate a strong shift toward biomanufacturing, complex APIs, and data-driven drug development.

Collaboration between academia, startups, and established players will be central to this evolution. Government initiatives such as the PLI schemes, Make-in-India, and the National Biopharma Mission will further strengthen India's position as a global leader in affordable healthcare innovation.

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What are some of the biggest challenges the industry faces today — regulatory, talent, or sustainability-related?

The industry faces several challenges:

- **Regulatory harmonisation** – aligning Indian quality systems with global standards.
- **Talent retention** – bridging the gap between academic knowledge and industrial application.
- **Sustainability pressures** – achieving ESG goals while

maintaining cost competitiveness.

At Sattvam, we tackle these challenges by investing in continuous training, adopting green chemistry, and maintaining transparent compliance frameworks.

In what ways does Sattvam contribute to India's position in global life sciences and healthcare innovation?

Sattvam contributes by building globally compliant manufacturing capabilities

and developing innovative chemistry solutions that reduce costs and environmental impact.

We collaborate with research institutions and technology partners to bridge lab-scale science with commercial-scale implementation.

Through our focus on API security, sustainable production, and intellectual property creation, we help strengthen India's role as a reliable and innovative life sciences hub.

Looking ahead, what is your long-term vision for Sattvam Life Science over the next five to ten years?

Our vision is to make Sattvam Life Science a globally recognised, innovation-led pharma company known for scientific excellence, sustainability, and trust.

Over the next decade, we aim to:

- Establish a state-of-the-art R&D and manufacturing campus with global regulatory approvals.
- Expand into biomanufacturing, green synthesis, and complex generics.
- Build partnerships that integrate India's scientific potential with global healthcare needs.

Ultimately, we aspire to make Sattvam synonymous with purity, innovation, and quality — true to the spirit of its name.

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Coding and FDCE: Redefining regulatory compliance in healthcare

Abhijeet Vaidya, Head of Data & AI Practice, Emids opines that as AI reshapes healthcare technology, regulatory compliance is shifting from rigid, rule-based systems to adaptive, intelligent frameworks. Concepts like Vibe Coding and FDCE are enabling this transformation

Regulatory compliance in healthcare and life sciences traditionally relied on rigid, rule-based systems, often treated as a checklist rather than a dynamic capability. With artificial intelligence reshaping how organisations design and deploy digital systems, compliance itself is undergoing a transformation.

Two emerging concepts such as Vibe Coding and Forward-Deployed Context Engineers (FDCE) are helping organisations shift from reactive oversight to proactive, context-aware compliance. But before diving into these ideas, it's important to understand how software development has evolved.

For decades, enterprise software followed a deterministic path, built around clearly defined business rules, workflows, and user requirements. In contrast, AI-driven development operates on probabilistic systems that learn from data and evolve over time. The difference is not just technical; it is philosophical.

In a traditional setup, or enterprise approach, engineers define exactly how the system should behave. In an AI-driven setup, however, engineers teach the system to learn from data and experience. For example, a nurse manually tracking patient cases represents the enterprise approach, while an AI model that predicts which patients are at risk of hospitalisation in the next 30 days reflects the data-driven mindset. Similarly, the enterprise approach might create a rule-based claims processing system that flags high-value claims, whereas an AI-driven system can detect subtle anomalies to identify potential fraud or waste.

This marks a clear shift not just in how software is built but



Whether in hospital accreditation under NABH, regulatory documentation for CDSCO, or data exchange initiatives under ABDM, the ability to build systems that are both empathetic and auditable will define leadership

also in how we think about building it. We are teaching systems how to learn, adapt and improve with experience.

Building on this shift, the concept of Vibe Coding extends engineering into the human realm. It focuses on creating software and AI systems that respond to tone, intent, and unstructured cues, essentially systems that can “read the room.” Instead of purely logical interactions, these

systems adapt to context, that means altering conversational tone, personalising recommendations based on subtle behavioural signals, or dynamically adjusting user interfaces. In short, Vibe Coding is about engineering empathy into technology.

Complementing this is the role of Forward-Deployed Context Engineers (FDCEs), domain-aware technologists embedded within business, clinical,

or operational teams who ensure that data products and AI models reflect the realities of workflows, semantics, and regulations. Their job is to translate the complex language of compliance such as FHIR resources, HEDIS metrics, and HIPAA rules in the U.S., or CDSCO and ABDM data standards in India into data pipelines and model logic. If Vibe Coding humanises technology, FDCEs operationalise it. Together, they ensure that systems are audit ready.

When these two converge, compliance transforms from a static control to an explainable process. Instead of adding audit trails later, FDCEs build systems that capture decision context automatically, while Vibe Coding reveals the human reasoning behind every action. Each model output, data source, and human input ties back to a policy reference, creating a living chain of evidence. The result is compliance that grows and adapts with the system.

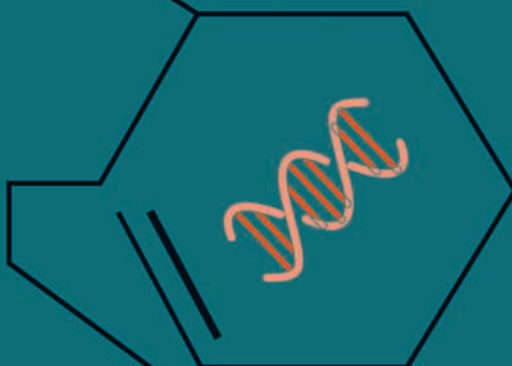
This combination delivers real, measurable outcomes in healthcare. Consider prior authorisation workflows in the US, where such models are already reshaping payer-provider interactions. A Vibe-coded interface can adjust the tone and detail of authorisation recommendations based on the urgency of a case, concise for critical care and comprehensive for elective procedures, while FDCE-built pipelines link each recommendation to claims history, clinical guidelines, and model versions. Regulators gain complete visibility into why a request was approved or denied, and clinicians receive contextual prompts that reduce resubmissions.

The same principle applies to quality measurement programs such as HEDIS, long es-

tablished in the US healthcare system. Patient reminders generated by a Vibe-coded outreach system can adapt tone based on past engagement and social determinants, while FDCEs ensure that every data point contributing to a numerator or denominator is documented and reproducible. In clinical decision support, model outputs expressed in plain language, supported by clear data lineage, help mitigate liability and build trust between compliance teams and clinicians.

These experiences from the US offer valuable insights for fast growing healthcare markets like India. They demonstrate that compliance is not about automation but about empathy and domain intelligence. When embedded through Vibe Coding and FDCE frameworks, compliance evolves into an active, self-learning capability. When a new reimbursement guideline or data privacy rule is introduced, agentic systems built on these principles can interpret the implications, map them across departments, update policies, and alert responsible teams, all without manual intervention.

For India's healthcare and life sciences ecosystem, these principles mark the next frontier. Whether in hospital accreditation under NABH, regulatory documentation for CDSCO, or data exchange initiatives under ABDM, the ability to build systems that are both empathetic and auditable will define leadership. As data volumes grow and global regulators demand greater transparency, the future of compliance will not be written in static rulebooks but in living systems that learn, adapt, and explain themselves, uniting the science of regulation with the art of human understanding.



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INTERVIEW

We help companies accelerate processes across manufacturing, QA, QC, R&D

Chandrachur Datta, Partner, Vector Consulting Group analyses the hidden costs of increasing unresolved deviations during production and how this operational fragility erodes regulatory trust, ultimately impacting profitability. In a free wheeling conversation with **Viveka Roychowdhury**, Datta also outlines some solutions that reduced error generation, speeded up incident investigation and the possible path ahead

To begin, could you explain why your organisation put together a report titled, 'From errors to excellence: A GMP-aligned approach to reducing incidents'? And why is this discussion around USFDA-regulated manufacturing plants and incident management important?

In USFDA-regulated pharma plants, every deviation or unexpected event during manufacturing must be documented in the Batch Manufacturing Record (BMR). These incidents may include variations in machine speed, deviations in temperature or humidity, or any operational error. Once an incident is logged, it cannot be ignored. The root cause must be identified, and corrective and preventive actions (CAPA) must be determined before the batch can be released.

The challenge is that the number of such incidents is high across many plants, which delays batch release. These delays affect inventory, working capital, supply reliability, and sometimes force companies to expedite production or increase changeovers. Our study focused on understanding why these incidents occur so frequently and how to reduce them, improving supply chain stability and plant performance.

If this problem has been known for some time, why has it persisted? Pharma

companies usually cite operator attrition and training gaps at the shop-floor level. Why hasn't the issue been resolved already?

You're right — the industry often attributes these incidents to operator mistakes, attrition, or insufficient training. As a result, the typical response has been to either train operators more or add additional checks and layers of supervision.

However, this leads to an ineffective "doer-checker" cycle. When more checks are added continuously, both operators and supervisors become overloaded. Operators must fill hundreds of BMR entries, often including redundant ones. Supervisors, responsible for multiple machines and lines, naturally prioritise only the most critical checks due to time constraints. As a result, checks aren't completed consistently, new errors arise, and more checks are added, creating a vicious cycle in which errors keep rising rather than reducing.

So, how do you simplify this and break the cycle? What solutions have worked in practice?

We worked at two levels — reducing error generation and speeding up incident investigation.

1. Reducing errors at the shop-floor level

- Simplified BMRs by removing redundant entries and ensuring only necessary fields remained.

- Reallocated some checks



from operators to the BMR team to avoid duplication and overload.

- Added visual cues in BMRs for critical entries (like total fields) so nothing is missed.

- Linear document flow so operators don't move back and forth between pages.

- Supervisor workload rationalisation — we scientifically mapped the number of machines and checks each supervisor can realistically handle in a shift.

2. Speeding up incident investigation

- A rapid response team deployed to investigate incidents within 15–30 minutes to capture real evidence — similar to first-response protocols.

- Standard investigation framework specifying lookback periods, roles, and timelines for different incident types.

- Priority management system

prevents teams from jumping to the newest incidents and abandoning older ones.

- Template-based investigations for recurring incident types reduced documentation time and prevented common errors.

Together, these actions reduced errors and dramatically sped up incident closure timelines.

How long did it take to implement these changes, and across how many teams or locations?

The most time-intensive phase was revising BMR documents and creating investigation templates, since multiple teams had to agree on the approach. Typically:

- -20 days to finalise principles and standard formats

- 1.5–2 months to revise BMRs and create templates (depending on plant size)

- Parallel handholding for teams as the system rolled out

Overall, it takes around three to four months. In one plant handling 400–500 SKUs, incident rates dropped from 30–35 a month to around 10–15 after implementation.

Can you share case examples or client names?

Where clients have formally approved, we publish detailed case studies on our website. Those are available for reference. For confidentiality reasons, we cannot name clients without permission.

Do companies engage you per

site or across their network?

Typically, companies engage us for their US business operations. We start with one plant to demonstrate results, and once proven, the approach is rolled out across other facilities.

Do such process changes align with regulatory expectations?

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The particle puzzle

Dr Ravikiran Allada, CEO, Alcoax outlines a scientific framework using advanced techniques, to systematically identify and control visible particles in injectables

Injectable medications, essential for the treatment of numerous medical conditions, demand the highest standards in formulation, manufacturing, and packaging. Among the various quality concerns, the presence of visible particles has consistently been one of the most critical issues. Historically, visible particles have accounted for more than 20 per cent of injectable product recalls⁽¹⁾, highlighting their significant impact on product quality and patient safety. These particles—whether originating from manufacturing processes, packaging ma-



terials, or even the formulation itself—pose a potential hazard to patients, as they can lead to embolism, blockage of blood vessels, or immune system reactions. As a result, regulatory agencies and pharmacopeia such as the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) have established standards to ensure the absence of visible particles in injectable drug products it requires 100 per cent of the product inspection. The particles are often detected during visual inspection, microscopic examination, or automated detection systems.

Controlling visible particles remains a major challenge in the pharma industry. Firstly, it is practically impossible to guarantee that products are entirely free from visible particles, even with robust product manufacturing control measures in place—hence, visual inspection and manual checks are still necessary. Secondly, there is no clear or quantitative definition of visible particles. For instance, the USP states that products should be "essentially free" from visible particles, while the EP uses the term "practically free". These qualitative definitions



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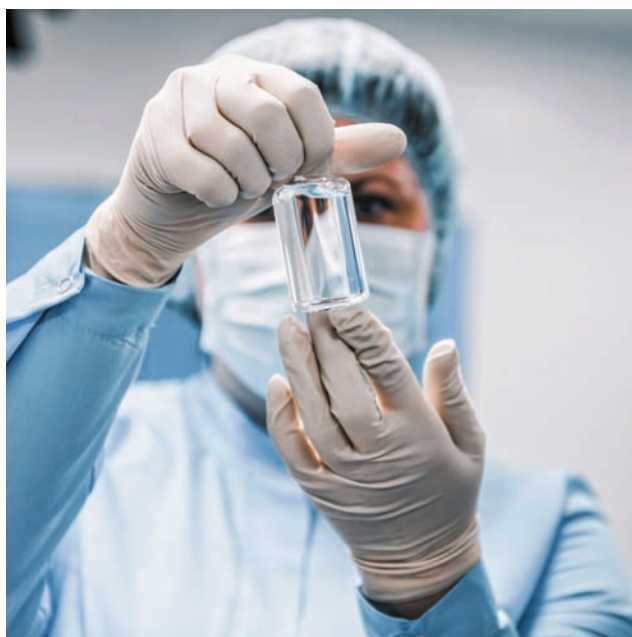
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are open to subjective interpretation and are not harmonised across pharmacopoeias. In contrast, sub-visible particles (SVPs) are well-defined and standardised, with specific limits on particle size and count, offering a much more consistent regulatory framework^[2,3].

The pharma industry continues to rely heavily on conventional visual inspection to ensure product compliance concerning visible particle (VP) risk. When visible particles are detected, it becomes crucial to identify their characteristics—such as type, appearance, chemical composition, and molecular structure—in order to determine and implement appropriate manufacturing or packaging controls based on their nature and origin. However, the identification and control of visible particles is far from straightforward. The wide variety of potential contaminants, along with the complexity of their detection and analysis, makes accurate identification a significant challenge.

This article aims to provide a scientific framework



for the identification and control of visible particles in injectable products. It highlights the methods, tools, and strategies that can be applied throughout the product lifecycle to address this critical quality concern. By adopting a structured, evidence-based approach, manufacturers can more effectively manage the risks associated with particulate contamination and safe-

guard patient safety. Additionally, the article discusses some of the latest technologies that can be leveraged to support a successful and efficient particle identification process.

Types of visible particles

According to USFDA guidance on visible particles & USP general chapter <788>, “Particulates refer to mobile,

undissolved particles other than gas bubbles that are unintentionally present in an injectable product”^[4,5]. Visible particles in injectable formulations can originate from a range of sources throughout the product lifecycle, and understanding their origin is critical for effective control. These particles are typically categorised as intrinsic, extrinsic, or inherent, based on their origin and relationship to the formulation and manufacturing process. Intrinsic particles are generated within the product itself, from manufacturing equipment, or through interaction with primary packaging materials—such as protein aggregates, precipitates, or fragments resulting from glass delamination or chemical incompatibility with rubber stoppers or tubing. Consider a scenario where a product batch is initially free of visible particles at the time of manufacture. However, over time, visible particles begin to appear during subsequent inspections. In such cases, these particles could be API precipitates, aggregates, or components generated through interactions

with primary packaging materials. This represents the most challenging type of intrinsic visible particle, as it may form during storage rather than being present initially—potentially leading to product recalls. Therefore, such risks should be thoroughly assessed during product development. Therefore, the timing of particle appearance becomes a critical piece of information during the investigation, as it can provide valuable insights into the origin and potential causes of the visible particle contamination. Extrinsic particles, by contrast, are foreign contaminants introduced from the manufacturing environment such as fibres. Inherent particles are those intentionally included in the formulation, such as microspheres or emulsions.

Refer to *Figure 1*—a fishbone diagram representing various possible sources of visible particles entering the injectable formulation. The table below summarises common particle types across these categories, highlighting their likely sources and typical visual characteristics.

TABLE 1: COMMON PARTICLE TYPES AND THEIR LIKELY SOURCES

Particle Type	Category	Common Source	Typical Appearance
Protein Aggregates	Intrinsic	Biologics; stress (agitation, freeze-thaw, pH shifts)	White, translucent, or opaque particles
Crystals/Precipitates	Intrinsic	Formulation instability; pH or temperature shifts	Crystalline, needle-like, or powdery
Silicon Oil Droplets	Intrinsic	Lubricated syringes or filling equipment	Clear, spherical, refractive droplets
Glass Delamination Fragments	Intrinsic	Poor-quality glass vials; chemical reaction	Thin, shiny, reflective flakes
Product–Packaging Interaction Particles	Intrinsic	Leachable or reactions with rubber stoppers/plastic components	Discoloured or irregular fragments
Fibers (Cellulose/Synthetic)	Extrinsic	Clothing, filters, packaging materials	Blue, Gray, or translucent fibres
Rubber Fragments	Extrinsic	Vial stoppers, syringe plungers	Black or Gray, irregular particles
Plastic Particles	Extrinsic	Tubing, seals, or plastic packaging degradation	Variable size, shape, and colour
Metal Particles	Extrinsic	Machinery, stainless steel needles	Silver, gray, reflective particles
Environmental Debris (Dust, Hair)	Extrinsic	Airborne contamination, poor cleanroom control	Variable
Particles from Raw Materials (APIs/Excipients)	Extrinsic	Insoluble residues, agglomerates, or poor filtration	White or coloured solid particles
Microsphere Aggregates	Inherent	Sustained-release injectable formulations	Aggregated or oversized particles
Emulsion Droplets (Coalesced)	Inherent	Instability in emulsion-based formulations	Visible oil droplets or globules

This classification helps guide root cause investigations, supports risk-based assessments, and informs the selection of appropriate analytical techniques. By systematically identifying and categorising visible particles, manufacturers can better address potential risks, ensure product quality, and maintain regulatory compliance.

A systematic approach to visible particles investigation

The primary objective of visible particle investigation is to identify the particles, understand their origin, and ultimately eliminate them. Achieving this requires a scientifically robust and methodical approach. This article outlines a basic framework for such a systematic investigation. However, the depth and nature of the analytical methods may vary depending on the specifics of each case.

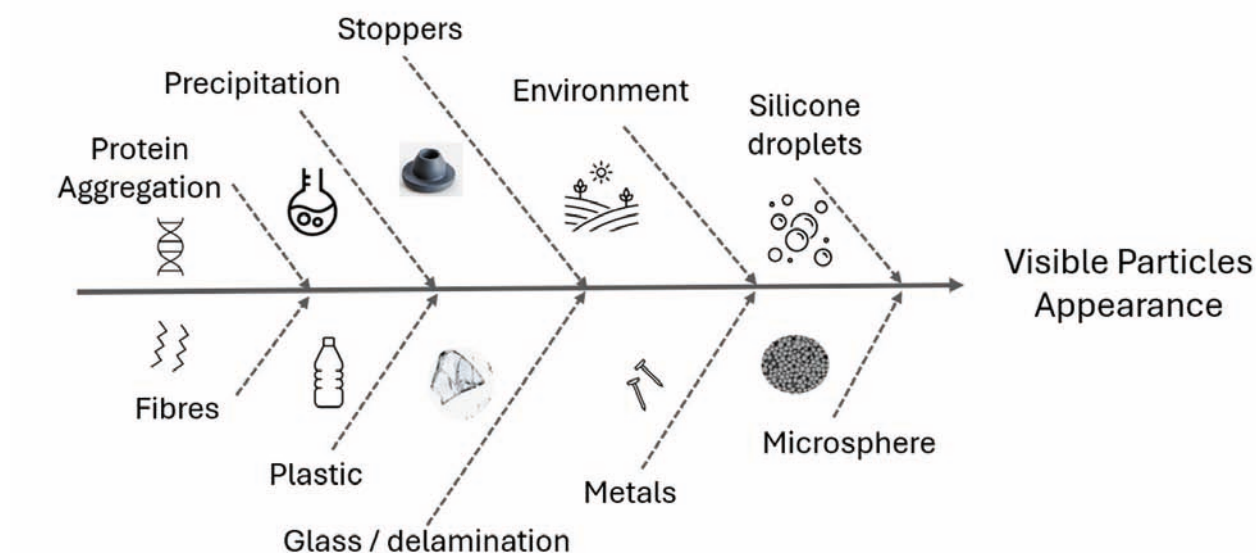


Figure 1: Fishbone Diagram representing key contributors of Visible Particles

At a broad level, three key steps are essential for effective control of visible particles:

1. Detection
2. Isolation
3. Identification

To ensure consistent and

reliable outcomes, organisations should establish dedicated expert teams to conduct investigations, analyse trends, and implement preventive measures. Such a structured approach will significantly aid in managing and minimising

visible particle-related issues.

Refer to *Figure 2* below for a schematic representation of the three-step process.

● **Particle detection:** Detection of visible particles typically occurs during visual inspection of the product.

Despite the use of trained and qualified visual inspectors, several factors can influence the likelihood of detection. There is no definitive lower detection limit, as the human eye generally detects particles in the range of 50 to 200 μm

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or larger. Detection by the naked eye is highly probabilistic— as particle size decreases, the likelihood of detection drops significantly. To maintain inspection reliability and consistency, organisations must ensure that visual inspectors are periodically trained and qualified. Adequate time should be allotted for each inspection to improve accuracy and reproducibility. Once visible particles are detected, the affected units or vials must be promptly segregated for further investigation.

● **Particle isolation:** Once a visible particle is detected, a critical next step for successful identification is its isolation from the surrounding matrix without compromising its integrity. This is especially important to ensure accurate characterisation and traceability. In real-world scenarios, most visible particles are extremely small—often less than 50 to 100 microns in size—which makes their isolation considerably more challenging. These tiny particles are frequently on the threshold of human visibility, and sometimes even trained inspectors may disagree on whether a given speck is truly a particle or merely an artifact. This ambiguity further highlights the importance of a precise and reliable isolation method. Filtration under a controlled environment is one of the most effective techniques for isolating such minute particles. Membrane filtration is generally the preferred approach, offering a gentle yet effective means of capturing and preserving the particle. The choice of filtration membrane is critical to the success of the isolation. If the particles are dark-coloured, standard white membrane filters typically provide good contrast for visibility and analysis. Conversely, when dealing with white or off-white particles, black polycarbonate membranes offer superior visual contrast, facilitating more reliable inspection and documentation.

To minimise contamina-

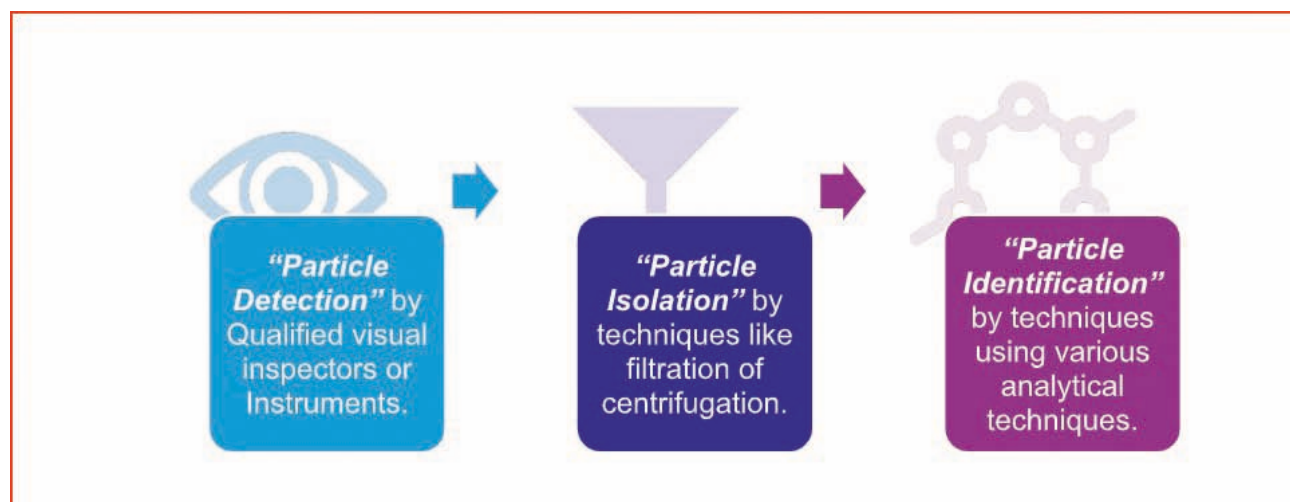


Figure 2: Schematic Representation of three step of particle investigation - detection, isolation and Identification of visible particles

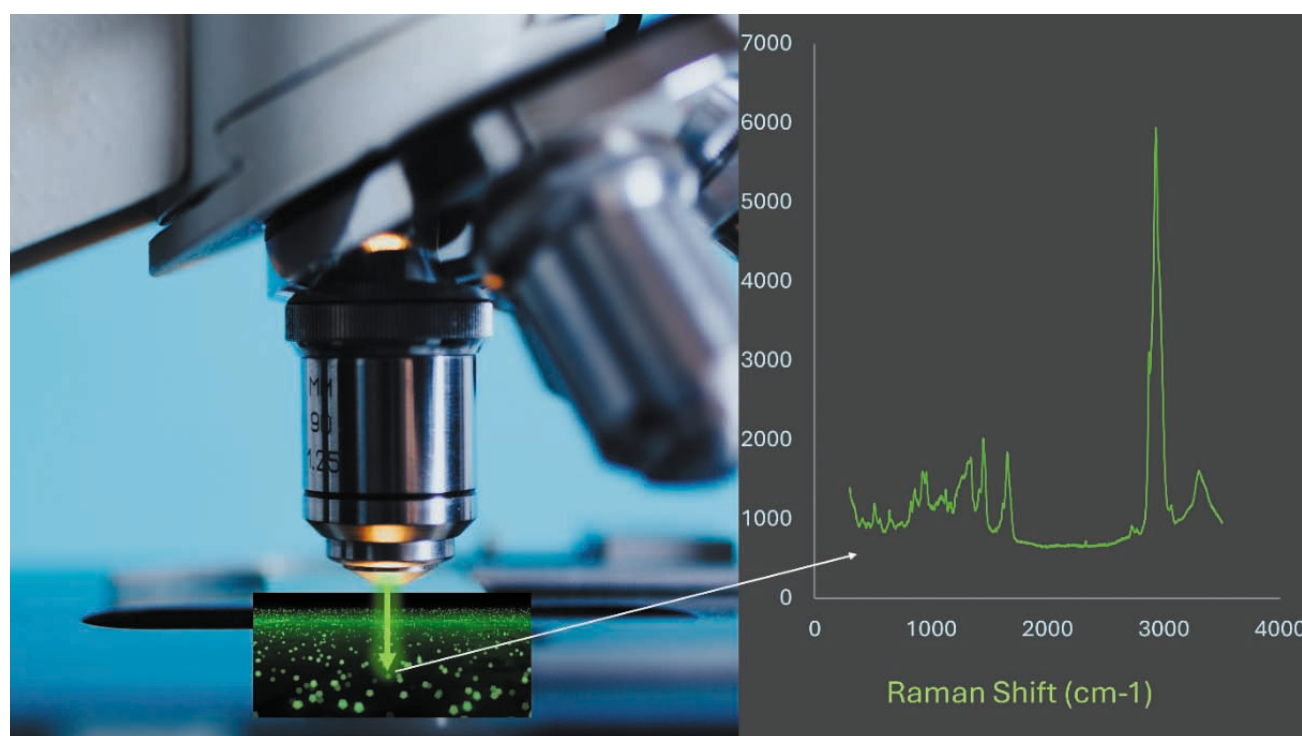


Figure 3: Representative microscopy and Raman spectrum of the particle under analysis

tion and avoid misidentification, all particle isolation procedures must be performed under particle-free conditions—ideally within a certified laminar airflow cabinet.

Particle identification: Particle identification represents the final and most critical step in any visible particle investigation. It is the ultimate objective, as successful identification enables correlation with the particle's origin and supports the implementation of effective control measures. Meaningful corrective and preventive actions (CAPA)

greatly depend on accurately determining both the identity and the source of the particle. A wide array of analytical techniques is available to support this endeavour. These methods can be applied individually or in combination, depending on the particle's composition, morphology, and the depth of information required.

In the pharma industry, Microscopy or Scanning Electron Microscopy (SEM) combined with Energy Dispersive X-ray Analysis (EDX or EDAX) is among the most used techniques for investi-

gating visible particles. This combination enables high-resolution imaging of particle surfaces along with basic elemental analysis. The results are typically interpreted by comparing them with known reference materials or spectral libraries.

While SEM-EDX is especially useful for identifying inorganic contaminants based on particle morphology and elemental content, it has notable limitations. It does not provide molecular-level information, making it inadequate for identifying organic sub-

stances. As a result, investigations relying solely on SEM-EDX may remain incomplete and are often closed based on assumptions rather than definitive evidence. This can lead to recurring issues due to unresolved root causes.

Therefore, a more comprehensive and systematic approach is essential for accurate particle identification. The following sections highlight commonly used techniques, outlining their principles, strengths, and typical applications. In addition, we discussed advanced

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New

microscopy-spectroscopy hybrid tools that support more holistic and accurate identification of visible particles.

Light microscopic observation

Optical/Light microscopy is a fundamental and widely accessible technique used in the initial stages of visible particle investigation. It employs visible light and a system of optical lenses to magnify and visualise particles, typically at magnifications up to 1000x. Although it does not provide detailed chemical information, it offers valuable visual insights into the physical characteristics of particles.

This technique enables analysts to examine key morphological features such as shape, size, colour, texture, and surface characteristics. Through light microscopy, particles can be broadly categorised based on their physical appearance—for example, whether they are crystalline, fibrous, amorphous, metallic-looking, or proteinaceous in nature. These distinctions can offer critical preliminary clues about the possible origin or nature of the contaminant.

While light microscopy alone cannot confirm the chemical identity of a particle, it serves as a strategic screening tool. The morphological observations obtained during this stage help guide the selection of subsequent, more advanced analytical techniques (e.g., SEM-EDX, FTIR, Raman spectroscopy). For instance, a shiny, opaque particle may suggest a metallic contaminant, leading to prioritisation of elemental analysis methods, while a translucent, irregular mass might indicate a biological or proteinaceous material, directing the investigation toward spectroscopic methods. In summary, light microscopy plays a vital triaging role in visible particle analysis. It offers a quick, non-destructive, and informative first look, helping to classify particles and define the analytical roadmap. Though limited in its ability to provide definitive identification, it is an essential step in establishing

the investigative direction and determining the most appropriate follow-up techniques.

SEM-EDAX analysis

SEM provides high-resolution imaging that reveals detailed surface morphology, including texture, cracks, layering, and porosity—offering insights well beyond the capabilities of conventional light microscopy. These morphological details help distinguish between process-related contaminants, such as metal fragments or glass particles, and formulation-derived materials like protein aggregates or crystallised excipients.

EDAX enhances this analysis by providing elemental composition through X-ray emission, enabling the detection of metals, non-metals, and trace elements. SEM-EDAX is particularly effective in identifying metal particles, glass fragments, sand particles, and other inorganic contaminants due to their distinct elemental profiles. However, the technique has limitations in detecting trace levels and lighter elements (e.g., carbon, hydrogen, nitrogen, oxygen) and does not provide molecular-level information for organic compounds.

Maintaining a comprehensive library of all product-contact materials can greatly aid in identifying or ruling out potential sources. SEM-EDAX is especially useful for identifying extrinsic inorganic and metallic particles. Where feasible, and if the particle quantity is sufficient, Inductively Coupled Plasma Mass Spectrometry (ICP-MS) can provide orthogonal, highly accurate elemental composition data.

Confocal Raman spectroscopy

Confocal Raman Microscopy integrates Raman spectroscopy with optical microscopy to deliver high-resolution, non-destructive chemical analysis and imaging. By collecting Raman spectra with precise spatial resolution—down to spot sizes as small as 1 micron—it allows detailed mapping of molecular composition in microscopic

areas. Alongside producing sharp optical images, this technique captures Raman spectra from targeted regions on a particle, providing rich molecular information that acts as a chemical fingerprint. Refer to Figure 3 for a representative microscopy and Raman spectrum of the particle under analysis.

By comparing these spectra to reference libraries or standards, analysts can accurately determine the particle's molecular makeup, whether it's organic, polymeric, crystalline, or a complex mixture. This combination of detailed imaging and localised chemical analysis makes confocal Raman microscopy a powerful tool for identifying unknown particles, addressing contamination problems, and supporting thorough root cause investigations. Its ability to differentiate chemically similar materials, even within layered or mixed structures, offers insights often beyond the reach of conventional elemental analysis methods.

If visible particles are suspected to be protein or peptide aggregates, Raman spectroscopy is a valuable tool for detection and confirmation. It measures molecular vibrations, providing a unique spectral fingerprint. Key regions—amide I (1600–1700 cm⁻¹) and amide II (1500–1600 cm⁻¹)—reflect secondary structures like α -helices, β -sheets, and random coils. Aggregation often increases β -sheet content, leading to noticeable shifts or intensity changes in these bands. Being non-destructive and label-free, Raman spectroscopy is ideal for monitoring protein stability, evaluating formulation effects, and analysing visible or subvisible particles. Combined with imaging in Confocal Raman Microscopy, it also enables spatial localisation and detailed chemical characterisation of aggregates within a sample.

Laser Direct Infrared Imaging (LDIR) technique

Laser Direct Infrared Imaging (LDIR) combines imaging with infrared spectroscopy to

provide fast, accurate, and automated particle analysis. It uses a quantum cascade laser (QCL) to generate mid-infrared light, which scans the sample surface and collects IR spectra at each pixel. This creates chemical images that show both the shape and size of particles and their chemical composition. LDIR can analyse particles as small as 10 microns with little to no sample prep. It is especially effective for identifying organic materials like excipients, polymers, residual actives, and formulation components. By matching particle spectra to IR libraries, the system can reliably identify materials based on their molecular "fingerprints." A key benefit of LDIR is its ability to distinguish chemically different particles that may look similar, which is often challenging in contamination studies. The method is non-destructive, requires no staining or labelling, and provides both qualitative and quantitative data. Thanks to its automation and speed, LDIR is ideal for routine visible particle investigations. It offers faster analysis than traditional FTIR microscopy while maintaining high chemical specificity, making it an excellent complement to Raman microscopy or SEM-EDAX, especially for identifying organic or polymer-based contaminants.

In addition to the techniques mentioned earlier, several advanced spectroscopic methods can be coupled with microscopy for detailed chemical and molecular analysis at the microscale. Techniques like AFM-IR, XPS with imaging, and ToF-SIMS use highly focused beams to analyse small areas, making them well-suited for identifying both visible and sub-visible particles. Each method offers distinct benefits—such as surface sensitivity, molecular characterisation, or elemental mapping—and can be chosen based on the specific requirements of the analysis.

Conclusion

A structured, systematic approach to visible particle iden-

tification in injectable formulations is vital for establishing comprehensive control and ensuring patient safety. This article has outlined a risk-based strategy across three key stages—detection, isolation, and identification—highlighting the importance of each step in effectively controlling visible particle contamination.

While traditional techniques such as light microscopy and SEM-EDX remain valuable for initial assessment and elemental analysis, the integration of advanced microscopy-enabled spectroscopic techniques—including Confocal Raman Microscopy and LDIR—has significantly improved the ability to accurately identify and characterise particles. These tools provide rapid, non-destructive chemical profiling with high specificity and spatial resolution, making them essential in modern visible particle investigations.

Although there remains a need for faster and more precise methods, future advancements in spectroscopy and instrumentation may further enhance identification capabilities. For now, a scientific and systematic approach using currently available techniques allows for robust investigation and effective control, supporting the prevention of visible particle contamination in injectable products.

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India's pharma packaging: Evolving from cost to care

India's pharma packaging industry is undergoing a profound transformation, evolving from a cost-driven supplier ecosystem into a global hub of innovation that blends technology, sustainability, and patient-centered design. As the nation's role as the "pharmacy of the world" expands beyond drug manufacturing, packaging is emerging as a strategic enabler of quality, safety, and trust. From bio-based polymers and recyclable laminates to IoT-enabled smart packs and personalised delivery systems, the next generation of pharma packaging is redefining how medicines are protected, authenticated, and experienced. Packaging experts and leaders explain how driven by regulatory rigour, digital integration, and environmental responsibility, packaging is no longer just about securing medicines, they're shaping the very future of healthcare delivery

From cost efficiency to global innovation

Sekhar Babu Puli, Associate VP - Packaging Development, MSN Laboratories

India's pharma packaging industry is undergoing a decisive evolution, transitioning from a cost-efficient supplier base to a globally integrated innovation ecosystem. The shift is driven by converging global forces: stricter regulatory compliance, sustainability imperatives, digitisation, and a patient-centered healthcare model.

For years, India has been the "pharmacy of the world," supplying affordable medicines to over 200 countries. Now, the same narrative is extending into the packaging domain. Indian packaging manufacturers are no longer focusing merely on containment; they are moving toward value creation through functionality, safety, and sustainability.

The adoption of global GMP, US FDA, and EMA-compliant systems is no longer optional. Companies are investing in ISO Class 7 and 8 cleanroom facilities,



tamper-evident solutions, advanced barrier coatings, and 100 per cent inspection systems. There is also a visible focus on data-integrated packaging lines—from serialisation to aggregation—to strengthen the authenticity and traceability of every pack shipped globally.

At the same time, the global push for environmentally responsible packaging is strongly influencing local strategies. India's leading converters are now experimenting with bio-based polymers, recyclable mono-material laminates, and low-carbon film structures to align with multinational sustainability roadmaps. This shift marks a transformation from a linear to a circular packaging economy.

Looking ahead, several emerging technologies are set to transform the pharma packaging landscape in the next five years. The next five years will be transformative,

and technology will redefine the landscape. India's pharma packaging sector will be shaped by a convergence of digital technologies, material science, and functional innovation.

● **Smart and connected packaging:** With the rise of data-driven healthcare, smart packaging will move from pilot to mainstream. QR codes, NFC tags, and blockchain-linked identifiers will enable real-time authentication, patient engagement, and remote adherence monitoring. Such solutions will also strengthen the supply chain against counterfeiting—a persistent challenge in global distribution.

● **Sustainable and high-performance materials:** The industry is rapidly shifting toward bio-based and recyclable materials without compromising barrier properties. Collaboration between polymer scientists, converters,

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and pharma formulation teams is yielding new structures that are both eco-efficient and regulatory compliant. The focus is clear: reduce carbon footprint while safeguarding product efficacy. However, this is going to take a little longer for implementation.

● **Digital printing and on-demand customisation:** As clinical trials and personalised therapies grow, digital printing is emerging as a game-changer. It allows variable data, short runs, and localised content for multiple markets—all while reducing waste and inventory.

This flexibility is especially critical for export-oriented Indian manufacturers handling diverse regional regulations.

● **Combination product and device-integrated packaging:** With the rise of biologics and self-injectable therapies, packaging is becoming an enabler of drug delivery. The next generation of packs will integrate mechanical and electronic functionalities—from pre-filled syringes and auto-injectors to dual-chamber systems and connected inhalers. This trend demands a deeper understanding of material compatibility, usability engineering, and mechanical

precision.

One of the most significant paradigm shifts is the early collaboration between pharma companies and packaging providers. Historically, packaging was addressed late in the product lifecycle—often post-formulation. Today, it is being integrated at Phase II or even pre-clinical development, especially for complex molecules and combination products.

This early involvement allows cross-functional teams—comprising formulation scientists, device engineers, regulatory specialists, and packaging technologists—to co-develop optimal contain-

ment and delivery systems. Such collaboration helps mitigate risks related to extractables and leachables, container closure integrity, and user experience at the earliest stages.

Leading packaging companies in India are also evolving into development partners rather than suppliers. Many have established packaging innovation centers and simulation labs, enabling joint design, rapid prototyping, and performance validation. This collaborative, data-driven approach is helping accelerate time-to-market while maintaining global quality standards.

India's pharma packaging

landscape is at an inflection point. The country's strengths—scalable manufacturing, regulatory agility, and technical talent—are now being complemented by innovation, digitalisation, and sustainability consciousness.

The future belongs to those who can integrate science, sustainability, and smart technology into every layer of the packaging value chain. As the global pharma industry moves toward patient-centered, data-driven healthcare, India is not just keeping pace—it is preparing to lead the transformation from a supplier nation to a strategic innovation partner.

Packaging: A platform for progress

Raheel Shah, Director, BDR Pharmaceuticals

In an era where healthcare is being reimagined every day, it's time we look beyond molecules and formulations to another silent yet powerful force shaping the future of medicine—the way we pack, protect, and present our drugs. Once seen merely as a safeguard, this aspect of pharma operations has evolved into a critical driver of innovation, sustainability, and patient engagement.

At its core, the purpose has always been to preserve integrity—ensuring every dose that leaves the lab reaches the patient with its efficacy intact. But as healthcare becomes more digital, decentralised, and design-led, the role of the outer layer has expanded far beyond protection. It now carries the burden of trust, traceability, and transparency—values that define the very future of our industry.

Tomorrow's solutions will do more than hold medicines—they will hold information. Technologies like RFID, NFC, and digital barcoding are already transforming how drugs are tracked and veri-



fied. Smart formats embedded with sensors or scannable identifiers enable real-time monitoring, ensuring authenticity at every point in the

supply chain.

Counterfeiting continues to be one of the most pressing challenges for global healthcare. As India's pharma ex-

ports extend to new markets, digital traceability will become essential—not just for compliance, but for confidence. A connected ecosystem ensures every vial, blister, or carton carries a verifiable digital footprint, reducing risk, improving accountability, and empowering patients.

However, innovation cannot come at the cost of the planet. Environmental impact is now central to every design decision. Sustainability must evolve from a box to tick to a pillar of design thinking. At BDR, we see innovation as a balance between safety, scalability, and sustainability—a triad that demands new materials, smarter technologies, and more conscious choices.

We are transitioning towards recyclable laminates, solvent-free adhesives, and reduced secondary layers—all without compromising product stability.

The journey to net-zero must begin with such incremental shifts, because environmental responsibility has become intrinsic to pharmaceutical ethics.

As pharma becomes more human-centric, empathy too must shape our design principles. Accessibility, usability, and inclusivity are taking centre stage. From easy-open packs for the elderly to tactile markings for the visually impaired and clearer dosage instructions, the focus is steadily moving from compliance to comfort. When we create designs that are intuitive and inclusive, we uphold the dignity of care itself. That, I believe, is where the true heart of healthcare lies. Packaging of a medicine is no longer a silent protector—it has become a strategic enabler at the crossroads of technology, sustainability, and humanity.

At BDR Pharmaceuticals, this belief is embedded in our philosophy: innovation with purpose. The future belongs to companies that view packaging not as an afterthought, but as a platform for progress. Because ultimately, every box, bottle, and blister is far more than a container—it's a carrier of trust, responsibility, and hope.

Packaging for biologics and complex therapies

Swati Mukherjee, AVP & Head, Formulation & Packaging R&D, Kusum Healthcare

The pharma packaging landscape is evolving rapidly, driven by technological advancements, sustainability demands, and the need for patient-centric solutions. As biologics, complex formulations, and personalised therapies become more prevalent, packaging innovations are playing a critical role in ensuring product integrity, patient compliance, and safety.

To meet these growing demands, packaging strategies are being approached from multiple perspectives:

● **Technology-wise:** Smart packaging solutions with digital integration are being implemented to enhance patient compliance, improve convenience, and enable traceability throughout the supply chain.



● **Material-wise:** Sustainability is at the core of material choices, with a strong focus on maximising the use of biodegradable and recyclable materials. Packaging design now emphasises minimal material usage to reduce waste, and the adoption of plant-based polymers has the potential to be a game-changer for future packaging solutions.

● **Design-wise:** Packaging is increasingly tailored to meet the needs of specific patient groups, including geriatric and pediatric populations. Personalised packaging options help ensure easy product recognition, simplified handling, convenient font choices, appropriate pack sizes, and suitable delivery formats for improved

usability.

Additionally, pharma packaging innovations are being expanded to support biologics, complex formulations, and personalised therapies. Anti-counterfeiting measures, such as authentication code verification, are being strengthened to safeguard potent and lifesaving biologics, ensuring both patient safety and product integrity. The convergence of smart technology, sustainable materials, and patient-centric design is redefining pharma packaging. By integrating these innovations, the industry can provide safer, more efficient, and environmentally responsible solutions that meet the evolving needs of patients and healthcare providers alike.

Emerging technology in pharma packaging

B Ganesh, General Manager, Packaging, Inventia Healthcare

India's pharma packaging ecosystem is rapidly evolving to align with global shifts toward sustainability, advanced technology, and enhanced patient safety. The country's strong generics market and expanding biopharma sector are propelling demand for innovative and compliant packaging solutions. Understanding the key trends and innovations in this space is essential to grasp how the industry is adapting to meet future challenges.

Key levers shaping the ecosystem are as follows:

Shift toward sustainable and eco-friendly packaging solutions

Global sustainability mandates are pushing India's packaging industry away from traditional plastics and toward more eco-friendly materials.

● **Biodegradable options:** The adoption of plant-based and other biodegradable polymers is on the rise to minimise long-term environmental impact.



Biodegradable secondary and tertiary packaging materials are being used for transporting products from the manufacturer to the end consumer without affecting product quality.

● **Packaging material optimisation:** Companies are focusing on minimalist designs and lightweighting to reduce material consumption. The QdB approach is essential to design and

arrive at an optimum packaging solution for any given drug product; this is very important and cannot be overlooked.

● **Waste management:** Packaging material suppliers and drug product manufacturers are initiating pilot take-back programmes to secure traceable, recycled feedstock.

Adoption of smart packaging

To combat counterfeiting and improve patient engagement, the ecosystem is embracing smart packaging technologies.

● **Traceability and anti-counterfeiting:** The use of unique identifiers like QR codes and RFID tags is becoming essential for product authenticity. This is critical as up to 40 per cent of medicines in emerging markets are estimated to be counterfeit.

● **Patient adherence monitoring:** Smart caps and integrated sensors track medication usage, sending reminders to patients and data to healthcare providers.

Increased focus on patient-centric design

Packaging is becoming more than a protective container and is being designed with the patient's needs and safety in mind.

● **Child-resistant and senior-friendly features:** New designs incorporate dual-purpose features that are difficult for children to open but easy for seniors.

● **Enhanced dosing and convenience:** Innovations include single-unit dose packaging, ready-to-administer pre-filled syringes, and packaging with calendar features to help patients track their medication.

● **Clearer communication:** Efforts are being made to provide better dosage instructions, multilingual information, and interactive digital interfaces for patient education.

With this evolution underway, the next question naturally arises: which emerging technologies will drive the future of pharma packaging in the coming



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years? So, several emerging technologies are set to transform the pharma packaging landscape in the next five years:

Smart packaging technologies

One of the most significant trends is the adoption of smart packaging. These solutions increase patient engagement and adherence to medication regimens, crucial factors in treatment outcomes. Smart blisters and bottles with embedded sensors can track dosage and provide reminders via smartphone apps, while relaying adherence data back to healthcare providers for real-time adjustments. The integration of Near Field Communication (NFC) and the Internet of Things (IoT) is expected to become mainstream, offering new ways to interact with patients and gather data.

Sustainability in pharma packaging

Sustainability remains a major focus across industries. Biodegradable and recyclable

materials are becoming more prevalent, with companies increasingly opting for plant-based plastics and recycled materials. There is also a push to minimise packaging layers and optimise designs to reduce material usage without compromising product integrity or safety.

Enhanced safety features

With increasing medication complexity, packaging safety features are more crucial than ever. Tamper-evident and child-resistant designs, holographic images, and color-shifting inks help combat counterfeiting, making it easier to verify product authenticity.

Serialisation and traceability

Tightening global regulations emphasise serialisation and traceability. Unique identifiers compliant with global standards like the US Drug Supply Chain Security Act (DSCSA) enable product tracking, efficient recall management, and prevention of illegal trade.

Automation and digital integration

Automation increases efficiency and reduces human error. AI-enabled systems manage filling, sealing, labeling, and packing with precision, while digital integration allows real-time monitoring of packaging operations and quality control.

As these technologies gain traction, pharma companies are also rethinking how they collaborate with packaging providers to fully leverage these innovations from the earliest stages of product development. Pharma companies and packaging providers are increasingly collaborating earlier in the product development cycle to tackle challenges in patient-centric design, sustainability, and regulatory compliance. This shift positions packaging providers as strategic partners and innovation advisors rather than late-stage vendors.

Key areas of early collaboration

Patient-centric innovation

● **Medical devices:** Early collaboration ensures the concurrent design of drug delivery devices and packaging for ease of use, particularly for complex or at-home self-administration.

● **Accessibility and usability:** Human-factors engineering and prototype testing with patient groups improve ease of opening, labeling clarity, and usability for vulnerable populations.

● **Compliance packaging:** Customised, patient-specific designs, such as calendarised blister packs or personalised pouches, support medication adherence.

Sustainability

● **Material innovation:** Packaging providers are engaged in R&D to develop sustainable, drug-compatible materials that meet regulatory standards, including lighter, mono-material designs and reusable or recyclable packaging.

● **Full lifecycle planning:** Early collaboration allows for circular economy principles in design, including responsible

sourcing, recyclability, and post-consumer waste management.

Supply chain security and digitisation

● **Smart packaging integration:** Digital features like RFID, NFC, and QR codes are integrated early, enabling real-time tracking, anti-counterfeiting, and patient verification of authenticity.

● **Blockchain-enhanced traceability:** Blockchain creates secure, tamper-proof records of the drug journey, improving supply chain transparency and regulatory compliance.

India's pharma packaging ecosystem is evolving rapidly, driven by sustainability, patient-centricity and digital innovation. Emerging technologies and early collaboration between pharma companies and packaging providers are creating safer, smarter and more efficient packaging solutions. Together, these developments promise a more reliable, eco-friendly and patient-focused future for the pharma industry.

Technology, sustainability, and patient-centric design

Dhananjay M Chaudhari, DGM – Packaging Development (Formulations), Indoco Remedies

Pharma packaging in India has witnessed major advancements, driven primarily by the integration of technology and the development of sustainable materials. While all three pillars—materials, design, and technology—are undergoing transformation, technology-led smart packaging and eco-friendly materials are leading the way in shaping the industry's future. Some notable examples include:

Technological innovation: Smart packaging

● The adoption of digital and smart solutions, such as RFID tags, NFC labels, and humidity sensors, is rapidly gaining traction in India's pharma sector.

● Serialisation and track-and-trace systems enhance supply chain security, enabling dose-level authentication and anti-



counterfeiting measures, which are critical for regulatory compliance and export markets.

Materials: Sustainability takes priority

● There is a strong push toward biodegradable materials, post-consumer recycled (PCR) plastics, and rPET rigid containers. Tracking and tracing of plastic loads at various stages are increasingly influenced by regulatory mandates and consumer demand for greener options.

● Biodegradable and reusable packaging solutions not only reduce environmental waste but also support pharma brands' sustainability reputation.

● Market leaders are investing in local and global collaborations to develop high-barrier films suitable for biologics, pre-filled syringes, and cold-chain

packaging for vaccines and personalised therapies.

Design: Patient-focused and adaptive solutions

● Child-resistant and senior-friendly designs are now combined with user-centric features such as adaptive closures, pre-filled syringes with silicon-oil-free plungers, and micro-dosing devices.

● Flexible formats—pouches, bags, blisters—designed for e-pharmacy and home delivery are seeing rapid growth, with digital integration supporting patient adherence and convenience.

Building on these foundational pillars—technology, materials, and design—pharmaceutical packaging has seen significant advances specifically for biologics, complex formulations, and personalised

therapies. Pharma packaging for biologics, complex formulations, and personalised therapies has undergone significant innovation to address stability, safety, patient convenience, and regulatory demands.

Innovations for biologics packaging

- Biologics are highly sensitive to temperature, oxygen, and container interactions. Cyclic olefin polymers (COP) and fluoropolymers are increasingly preferred for vials, syringes, and cartridges, offering protection from extractables and mitigating protein degradation risks associated with conventional plastics and glass.
- Devices for self-administration, such as wearable injectors and smart auto-injectors, utilise COP for break resistance and stability while integrating lubricant-free technologies and film-laminated rubber to reduce contamination and extractables.
- Ready-to-use (RTU) containers, prefilled syringes,

and freeze-resistant designs ensure efficacy for biologics requiring cryogenic storage or long dosing intervals.

Solutions for complex formulations

- Moisture- and oxygen-sensitive drugs rely on desiccant packaging and modified atmosphere packaging to extend stability.
- Advanced barrier systems and antimicrobial or ultraviolet additives reduce contamination and degradation from external factors.
- Container closure integrity and compatibility between components—plungers, stoppers, liners—are engineered specifically for complex drugs, preventing auto-injector malfunctions, particulate generation, and silicone migration.

Personalised therapy packaging

- Customised dosing packaging, such as unit-dose blister packs and smart pill dispensers, tailors drug delivery to individual patient regimens

and genetic profiles.

- Patient-centric designs incorporate ergonomic features, user-friendly mechanisms, and QR codes for educational and support resources.
- Smart packaging solutions assist patients, for example diabetics, with dose reminders and adherence support.

To meet these evolving needs, research and development in pharma packaging is advancing rapidly, combining technology, materials, and human factors to address the unique challenges of new therapies.

Advances in pharma packaging R&D

Pharma packaging research and development is evolving rapidly to meet the challenges posed by biologics, specialty medicines, and personalised therapies. The new landscape demands solutions that enhance product protection, maintain package integrity, facilitate traceability, support complex administration, and uphold sustainability standards without compromising

drug quality.

Personalisation and patient-centric solutions

- As therapies become increasingly individualised, packaging designs are tailored for specific patient demographics, with tactile indicators, easy-open features, and custom-dosed packs produced via digital or 3D printing.
- Such personalised packaging not only supports patients with unique adherence needs but also improves user experience for seniors and individuals with disabilities.

Advanced protective designs for novel therapies

- Protecting fragile biologics and cell/gene therapies requires packaging with advanced barrier properties.
- New multilayer films, specialty coatings, vacuum systems, and dual-chamber syringes ensure stability by controlling exposure to light, moisture, and oxygen. Shock-absorbing materials are increasingly integrated to main-

tain integrity during transport and storage.

Finally, smart and connected packaging is bridging the gap between product protection and patient engagement, offering real-time data and digital integration.

Smart and connected packaging

- Smart packaging, including embedded sensors, RFID tags, and intelligent labels, is being widely adopted to support patient adherence, enable real-time tracking of storage conditions, and collect dosing data.
- These technologies connect packaging to healthcare providers through digital ecosystems, allowing treatment plans to be adjusted based on usage insights.

Overall, pharma packaging R&D in India is leveraging a multidisciplinary toolkit—combining material science, digital technology, automation, and human factor engineering—to ensure product safety and efficacy in a rapidly evolving therapeutic landscape worldwide.

Shifting to smart and sustainable packaging

Nikhil Sahu, Sr Group Leader – Packaging Development (R&D), Knovea Pharmaceuticals

The future of pharma packaging in India is shifting from simply protecting medicine to providing active, smart safety solutions while focusing on sustainability. To maintain its global status, India's pharma packaging must now balance strict international regulations with domestic priorities, such as improving medicine accessibility and combating the extensive threat of counterfeiting.

To address these demands, innovation in pharma packaging is emerging across three key pillars—Materials, Design, and Technology—with the most impactful changes happening where design intersects with technology.

Where innovation is coming from

Innovation in pharma packag-



ing focuses on three areas: Materials, Design, and Technology. While material science is evolving, the application of digital technology to traditional packaging formats is driving the most immediate and transformative change in India's pharma landscape.

The anti-counterfeit and compliance revolution

The primary driver for new technology is safety, particularly compliance with serialisation (Track & Trace), which enables medicine tracking and authentication to fight counterfeits. Packaging is evolving from a simple container into a data-enabled tool.

- **Anti-counterfeiting:** QR codes, NFC (Near Field Communication) tags, tamper-evident stickers, tamper-evident

printing, and holograms are integrated into primary and secondary packaging. These features allow instant, verifiable authentication by distributors and consumers, safeguarding the supply chain.

- **Patient adherence (digital compliance):** Intelligent caps, electronic blisters, and NFC-enabled labels track dose removal, send reminders via SMS or app, and provide data to healthcare providers, aiding chronic disease management.

- **Cold chain monitoring:** For biologics and vaccines, packaging now includes Time-Temperature Indicators (TTIs) and real-time smart sensors to ensure product integrity from production to patient, alerting personnel to any temperature excursions.

Design: Patient-centricity and accessibility

Design innovation focuses on improving the user experience, especially for India's large elderly population and diverse linguistic groups.

● **Child-resistant, senior-friendly (CRSF) designs:** Complex closures prevent accidental ingestion by children while remaining easy for elderly patients with limited dexterity to open.

● **Compliance packaging (day-of-week packs):** Unit-dose or wallet-style blister packs marked with days of the week simplify complex regimens, boosting adherence.

● **Accessibility:** Braille printing and scannable codes that launch audio instructions support visually impaired patients and regional language requirements.

Materials: The drive for sustainability

Material innovation in pharma packaging is increasingly influenced by global environmental mandates and India's Extended Producer Responsibility (EPR) regulations.

● **High-barrier recyclable materials:** Glass and aluminium remain key, but non-recyclable PVC/aluminium blister packs are being replaced by high-barrier monomaterials like specialised PET or PP films, which offer protection while being fully recyclable.

● **Bio-based and PCR content:** Companies are exploring Post-Consumer Recycled (PCR) content for secondary packaging and bio-based polymers (plant-derived plastics) to reduce the carbon footprint.

As the industry embraces smart, sustainable, and patient-centric packaging, these innovations become even more critical for high-value, highly sensitive drugs such as biologics and personalised therapies, where stability, safety, and adherence are paramount. The pharma industry is handling increasingly complex and sensitive drugs,

including biologics and personalised therapies. These high-value medicines have transformed packaging from a passive container into an active participant in treatment, making packaging innovation critical for three main reasons:

- Product stability – maintaining drug efficacy
- Anti-counterfeiting – combating fake drugs
- Patient adherence – ensuring proper usage

The primary objective

● **Protecting sensitive molecules:** Many modern drugs, including biologics and complex formulations, are extremely sensitive. Because their effectiveness can be destroyed by light, oxygen, moisture, and temperature changes, protecting these

fragile molecules is absolutely critical.

● **Enhanced barrier technologies:** High-performance barrier films (e.g., ACLAR) and surface-treated vials prevent chemical interactions, minimise leachables, and block moisture and oxygen ingress.

● **Ultra-cold chain:** Certain cell and gene therapies require cryogenic or ultra-low temperatures (-80°C). Specialised secondary and tertiary cold-chain shippers, advanced insulation, and phase-change materials maintain integrity during global transport.

● **Ready-to-use (RTU) formats:** Prefilled syringes, cartridges, and auto-injectors reduce dosing errors, contamination, and support patient self-administration.

Smart and digital packaging

The most significant innovation for high-value drugs is the use of smart packaging—integrating digital intelligence directly into the container.

● **Real-time condition monitoring:** IoT-enabled sensors track temperature, humidity, and shock, alerting supply chain managers or pharmacists instantly if a breach occurs.

● **Authentication and traceability:** QR codes, NFC/RFID tags, and blockchain verification link directly to a product's provenance, allowing patients and pharmacies to

confirm authenticity via smartphones.

● **Patient engagement and adherence:** Smart dispensers track dose removal, send programmable reminders, and share adherence data securely with healthcare providers. QR codes can link to instructional videos, e-leaflets, or virtual consultation portals.

Packaging for personalised medicine and personalised therapies, which are often single-batch and patient-specific (e.g., CAR-T cell therapy), present unique logistical and packaging demands.

● **Small-batch, on-demand packaging:** Flexible, modular systems and digital printing allow rapid, compliant labelling of patient-specific doses and unique identifiers.

● **Unique labeling and instructions:** Detailed patient-specific instructions reduce errors in complex regimens.

● **Focus on delivery devices:** Auto-injectors are being designed for precision, reliability, and user-friendliness, even for highly viscous or delicate formulations.

These innovations in personalised packaging are mirrored in R&D, which now focuses on active, smart, and patient-centric solutions. Pharma packaging research has shifted from simple containment to dynamic, smart components that actively protect highly sensitive drugs (biologics, vaccines, and personalised medicines). R&D is

focused on three main areas:

The rise of 'Active' materials

● **Oxygen and moisture scavengers:** Materials absorb trace oxygen or humidity to maintain long-term stability.

● **Advanced barrier films:** Next-generation polymers and coatings create nearly impenetrable barriers to light and vapor, extending shelf life.

Digital intelligence and IoT integration

● **IoT-enabled sensors:** Monitor temperature, light, and orientation in real time, communicating violations to manufacturers and patients.

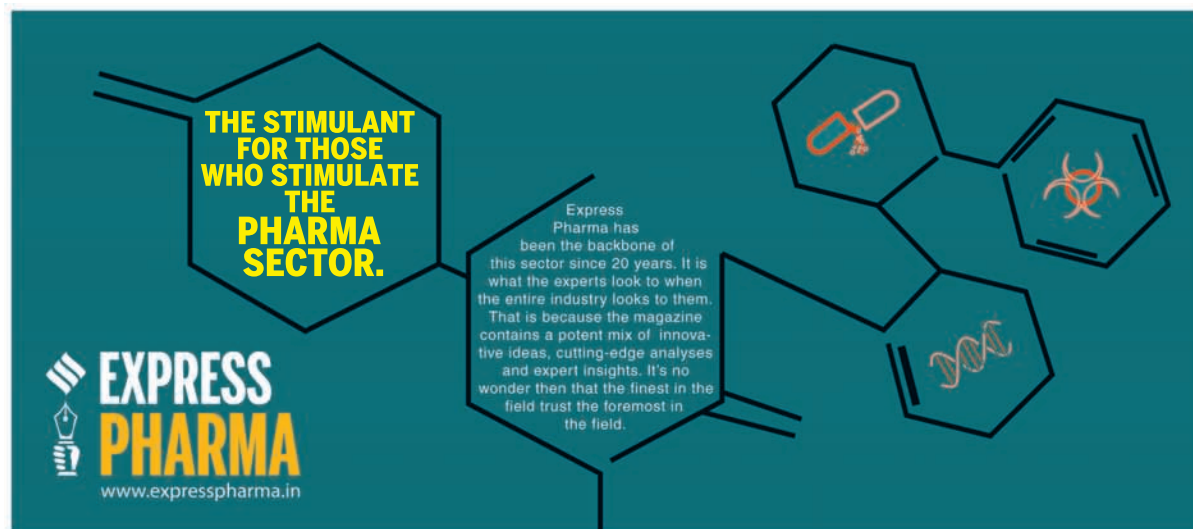
● **Anti-counterfeiting:** Sophisticated serialisation, blockchain-linked QR codes, and tamper-evident features verify authenticity throughout the supply chain.

Enhancing patient engagement and adherence

● **Smart adherence systems:** Track dose removal, send reminders, and boost compliance.

● **Intuitive designs:** Simplify complex self-injection or administration steps, reducing patient errors.

In short, pharma packaging R&D today is about connectivity, visibility, and guaranteed efficacy, transforming packaging from a passive container into a critical link between the factory and the patient.



The invisible threat: Why packaging inks are the next major recall risk for pharma

Jatin Takkar, Head – Product Safety & Regulatory, Siegwirk India writes that packaging is emerging as a potential source of contamination due to unsafe ink chemistries. With global standards evolving, the industry must shift from reactive compliance to a proactive 'Safe by Design' approach that ensures packaging inks are as safe as the medicines they guard

For decades, the food and pharma industries have relied on packaging to be the final, infallible guardian of its products. Yet, high-profile contamination events and evolving global standards have exposed a critical truth: the protector, if not meticulously controlled, can become the source of profound risk. Achieving true compliance and securing consumer safety demands that the industry moves beyond simply ticking regulatory boxes to embrace a proactive, "Safe by Design" philosophy that starts with the chemistry of packaging inks.

The fundamental expectation of pharma packaging, be it a blister foil, a folding carton, or a label, is to protect the Active Pharmaceutical Ingredient (API) from external factors like moisture, light, and microbial ingress. Packaging is basically the barrier against the outside world.

However, the raw materials used in packaging materials, particularly printing inks, represent a significant, often unmonitored contamination pathway. The chemicals from the inks, applied to the outer layer, can migrate into the drug itself, compromising patient safety.

The Indian ink industry, especially in the absence of explicit, mandatory pharma-specific guidelines for packaging inks, has historically deployed several controversial chemicals. These include:

- **Toluene:** A common solvent, Toluene is classified as a Carcinogenic, Mutagenic, or Reprotoxic (CMR) Category 2 substance. While the Food Safety and Standards Authority of India (FSSAI) and the Bureau of Indian Standards (BIS) have banned its use in food packaging

inks, its prevalence elsewhere poses a critical cross-contamination risk that contradicts fundamental food and drug safety principles.

- **Mineral oils (MOAH/MOSH):** Components of mineral oils, specifically the aromatic hydrocarbons (MOAH), are considered potential genotoxic carcinogens that have been widely documented to migrate from packaging (especially recycled board) into products. The use of mineral oil-based inks undermines the principle of providing a safe packaging material.

- **Benzophenone and photoinitiators:** These compounds are essential for UV-curing inks, but their unreacted residues are highly prone to migration. Benzophenone, in particular, has repeatedly haunted the pharma industry, resulting in issues due to its discovery in packaging component where it can permeate the material and contaminate the product itself.

These are only the most recognised threats. The future of packaging safety is already under threat from numerous other chemicals, including:

- **PFAS (Per- and polyfluoroalkyl substances):** Often used for grease resistance, these "forever chemicals" are facing global bans due to extreme persistence and health concerns.

- **Synthetic dyes:** Many synthetic dyes contain aromatic amines, which are linked to carcinogenicity and mutagenicity, posing a quiet but severe risk when used in primary or secondary packaging.

The cost of non-compliance

Packaging safety is no longer just a technical issue; it is a business imperative that impacts:



● Consumer safety and trust:

The ultimate failure is the patient/customer-level impact. High-profile incidents, such as the Sartan contamination (where N-nitrosamine carcinogens were found in certain blood pressure tablets, leading to massive global recalls) and the tragic Diethylene Glycol (DEG) contamination in Indian-made cough syrups, obliterate consumer trust and permanently scar brands and nations.

- **Perceived safety:** Even the fear of contamination can destroy consumer confidence overnight, especially when international scrutiny is involved.

- **Indian exports and global image:** When a product is recalled globally, it severely restricts international market access, damaging India's image as a reliable global pharmacy and threatening its export economy.

Pharma industry needs to understand what is safe packaging inks

Given the absence of a specific mandate, the pharma industry must proactively define its requirements for packaging safety. True safety begins with understanding the core concept of migration-optimised inks.

A migration-optimised ink is

far more than just "Toluene-free ink". It is a solution "Safe by Design," meaning every single component, from solvents, binders and pigments to photoinitiators and additives, has been carefully selected and assessed to minimise the risk of chemical transfer into the drug.

Key considerations for the pharma industry must include:

- 1. Strict raw material selection:** The supplier must adhere to a positive list approach, where only substances explicitly evaluated for their migration limits are used, following the highest global standards.

- 2. Mitigation of non-intentionally added substances (NIAS):** NIAS are chemical compounds that have not been intentionally added to the packaging component but may be present as impurities, reaction by-products, or degradation products. A truly safe ink supplier must have stringent quality control and supply chain transparency to identify and mitigate NIAS formation.

- 3. Debunking marketing gimmicks:** The industry should not be misled by simple marketing claims like "Toluene-free inks" or "mineral oil-free inks." The replacement of just one hazardous chemical with an unverified or less-controlled alternative often results in "regrettable substitution," where the replacement chemical poses a new, equally dangerous, or even unknown risk. Safety is about the careful selection of all raw materials, not the mere replacement of one.

Addressing the regulatory gaps

The pharma sector, unlike the food industry, lacks specific, dedicated guidelines for printing inks used on its packaging. This

regulatory absence creates a dangerous scenario: pharma companies, whose core expertise lies in drug formulation and manufacturing, are inadvertently placed in the role of packaging and ink safety experts - a field where they inherently lack deep knowledge.

The closest concept often adopted by the Pharma Industry as a best practice is the Food Grade Ink concept, which in the Indian context, translates to the BIS Standard – IS 15495. While adopting IS 15495 is a crucial first step for domestic compliance, it is fundamentally insufficient for global export markets.

For companies dealing with exports, particularly in highly regulated markets like the EU and the US, a much higher degree of sensitivity and care is required. These global markets demand adherence to global standards that rigorously consider the chemical migration aspects. Therefore, companies must adopt globally benchmarked standards.

Securing the future of pharma

The path to safeguarding the pharma supply chain runs directly through the chemistry of its packaging. The days of treating packaging as a commodity are over. Pharma companies must recognise the inherent risks associated with printing inks and elevate their standards to global best practices immediately. This vigilance requires strong, knowledgeable partners who not only possess the correct know-how and expertise in migration concepts but also deeply understand the complex, fragmented regulatory landscape and, critically, operate with complete transparency.

INNOVATION MADE IN INDIA

As the world closes its doors and builds walls, India can chart its own course by leading the next wave of affordable, accessible pharma innovation. This feature, first in a three-part series, examines India's opportunity to drive progress in global healthcare through science, scale and purpose

By Lakshmipriya Nair



When India innovates, the world benefits. And we've seen this proven time and again. Take the Mars Orbiter Mission (MOM), for instance. With just Rs450 crore, India reached Mars on its very first attempt. A notable feat that showed what's possible with home-grown, fearless innovation.

In fact, there are examples where even popular culture has taken note. In the Netflix series Space Force, there's an episode where the US military learns of an Indian rocket launch and scrambles to find out whether there has been a leak of information. Later, when it's revealed that India simply built its own technology, a character concludes,

"So India was just... smarter." This captures a growing global realisation that India is now a nation capable of world-class innovation.

India's pharma story too has several such examples. During the HIV crisis, Indian pharma made life-saving drugs affordable, reducing the cost from over \$10,000 to under \$80 a year. During the COVID-19 pandemic, India didn't just protect its own citizens, it became one of the world's largest vaccine suppliers, with indigenous vaccines like Covaxin holding its ground with global ones.

But such stories shouldn't remain exceptions; they must become the norm. And, that calls for a clear, collective strategy, one that unites sci-

ence, policy and industry.

Today, it's no longer a choice but an imperative. As the world closes its doors and innovation becomes increasingly inaccessible, India must build the bridges. And, if we invest in research, nurture talent, and create an ecosystem where innovation is not by chance, but by design, we have a clear opportunity to lead. Why? Let's examine the global scenario to understand.

The India advantage

According to the recently released Cytiva Global Biopharma Index, global biopharma revenues rose eight per cent in 2024 and are expected to grow nearly 10 per cent annually through 2029. Yet, nearly half of com-

panies missed their revenue and profit targets. While there is innovation, it is not translating into business success. Thus, the world's biopharma sector is in a flux. The index highlights the need for a robust ecosystem that will thrive on policy, people, digital readiness, manufacturing agility and sustainability.

And, this is where India has a clear advantage because it checks most of these boxes. India rose five places in Cytiva's 2025 rankings, to become one of the top 10 biopharma ecosystems globally, ahead of France, Canada and Australia. The report links this rise to three things: a deep generics base, rising R&D investment and rapid digital adoption.

It states that India "punches above its income weight." In simple words, we're doing more with less, and doing it well.

The numbers support this finding. India's bio-economy crossed \$165.7 billion in 2024, as per the India BioEconomy Report 2024. It contributes more than four per cent of GDP and has been growing at a CAGR of nearly 18 per cent over four years.

Moreover, India's strength in generics and vaccine manufacturing is formidable. Together, these signal that India must position itself for innovation-led growth.

And, here are some of the key 'windows' India can step through, opportunities can drive growth, both at home



Global collaborations offer access to infrastructure, talent, investment, risk sharing, new markets, the sharing of best practices, and the establishment of global standards

Prashant Khadayat
Director – Lifesciences Consulting & Research, GlobalData



We are going through both, the promise and a paradox. Tremendous advances like next-gen sequencing and AI on one hand, but fundamental questions about the quality and speed of our trials on the other

Dr Mahesh Bhalgat
Group CEO & MD, Veeda Lifesciences



We have done a great job of creating 4,000 biotech startups at the bottom of the pyramid, now we need to bridge the middle gap

Dr Anand Anandkumar
Co-founder & CEO, Bugworks



If we can figure out how to address the Indian market in terms of cost, regulation and patient access, the rest of the world becomes easier

Jogin Desai
CEO, Ecosystem Research

and globally.

Upping the value game

There has been a growing realisation that India can no longer be just a manufacturing hub. We cannot wait for innovation to happen elsewhere and then scale it. We have to originate it. We cannot compete on cost alone.

Fortuitously, industry leaders are already signaling this shift through investments in R&D, global partnerships and manufacturing upgrades.

For instance, Serum Institute is building capabilities in mRNA and next-generation vaccines. Sun Pharma, Lupin and Dr Reddy's are investing in novel therapies and digital platforms. To cite a recent example, in the second quarter

of this financial year, reportedly Sun Pharma's US sales of innovative medicines surpassed its generics sales for the first time.

Leverage manufacturing at global scale

India's manufacturing strength is robust with proven capabilities in generics, vaccines and bulk APIs. Now, India can play a leadership role in global supply-chains as an innovation partner, with strategic measures.

In pharma and biotech this means shifting from mere "cost competitiveness" to "make what is new, better and globally competitive". This includes novel biologics, gene/cell therapies, advanced devices, digital therapeutics.

This also aligns with the path outlined in the BioEconomy Report 2024 report which states, "India's vision for the bioeconomy is rooted in innovation-led growth, sustainable development, and inclusive economic progress. The country aims to become a global hub for bio-manufacturing, backed by strong R&D infrastructure, cutting-edge technologies, and a skilled scientific workforce. The focus is on creating a resilient industrial ecosystem that promotes the development and commercialisation of new biotech products, while unlocking opportunities in both urban and rural regions. With an ambitious target of achieving a \$300 billion bioeconomy by 2030, India also seeks to

lead globally in bio-pharma, including vaccines, diagnostics, and therapeutics. This strategy directly contributes to the broader goals of India@2047, emphasising sustainability, economic self-reliance, and green growth."

However, it means not just more firms, but more complex manufacturing, more biotech startups, deeper upstream work so that global pharma, med-tech and diagnostics players can look to India, not just for cost benefits but for co-innovation.

Tackling global health challenges

India's large population, digital public infrastructure, price sensitive market and famed ingenuity also make it a great

choice for high-impact solutions at low cost. From diagnostics to drug delivery, India can build for itself and export to global markets, especially those with similar constraints.

India is also positioned to do global good in key areas like neglected diseases, affordable biologics or access-driven models. The convergence of science, manufacturing, access and digital gives India a unique advantage, particularly when global geopolitics, tariffs, supply-chain fragility and rising cost pressures are accentuating the need for diversified, resilient innovation hubs.

Pathways to progress

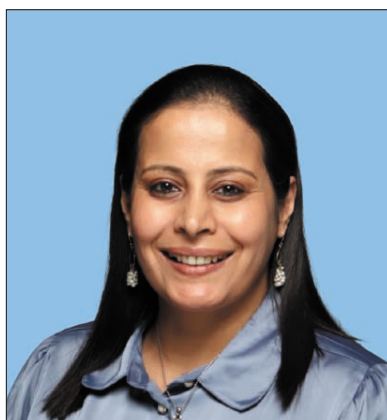
However, as Prashant Khadate, Director - Life-



India has great talent, but industry and academia need to understand each other's requirements. That's how an ecosystem matures

Murali Ramachandra

CEO,
Aurigene Oncology



The opportunity lies in creating an India ecosystem that allows the industry to pivot back, to build here, test here and partner here

Kavitha Iyer Rodrigues

Founder & CEO,
Zumutor Biologics



It's not enough to have one or two success stories, we need hundreds of them. And that requires investment at scale and a willingness to take risks

Dr Taslimarif Saiyed

CEO & Director,
Centre for Cellular and Molecular
Platforms (C-CAMP)



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

Srinath Venkatesh

MD - India & South Asia,
Thermo Fisher Scientific

sciences Consulting & Research, GlobalData, explains, India's pathway to becoming a global innovation partner will require systemic reform and stronger collaboration.

He elaborates, "For India to establish itself as a global partner in innovation, the country needs to focus on continuous regulatory reforms, collaboration between industry and academia, and improvements in innovation infrastructure, access to funding, and incentives. India has been making progress in these areas; however, there is still a long way to go from an innovation perspective. Furthermore, concerted efforts from both the government and industry could significantly advance India's innovation ambitions. In addition, India must enhance the quality of research in local academia and attract top Indian research talent from around the world to leverage their expertise on a much larger scale."

He adds that China's experience offers valuable lessons. Over the past decade, China implemented sweeping reforms from streamlined drug approvals to pricing and reimbursement incentives. These measures have propelled it into a major innovation-led pharma hub. The creation of high-quality innovation clusters further accelerated commercialisation and global integration.

China moved from a 'me-too' model to a global innovator in under a decade. If India can couple its scale and science talent with policy consistency and infrastructure, we can do the same, perhaps faster, opines Khadyate.

He states, "Global collaborations offer access to infrastructure, talent, investment, risk sharing, new markets, the sharing of best practices, and the establishment of global standards. Additionally, these collaborations can accelerate the overall innovation cycle, from execution to successful outcomes."

India's strength lies in its ability to build inclusive innovation, not innovation for the few, but for the many. But its innovation story is still being written. In its labs, startups and policies. The ecosystem is maturing and global partners are looking to collaborate. The time to build that bridge is now

A recent panel discussion hosted at *Express Pharma's* Bengaluru Pharma Summit also offered some great insights on similar lines. Dr Mahesh Bhalgat, Group CEO & MD, Veeda Lifesciences, who was the moderator for this session, shared that we are going through both the promise and a paradox. On one hand there's a huge amount of advances like next-gen sequencing, AI, data. On the other hand, there are still basic questions we need to address: how well are our trials designed, are they getting faster, are they getting leaner?

A sentiment that captures where India stands today, a point of inflection. Other panelists also offer great inputs on why India needs a scalable innovation ecosystem.

Dr Anand Anandkumar, Co-founder and CEO, Bugworks points out that while we have done a great job of creating 4,000 biotech startups at the bottom of the pyramid, we haven't been able to move up. We need to bridge that middle gap and create an ecosystem that can take companies from seed to scale, from Rs 50 lakh to \$200 million.

That "missing middle", the stage between seed and scale-up, is where India's next breakthrough stories will be written.

He also notes that India must chart its own model of innovation. He says, "We will never be China and we don't need to be." But if we use AI and tech smartly, we can cre-

ate our own model. India's stack is damn good, we put a billion people on a vaccine database. Let's build on that.

Jogin Desai, CEO, Eyestem Research, reinforces this thinking and says that if we can figure out how to address the Indian market in terms of cost, regulation, and patient access, the rest of the world becomes easier. India is the right place to build affordable, scalable innovation.

Murali Ramachandra, CEO, Aurigene Oncology stresses the need for tighter industry-academia linkages since talent and collaboration remain at the heart of the ecosystem's evolution. He highlighted that India has great talent, but industry and academia needs to understand each other's requirements. That's how an ecosystem matures.

During the discussion, the message was reiterated several times that innovation isn't just about capital or infrastructure, but about meaningful connections.

Kavitha Iyer Rodrigues, Founder & CEO, Zumutor Biologics is a strong advocate for decisive action. She believes that the time to act and play is now. Drawing from her organisation's US-first model, she says that the opportunity lies in creating an India ecosystem that allows the industry to pivot back, to build here, test here and partner here.

She asserts that India's innovation ecosystem can and must become more self-sustaining. A place where discov-

eries can be born and built locally, before expanding globally.

The policy push

And policy will be the real key to building such an ecosystem. Fortunately, the government has taken some crucial steps in this direction with initiatives like the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) and the RDI Fund. These programmes seek to drive research-led growth in India. PRIP, with an outlay of Rs 5000 crore, aims to build world-class R&D infrastructure, set up Centres of Excellence at NIPERs, and promote strong collaboration between industry and academia.

Yet, policy must go beyond funding. To truly unlock India's potential, we need faster regulatory clearances, flexible clinical trial frameworks, strong IP protection, and incentives that reward innovation. The focus should be on creating an environment where new ideas can move quickly from lab to market.

Building on this point of view, Dr Taslimarif Saiyed, CEO and Director, Centre for Cellular and Molecular Platforms (C-CAMP), opines that the right funding mechanisms are crucial. He emphasises that it's not enough to have one or two success stories. We need hundreds of them. And that requires investment at scale and a willingness to take risks.

He adds that recent policy moves could catalyse that

growth if executed with vision and speed. Schemes like PRIP and RDI can be game changers. If implemented well, they can fund not just seed ideas but also scale-up innovation.

Partnerships that build

The industry and government are also coming together in other ways to strengthen India's innovation foundation.

In an earlier interview with *Express Pharma*, Srinath Venkatesh, MD - India & South Asia, Thermo Fisher Scientific, points to Thermo Fisher's partnership with Startup India under DPIIT, called the BioVerse Challenge as an example of how this collaboration is taking shape.

The endeavour is to identify and support 500 startups across medtech, biopharma, biophysics, and proteomics. "We will mentor about 400 startups offline, and 100 will be brought into our Customer Experience Center (CEC) and Bioprocessing Design Center (BDC) in Genome Valley, Hyderabad, for hands-on support," he explains.

This model, where global players help nurture India's startups, can also make innovation scalable and sustainable.

Inclusive innovation: The way forward

India's strength lies in its ability to build inclusive innovation, not innovation for the few, but for the many.

But its innovation story is still being written. In its labs, startups and policies. The ecosystem is maturing and global partners are looking to collaborate.

The time to build that bridge is now. With the right vision, measures and partnerships, India can redefine global healthcare.

(The next articles in this series will look at India's challenges on this innovation journey and outline the way forward toward realising its ambition of becoming a hub for pharma innovation)

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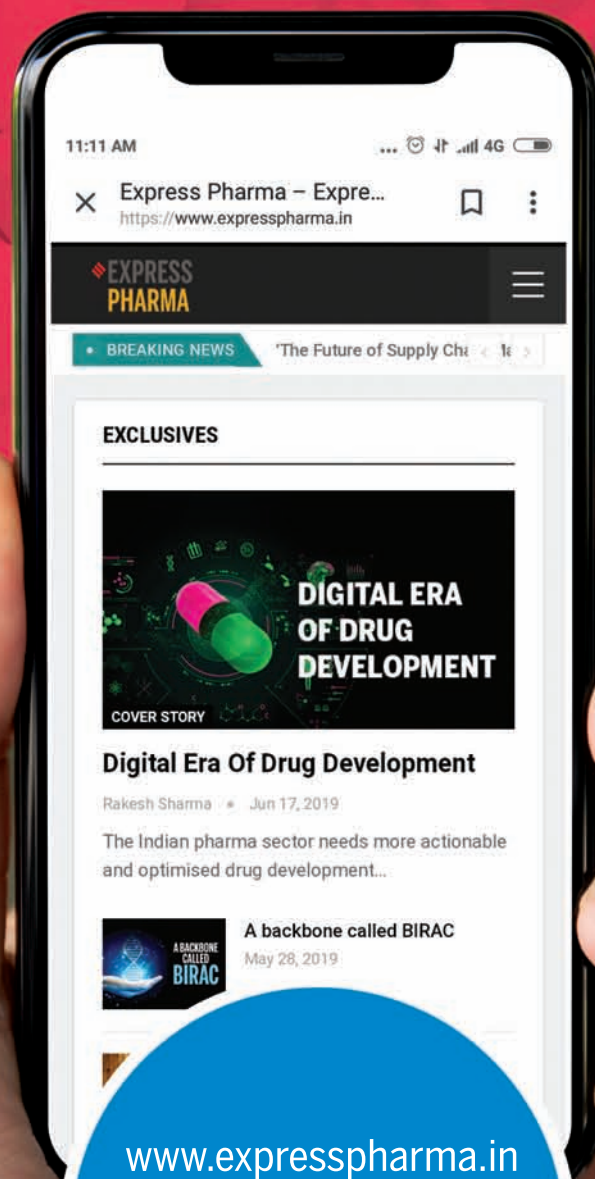
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INTERVIEW

India is a cornerstone of Fette Compacting's global strategy

Ashok Gourish, Managing Director, Fette Compacting India, discusses India's pivotal role in the company's global growth, backed by expanded services, digital transformation support, and a strengthened Competence Center in Goa, in conversation with **Express Pharma**

How does Fette Compacting view India's role in its global growth strategy? What are your priorities for the Indian market over the next few years?

Ashok Gourish: India is a cornerstone of Fette Compacting's global strategy. As one of the largest producers of generic pharmaceuticals and a rapidly growing hub for nutraceuticals, India offers a unique blend of scale, innovation, and ambition. Our approach is guided by our strategy, "Together – from lab to production", which reflects our commitment to supporting customers across the entire product lifecycle. We are expanding our service network and strengthening our Competence Center in Goa to provide advanced training, process emulation, and expert guidance. These initiatives ensure that Indian manufacturers have access to the knowledge, tools, and digital solutions needed to optimise efficiency, enhance compliance, and embrace Pharma 4.0. Our goal is to be a trusted partner in India's journey toward smarter, safer, and more sustainable pharmaceutical production.

How is Fette Compacting supporting Indian manufacturers in adopting advanced tablet production technologies?

Ashok Gourish: We support Indian manufacturers by combining advanced technology with deep process expertise to enable faster, smarter, and more efficient



tablet production. Our portfolio includes solutions such as FE CPS for Continuous Direct Compression, which sets new standards for continuous manufacturing with integrated real-time analytics, and Process Emulators that allow recipe validation and parameter optimisation under

real production conditions. The Qualified Expert Database (QED) provides instant access to decades of tableting knowledge for informed decision-making, while our i Series, FE Series and p Series tablet presses deliver high performance and containment for batch production

environments. Embedded Process Analytical Technology (ePAT) ensures real-time monitoring of critical quality attributes, reducing risk and improving compliance.

Through our Competence Center in Goa, we offer hands-on training, process emulation, and laboratory services such as material characterisation and formulation consulting. These capabilities help customers accelerate development, optimise processes, and adopt advanced technologies confidently ensuring efficiency, quality, and speed from development to commercial production.

How do you balance global innovation with local market needs in India?

Ashok Gourish: Our philosophy is simple: global innovation must meet local relevance. While our R&D centers in Germany and Belgium develop advanced technologies, our Indian operations ensure these

solutions are adapted to local market dynamics. We understand that Indian manufacturers operate in a highly competitive and cost-sensitive environment, so we focus on delivering scalable, modular systems that align with regulatory requirements and operational realities.

To strengthen this approach, we have already established a local mechanical design team and software team in India that actively supports our global engineering projects. This integration ensures faster customisation, quicker response times, and solutions tailored to the needs of Indian customers. At the same time, we are committed to developing local talent, investing in training and skill-building to create a strong knowledge base within India.

As Indian pharma moves towards digital and data-driven manufacturing, how is Fette Compacting helping companies transition to Pharma 4.0?

Ashok Gourish: All our tablet presses, be it the i Series, FE Series or p Series are Pharma 4.0 ready, designed to integrate seamlessly into intelligent and connected manufacturing environments. This readiness ensures that customers can leverage real-time data, advanced automation, and digital connectivity to optimise production processes and maintain compliance with evolving regulatory standards.

Our machines include features that enable predictive maintenance, remote



Fette Compacting Competence Center based out of Verna, Goa

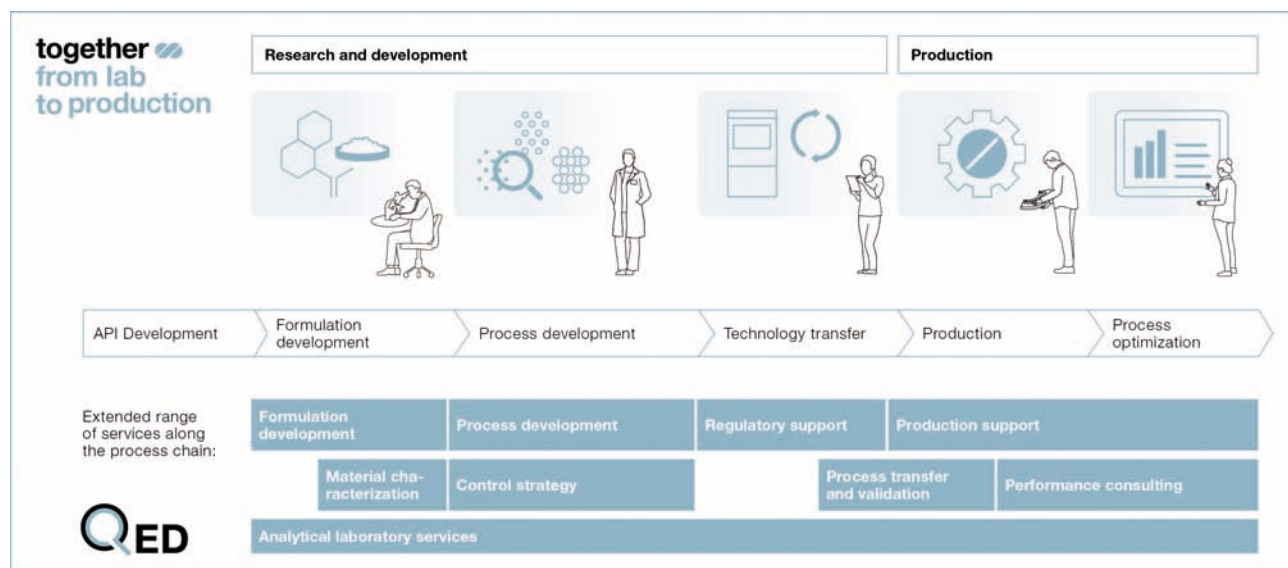
monitoring, and secure connectivity for faster troubleshooting and reduced downtime. Tools like SmartInterface provide real-time insights into machine performance, while remote support solutions enhance responsiveness and minimise disruptions. Combined with our expanding local service capabilities and training programs, these technologies help Indian manufacturers transition smoothly to digitalised, data-driven operations, making Pharma 4.0 practical, scalable, and value-driven.

How is Fette Compacting enabling sustainable, high-quality production for both domestic and export markets?

Ashok Gourish: Sustainability and quality go hand in hand in modern pharmaceutical manufacturing. Our tablet presses are designed for energy efficiency, minimal material waste, and long-term reliability. For example, FE CPS supports continuous manufacturing with a smaller footprint and reduced resource consumption, while our tablet presses, i Series, FE Series and p Series deliver high performance with optimised cleaning and changeover processes.

Beyond technology, we are proud to have achieved EcoVadis Silver status with 70 points, placing Fette Compacting in the top 5 per cent of companies in the mechanical engineering sector assessed globally. Our strongest areas were Environment and Ethics, reflecting our commitment to responsible business practices. By regularly reassessing our sustainability performance and sharing insights with customers, we identify opportunities for continuous improvement and alignment with their sustainability goals.

We also reduce environmental impact through digital tools that minimise travel and on-site interventions, lowering carbon emissions. Combined with our local engineering and service capabilities, these



Our approach: Together – from lab to production

initiatives contribute to shorter, more sustainable production cycles. Our mission is clear: to help customers meet global quality standards while advancing environmental responsibility.

What emerging trends in tablet production do you think will shape the next decade for Indian pharma and nutra companies?

Ashok Gourish: Several trends are poised to reshape the landscape:

- Continuous Manufacturing will become more mainstream, driven by the need for agility and efficiency.
- Digitalisation and AI will play a central role in predictive maintenance, real-time quality control, and process optimisation.
- Personalised and small-batch production will gain traction, especially in the nutraceutical and specialty pharma segments.
- Sustainability will become a key differentiator, with manufacturers seeking greener processes and equipment.

At Fette Compacting, we are actively investing in these areas to ensure our customers are future-ready and competitive in a rapidly changing market.

How does Fette Compacting plan to deepen its engagement with Indian pharma ecosystems? Are there plans to expand your



Fette Compacting_FE CPS with FE55 ePAT

footprint or service capabilities in India to meet growing local demand?

Ashok Gourish: We are committed to being a long-term partner to the Indian pharma and nutraceutical industries. To meet growing local demand, we are expanding our service network and strengthening our Competence Center in Goa, which offers advanced training, process, and application support. These initiatives ensure customers have access to expert guidance and hands-on experience across the entire product lifecycle.

In addition, we have established local mechanical and software design teams that actively support global engineering projects, enabling faster customisation and responsiveness for Indian customers. We are also investing in digital learning platforms and skill development programs to build local talent and enhance technical capabilities.

As part of our strategic roadmap for the Indian market, we have several initiatives and plans to strengthen local support – steps that will help improve availability and build greater supply chain resilience for our customers in the future. Our goal is clear: to provide comprehensive support - from formulation development to commercial production, so that our customers can achieve speed, compliance, and quality at every stage.

What is Fette Compacting showcasing at CPHI PMEC India 2025 this year? What message would you like to convey to your Indian customers and partners through your presence at the event?

Ashok Gourish: At CPHI PMEC India 2025, we are proud to present our strategy “Together – from lab to production”, which reflects our commitment to supporting

customers across the entire product lifecycle.

We are showcasing a comprehensive portfolio that includes:

- FE CPS with FE55 – our advanced continuous manufacturing solution for direct compression.
- F10i Containment Guard – ensuring operator safety and product integrity in high-potency environments.
- F30p – high-performance rotary tablet press for large-scale production.
- FE CPS Process Emulator – enabling virtual process development and optimisation.
- F Lab 10 – for early-stage formulation characterisation
- Tableting Tools and OEM Spares – ensuring long-term reliability and compliance.

Our message to the Indian pharma and nutraceutical community is clear: we are here as partners, not just technology providers. With our expanding local footprint, advanced service capabilities, and global expertise, we aim to help customers achieve smarter, safer, and more sustainable manufacturing - walking with them every step of the way, Together – from lab to production.

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The constraints and innovations in the packaging of biologic drugs

Biologic drugs are transforming the treatment of chronic and complex diseases, with Stevanato Group outlining packaging and device platforms for their administration

Yet due to the nature of these complex, protein-based therapies, their potential for interaction with packaging materials poses significant challenges for containment and delivery across the supply chain. At the same time, the growing preference for at-home treatment and self-administration is reshaping how patients use and interact with these new therapies.

To keep pace with shifting patient expectations and the complexity of biologic therapies, drug developers are embracing advanced delivery solutions, which are enabling safer, more convenient self-administration with improved drug stability and regulatory compliance.

We look at how modern packaging strategies are evolving to address the twin pressures of technical performance and patient-centric design - and why integrated systems like Alba® syringes, Nexa® syringes, and the Aidaptus® auto-injector are at the forefront of this transformation.

Market dynamics and patient-centric trends

Biologics are becoming increasingly favored for their targeted action and lower side effect profiles in treating complex and chronic diseases - including cancer, autoimmune disorders, and rare conditions - and are supported by advances in biotechnology, and an aging global population. Additionally, the emergence of biosimilars and evolving regulatory frameworks are driving further market expansion and influencing how biologics are developed, delivered, and administered.

A critical challenge in bio-

logic drug development is managing interactions between the product and its primary container. Leachables from materials like glass or silicone, or extractables from adhesives, can trigger protein aggregation or reduce efficacy. In addition, the large and structurally complex nature of biologic molecules makes them highly sensitive to environmental factors - requiring packaging strategies that maintain stability and prevent degradation.

In addition, patient preferences are increasingly shifting toward self-administration at home, driven by the desire for greater convenience and autonomy. As a result, drug developers face growing pressure to design packaging and delivery systems that support frequent, long-term use. To reduce the treatment burden, many biologics are being reformulated for less frequent dosing, often by increasing drug concentration. However, this creates additional challenges related to viscosity, stability, and administration time that must be addressed through innovative delivery solutions.

With growing demand and evolving treatment models,

expectations are expanding beyond efficacy to include how biologics are stored, delivered, and used by patients. These pressures are driving developers to rethink packaging strategies and ensure they not only protect product integrity but also support real-world administration and patient-centered care.

Regulatory considerations and lifecycle alignment

Alongside scientific and market pressures, regulatory expectations have grown more stringent to demand a lifecycle-oriented approach to biologic packaging. Global frameworks and guidance on container-closure integrity place increased emphasis on the need for validated, contamination-resistant packaging systems that ensure product quality and safety from manufacturing through to patient use.

Both EU Annex 1 and FDA regulations require validating the compatibility, integrity, and safety of packaging and delivery systems. Annex 1 (Section 8) mandates container closure integrity testing (CCIT) to ensure sterility is maintained, explicitly stat-

ing that visual inspection alone is insufficient. In the U.S., 21 CFR 211.94 and the FDA's container closure guidance call for rigorous testing of container systems to ensure adequate protection, chemical compatibility, and functional performance - especially for high-risk formats like injectables and inhalation products.

In parallel, extractables and leachables (E&L) testing is now considered essential to assess the potential for harmful chemical migration. USP <1663> evaluates extractables - compounds that could leach under worst-case conditions - while USP <1664> focuses on leachables that actually migrate into the drug under normal use. These studies are supported by ICH Q3C and Q3D, which set safety thresholds for residual solvents and elemental impurities respectively, both of which may originate from packaging or processing equipment.

Taken together, these evolving regulatory standards reinforce the need for manufacturers to not only understand but proactively address container-closure risks. This makes it essential in choosing a partner with the capabilities

to navigate complex regulatory demands and deliver validated packaging solutions.

Innovation in syringe design - Alba® and Nexa® platforms

The need to accommodate the specific demands of biologic drug delivery is accelerating innovation in syringe technology.

Stevanato Group's Alba® and Nexa® platforms represent next-generation solutions designed to overcome key challenges related to drug stability, device compatibility, and user-friendly administration that supports both regulatory compliance and patient-centric care.

Alba® Syringes: A breakthrough platform for sensitive biologics

Alba® platform is specifically designed for sensitive, high-value biologic drugs. Its proprietary plasma-treated, cross-linked silicone coating creates a stable barrier between the drug and container, minimising interaction between the drug and its container to maintain long-term drug stability.

Featuring an ultra-low extractables profile - reducing sub-visible particles, tungsten, and glue-related impurities - makes it ideal for formulations prone to degradation or requiring high purity. Functionally, Alba® provides consistent gliding force over its shelf life, to ensure reliable performance in auto-injectors and enhanced patient comfort.

With a strong focus on drug integrity, device performance, and patient safety, Alba® is the next-generation syringe platform that helps pharmaceutical companies



meet the stringent demands of biologic delivery while streamlining product development and lifecycle management.

Nexa® Syringes: Superior quality and performance for high-value sensitive injectables

The rise of GLP-1 receptor agonists for diabetes and obesity is reshaping injectable drug delivery and creating demand for systems that ensure safety, reliability, and seamless integration with auto-injector devices. Stevanato Group's Nexa® platform meets these demands with a syringe system engineered for consistency, precision, and compatibility.

Nexa® syringes are optimised for use in self-injection devices to deliver a smooth and predictable gliding and injection force - a critical factor in patient adherence and comfort. Featuring ultra-low levels of tungsten and glue residuals, it reduces the risk of interaction with sensitive biologics and supports higher

drug stability and safety standards.

Manufactured to the highest cosmetic and dimensional specifications, Nexa® syringes offer mechanical resistance reducing the risk of breakage during processing, transport, and use.

With each unit undergoing 100 per cent camera inspection, you can be sure of superior cosmetic quality and compliance with the most stringent regulatory and manufacturing requirements.

Designed for pharmaceutical companies launching high-value, self-administered therapies, Nexa® enables smooth integration into automated assembly lines and device systems, providing a robust container platform that enhances performance, simplifies quality assurance, to support the successful delivery of next-generation injectable treatments.

Together, Alba® and Nexa® represent the forefront of syringe innovation - combining pharmaceutical performance with patient-centric design.

By integrating a Special Thin-Wall Needle, they reduce extrusion force and injection time by nearly 50 per cent, thereby enhancing usability and patient experience.

Enabling innovation through auto-injector integration: The Aidaptus® platform

As the demand for self-administered therapies grows, so must the auto-injector technologies responsible for accommodating these complex formulations - without compromising reliability or patient experience.

Stevanato Group's answer comes in the form of its collaborative partnership with Owen Mumford Pharmaceutical Services (OMPS), a pioneer in the auto-injector space whose portfolio includes the Aidaptus® auto-injector platform.

At its core, Aidaptus® is a 2-step, single-use auto-injector with a versatile design that accommodates both 1mL and 2.25 mL prefilled glass syringes in the same base de-

vice. Stevanato Group is the exclusive manufacturing and commercial partner for Aidaptus®.

One key feature of this device is its self-adjusting plunger, which compensates for variations in stopper positions. This eliminates the need for device reconfiguration when switching drug batches or formulations, enhancing patient usability and simplifying production logistics.

Precision engineering is another defining attribute of Aidaptus®, with tight dimensional tolerances that maintain consistent injection depth and support safe subcutaneous delivery, with a robust mechanical design that enhances durability for a wide range of drug characteristics and patient conditions.

Critically, Aidaptus® is compatible with both Alba® and Nexa® syringe platforms. This flexibility enables pharmaceutical companies to optimise for specific drug and formulation requirements without compromising device

performance or patient experience. By aligning drug containment and delivery systems in a single integrated platform, Aidaptus® empowers both innovation and operational efficiency with commercial scalability.

Meeting the dual demands of innovation and usability

Together, these platforms form a connected ecosystem that supports both technical and commercial objectives that enable pharmaceutical companies to meet increasing regulatory expectations while delivering therapies that are not only safe and effective but also accessible and user-friendly.

As the biologics market grows and patient preferences continue to evolve, solutions like Alba®, Nexa®, and Aidaptus® will be instrumental in bridging the gap between complex formulations and patient-centric delivery to ensure the future of drug development is both innovative and inclusive.

Stevanato Group outlines packaging solutions for the expanding biologics market

With biologic drugs projected to grow at a CAGR of +15 per cent through 2027, Stevanato Group details glass converting capabilities and container platforms designed to support evolving biologic formulation and delivery needs

Biotic drugs are the fastest-growing segment in the pharmaceutical industry, with a projected CAGR of +15 per cent through 2027, according to IQVIA and Stevanato Group internal analysis. Their complexity and sensitivity demand stringent quality standards, especially regarding packaging, which must prevent interactions, contamination, and degradation while supporting advanced delivery systems.

As biologics evolve—requir-

ing higher volumes, viscous formulations, and longer dosing intervals—packaging must adapt. Stevanato Group addresses these needs with proprietary glass converting technology and integrated solutions that ensure safe containment and precise delivery.

Advanced glass converting technology

Stevanato Group can provide fully automated, high-speed, high-precision in-house glass converting. Key features include:

- 100 per cent forming temperature control
- Forming speed monitoring
- Inline dimensional and cosmetic defect inspection
- Optimised tooling for container handling

Full control over the forming process enables optimised internal shapes for accurate dosing and enhanced glass strength. This ensures containers meet the rigorous demands of biologic packaging, offering mechanical strength and dimensional accuracy.

High-performance container platforms

Stevanato Group's Fina®, Nexa®, and Alba® platforms offer:

- Superior mechanical strength and cosmetic quality
- Tight dimensional tolerances
- Compatibility with delivery devices

Alba® is ideal for biologics sensitive to silicone oil, using cross-linked coating to minimise interaction. Nexa® offers top-tier performance and quality both in glass and COP/COC versions, while Fina® provides customis-

able solutions with high cosmetic standards. All platforms are available in EZ-fill® format—ready-to-use solutions that reduce costs and accelerate time to market.

Conclusion

Stevanato Group delivers innovation, precision, and reliability in biologic drug packaging, offering end-to-end solutions that meet the evolving demands of this dynamic market.

Come meet us: Hall 14 booth C19

INTERVIEW

We continue to invest heavily in quality, regulatory compliance, and modernisation

Rishad Dadachanji, MD, Kaisha Packaging shares insights on emerging industry trends, new technologies showcased at CPhI & P-MEC, and how the Dadachanji Group is strengthening its integrated ecosystem to serve both domestic and global pharma markets

What key industry trends are visible at CPhI & P-MEC this year, and how is your company positioning itself in response?

At CPhI & P-MEC India 2025, we see the pharma landscape evolving rapidly toward integration, innovation, and sustainability. Companies are moving from standalone operations to end-to-end partnerships, seeking collaborators who can deliver quality, compliance, and reliability across the product lifecycle — all while embracing digitisation, automation, and environmental responsibility.

The Dadachanji Group is fully aligned with this shift. Through our integrated ecosystem — spanning engineering solutions to machine building, automation & cleanroom equipment (Kairish Innotech), primary and secondary packaging (Kaisha Packaging), sterile contract manufacturing (Sovereign Pharma), and injectable product development (Kaisha Lifesciences) — we offer seamless, turnkey solutions that meet global standards.

We continue to invest heavily in quality, regulatory compliance, and modernisation, including EU GMP (Annexure 1)-ready isolator upgrades at Sovereign Pharma. Across all businesses, we're embedding automation, sustainability, and digital traceability into our operations, while expanding our export footprint — with Kaisha Packaging now serving over 24 countries worldwide.

Which new products, technologies, or solutions are you showcasing at this year's event?

This year marks a milestone



for the Dadachanji Group, as we showcase our physical machines live for the very first time — a significant step forward in demonstrating our engineering and manufacturing capabilities. KAIRISH Innotech will present its next-generation Autoloading System for Aluminium Seals and Rubber Stoppers, along with reliable Passboxes featuring HEPA filtration and innovative gasket protection, precision Change Parts designed for diverse line requirements, and custom SS 316L needles with flexible, weld-free designs. We'll also be unveiling a special new machine, set for an exclusive launch at the event — a major leap in automation and process efficiency.

KAISHA Packaging, the silent guardian of sterile drug delivery, will showcase its comprehensive range of Aluminium Seals (CTD, CTO, FTO) and Injection Molded Products, including vial adapters, Sycure AD & TE systems, intra-dermal adapters, spray connectors, and IV & injection ports. The company will also highlight its expanded portfolio of primary packaging for injectables,

featuring aluminium and glass containers engineered for product protection and global distribution.

On the pharmaceutical front, Sovereign Pharma will showcase its strengths in sterile contract manufacturing featuring upgraded fill-finish lines, automation, and integrated tech-transfer support. Meanwhile, Kaisha Lifesciences will spotlight its innovative injectable formulations and the Sycure AD™ safety-device platform, designed to make self-administration simpler and safer.

How have your products evolved to meet current global pharma requirements such as quality, compliance, and cost?

Quality has always been our foremost priority and remains a continuous mission across all our operations. We ensure this not only through stringent manufacturing practices but by embedding quality into the very design and functionality of our products. Our evolution has been guided by global trends and the real challenges faced by both pharmaceutical companies and end consumers

— leading us to introduce innovations such as tamper-evident features to combat counterfeiting and auto-disable systems to prevent syringe reuse, both aimed at enhancing patient safety and product integrity.

In partnership with B&R Industrial Automation, Kairish Innotech has pioneered and become the first in India to commercially integrate B&R's Maglev transport technology, setting a new benchmark in smart manufacturing and motion control. Kaisha Packaging has elevated its product lines to deliver superior container-closure integrity, enhanced barrier protection, and compatibility with automated fill-finish lines — all while maintaining cost competitiveness. Notably, over 50 global and domestic companies have transitioned from international suppliers to Kaisha Packaging, recognising its unmatched quality and responsiveness. Adding to this, an industry-first hidden authentication feature built into the flip enables customers to verify product genuineness using a dedicated device — invisible unless known — providing a strong layer of brand protection and anti-counterfeiting assurance.

Sovereign Pharma continues to strengthen its aseptic operations, digital quality systems, and regulatory readiness to support clients across global submissions. The company has invested over Rs 250 crore to upgrade and modernise its already EU-, ANVISA-, and MHRA-approved facility, adding advanced isolator lines and future-ready systems to ensure reliability and compliance for

the next two decades.

Meanwhile, Kaisha Lifesciences integrates patient-centric design with manufacturing excellence, ensuring its injectable products meet evolving global safety and efficacy benchmarks.

What is your growth strategy in emerging markets, and which regions are your current priorities?

We're steadily expanding our global footprint across all group companies, each contributing to the Dadachanji Group's vision of becoming a trusted partner in emerging and regulated markets alike. Sovereign Pharma already supplies to a growing list of international markets, backed by strong regulatory accreditations. Kaisha Packaging too has significantly expanded its reach, with exports now spanning over 24 countries. Kairish Innotech is scaling up rapidly and has begun engaging with international clients for the export of cleanroom and process equipment — a testament to India's rising engineering capabilities. Meanwhile, Kaisha Lifesciences is advancing clinical trials for its injectable products and building partnerships in key emerging markets such as Latin America, Southeast Asia, and the Middle East, positioning itself as a reliable supplier of safe, effective therapies.

At the same time, we remain deeply committed to serving the Indian pharmaceutical ecosystem, ensuring that domestic partners have access to the same world-class quality and innovation — without compromise.

INTERVIEW

Our goal is to drive sustainable growth by being a trusted partner

Durgesh Sharma, MD, CBC Corporation India, shares how the company is driving growth through global partnerships, innovation in excipients, and a strong focus on quality, compliance, and customer-centric value, in an interaction with **Express Pharma**

What key industry trends are visible at CPHI this year, and how is your company positioning itself in response?

Our corporate value embodies our corporate philosophy: “Co-existence and Co-prosperity/Dream Together”

At CPHI this year, we’re seeing strong momentum towards sustainable sourcing, regulatory transparency, and digital enablement across the pharma value chain. CBC India is aligning with these trends by strengthening partnerships with globally compliant manufacturers, expanding our portfolio of high-quality and sustainable ingredients, and enhancing our technical and regulatory support. Our focus remains on delivering reliable, compliant, and value-driven solutions that help our customers stay ahead in a rapidly evolving market.

How has CPHI influenced your product or market strategy over time?

CPHI has been instrumental in shaping CBC’s market approach by offering valuable insights into emerging industry trends, technologies, and customer needs. It has helped us expand our product portfolio, strengthen partnerships with global manufacturers, and align our strategies with evolving regulatory and sustainability priorities. For CBC, CPHI continues to be a key platform that drives innovation, collaboration, and growth in our life sciences business.

Which new products,

technologies, or solutions are you showcasing at this year’s event?

CBC is showcasing an expanded range of high-performance excipients designed to support advanced formulation needs in solid dosage, injectables, and topical applications. Our focus is on multifunctional, high-purity excipients that enhance stability, bioavailability, and process efficiency. Through collaborations with leading global manufacturers, CBC continues to bring innovative and compliant excipient solutions that empower formulators to achieve consistent quality and performance.

How have your products evolved to meet current global pharma requirements, be it quality, compliance or cost?

Our products have continuously evolved in response to the increasingly stringent global pharma standards around quality, compliance, and cost efficiency. We work closely with our manufacturing partners to ensure every ingredient meets the latest regulatory expectations across key markets — from cGMP, ICH, and FDA guidelines to emerging local requirements.

We’ve also strengthened our quality systems with enhanced traceability, supplier qualification, and end-to-end documentation to ensure full compliance and transparency. At the same time, we recognise that cost



Our partnerships are built on transparency, ethical sourcing, and full traceability — key pillars in the life sciences ecosystem

pressures remain a constant in the industry. By optimising sourcing networks, leveraging regional supply bases, and improving logistics efficiency, we’ve been able to maintain competitive pricing without compromising on quality or service reliability.

What is your growth strategy in emerging

markets, and which regions are your current priorities?

At CBC, our growth strategy in emerging markets focuses on strengthening local partnerships, deepening regional presence, and offering tailored solutions that align with specific market dynamics.

We are investing in hiring talents with technical expertise, providing regulatory support, and localised distribution capabilities to serve customers more effectively and efficiently. By leveraging CBC’s global sourcing network and long-standing relationships with leading manufacturers, we ensure consistent product quality, supply reliability, and full regulatory compliance.

Our goal is to drive sustainable growth by being a trusted partner — delivering value beyond products through collaboration, agility, and customer-centric innovation in every market we operate.

The next phase of growth in life science distribution will come from deeper integration between science, logistics, and digital intelligence.

How is your company addressing ongoing challenges like supply chain disruptions and shifting regulatory frameworks?

At CBC, we recognise that supply chain resilience and regulatory agility are critical to sustaining customer confidence in today’s evolving pharma landscape. To address these challenges, we’ve

strengthened our global and regional sourcing networks, ensuring multi-supplier strategies and buffer inventories for key ingredients to minimise disruption risks.

On the regulatory front, we work closely with our principals and customers to stay aligned with changing global and local compliance requirements.

By combining strong supplier relationships, transparent communication, and proactive compliance management, CBC continues to deliver reliability, quality, and peace of mind — even in a constantly changing operating environment.

Are you announcing any new partnerships, distribution tie-ups, or co-development agreements at CPHI?

We are expanding our portfolio through new distribution tie-ups with globally reputed manufacturers, enabling us to offer a wider range of high-quality excipients, and specialty ingredients to our customers.

While some partnerships are still in the finalisation stage, these alliances reflect our commitment to bringing innovative, compliant, and sustainable solutions to the Indian and broader Asian markets. CPHI serves as an ideal platform for us to reinforce existing relationships and explore new opportunities for co-development and technology collaboration with partners who share our vision of quality, reliability, and growth.

INTERVIEW

We are enhancing our smart equipment portfolio with IoT-enabled control systems and cloud connectivity

In an interaction with **Express Pharma**, **Dr Manoj Chaudhari**, Managing Director, Mack Pharmatech Pvt. Ltd., highlights the company's focus on digitalisation and compliance-driven innovation, detailing how their next-generation smart stability chambers, cold rooms, and ultra-low freezers are being designed to meet the evolving demands of Pharma 4.0 and advanced therapy applications

What key industry trends are visible at CPHI this year, and how is your company positioning itself in response?

Trend at CPHI:

- The pharma sector is rapidly adopting digitalisation, AI, and IoT—from manufacturing through QC and stability testing.
- Companies are investing in smart, connected lab environments for real-time monitoring, predictive maintenance, and data integrity compliance (especially with FDA 21 CFR Part 11 and EU Annex 11).
- Growth in biologics, cell, and gene therapies is creating new needs for precise temperature and humidity control, especially for biologic sample storage, stability, and transport validation.

Mack Pharmatech's positioning:

- We are enhancing our smart equipment portfolio with integrated data-logging, IoT-enabled control systems, and cloud connectivity.
- Our latest stability chambers and cold rooms feature real-time remote monitoring, automated alarms, and data security features.
- We are collaborating with automation specialists to ensure our products fit



seamlessly into digital QC and stability workflows.

- We're developing customised stability and cold-chain simulation

systems for biologics and vaccine testing.

- Our ultra-low temperature freezers and precision cold chambers are validated for

advanced therapy applications.

- Every Mack Pharmatech system is delivered with comprehensive

DQ/IQ/OQ/PQ documentation, traceable calibration, and data-integrity compliant software.

- We've built an internal compliance and validation support team to assist customers during audits and regulatory submissions.
- We are integrating Part 11-compliant digital interfaces for secure audit trails and electronic record management.

How has CPHI influenced your product or market strategy over time?

Over the years, CPHI has been more than an exhibition for us—it's been a strategic learning platform. By engaging with global pharma manufacturers, R&D leaders, and quality professionals at CPHI events, we've continuously evolved our product portfolio and market approach to align with the direction in which the pharmaceutical ecosystem is moving.

In essence, CPHI has been a key catalyst in shaping Mack Pharmatech's journey—from a product-focused manufacturer to a solution-driven, globally competitive partner for pharmaceutical stability and environmental equipment. Each year's event provides us with a pulse on where the

industry is heading, and we've used those insights to drive innovation, sustainability, compliance, and customer trust at the core of our strategy.

Which new products, technologies, or solutions are you showcasing at this year's event?

● We are showcasing a next-generation stability chamber with features such as: PLC-based control (Allen-Bradley), 21 CFR Part-11-compliant software for data integrity, cloud/ethernet connectivity, audit trails, and remote monitoring alerts (SMS/GSM) as optional add-ons.

● The product supports ICH conditions (e.g., 25 °C/60 % RH, 30 °C/65 % RH, 40 °C/75 % RH) with tight uniformity and accuracy specs (ffl0.2 °C / ffl2 % RH) as we've done historically. Mack Pharmatech Pvt. Ltd.+2ExportersIndia+2

● We're emphasising how this "smart chamber" helps pharma organisations comply with regulatory demands, digitise their stability workflows, and integrate into Lab 4.0 environments.

● Reflecting the growing biologics / advanced-therapy market, we are promoting large-capacity walk-in cold chambers (and ultra-low freezers down to -80 °C) and cold-chain / stability rooms for biologic/vaccine storage. cdn.expresspharma.in

● For example: walk-in humidity & cold chambers, modular panel construction, full-view glass doors, dual standby refrigeration/humidity systems for zero downtime. ips.co.in+1

● The differentiation: high-capacity, customisable, verified for biologics-type environments (which is quite timely given market demands).

How have your products evolved to meet current global pharma requirements, be it quality, compliance or cost?

We are showcasing a next-generation stability chamber with features such as: PLC-based control (Allen-Bradley), 21 CFR Part-11-compliant software for data integrity, cloud/ethernet connectivity, audit trails, and remote monitoring alerts (SMS/GSM) as optional add-ons

At Mack Pharmatech Pvt. Ltd., our evolution has been guided by three key pillars — quality, compliance, and cost-effectiveness — to ensure our products align with the ever-rising standards of the global pharmaceutical industry.

1. Quality: Precision, reliability and lifecycle durability

Global pharma companies now demand high accuracy, uniformity, and reproducibility in stability and environmental testing. To meet this, our products have evolved through:

● **Advanced control systems:** We've transitioned from basic PID controls to PLC-based intelligent controllers with auto-tuning and tighter control tolerances (± 0.2 °C / ± 2 % RH).

● **High-performance components:** All chambers and incubators use internationally certified sensors, compressors, and controllers ensuring reliability across long stability studies.

● **Continuous testing and validation:** Each unit undergoes rigorous factory acceptance testing (FAT) and performance mapping before dispatch, ensuring compliance with ICH and WHO standards.

● **Long-term robustness:** Modular design and redundancy features (like dual refrigeration systems in walk-in chambers) minimize downtime and protect critical stability studies.

Compliance: Global regulatory and data integrity standards

The pharma industry's shift toward data integrity and audit-readiness has directly shaped our R&D. Our

latest generation of equipment meets the highest global compliance benchmarks:

● 21 CFR Part 11 and EU Annex 11 compliant software with secure audit trails, password control, and electronic signatures.

● Real-time data logging with cloud or Ethernet connectivity, enabling remote validation and audit access.

● Comprehensive documentation packages (IQ/OQ/PQ, calibration certificates, traceability records) supplied with every system.

● Integration with digital lab systems to support Pharma 4.0 environments. Through these upgrades, we ensure that our customers' compliance burden is reduced — our systems are ready for regulatory scrutiny worldwide.

3. Cost efficiency: Sustainable, smart and scalable

Balancing quality and cost is critical, especially for emerging markets and generic manufacturers. We've addressed this by:

● **Energy-efficient designs:** Using eco-friendly refrigerants (low GWP), high-efficiency compressors, and optimised insulation to reduce power consumption by up to 30 per cent.

● **Smart maintenance features:** IoT-based predictive maintenance and diagnostic alerts reduce downtime and service costs.

● **Modular configurations:** Allowing clients to scale up chamber capacity or add features as their operations expand.

● **Local manufacturing with global standards:**

"Made in India for the world" keeps costs competitive without compromising on performance or compliance.

What is your growth strategy in emerging markets, and which regions are your current priorities?

Emerging-market pharma companies require equipment that balances regulatory compliance with operational simplicity and cost control.

● We are customising our chambers and incubators with modular designs, multi-condition stability configurations, and energy-efficient components suitable for variable infrastructure environments.

● All equipment meets ICH and WHO stability guidelines, giving regional players confidence to export to regulated markets.

Our long-term vision is to make Mack Pharmatech a global benchmark for stability and environmental simulation equipment — "Made in India, trusted worldwide." We will continue to invest in smart technology, sustainability, and service localisation to ensure we remain the preferred partner for pharmaceutical, biotech, and life-science companies in every emerging market we enter.

How is your company addressing ongoing challenges like supply chain disruptions and shifting regulatory frameworks?

At Mack Pharmatech Pvt. Ltd., we recognise that global pharma operations are evolving amid persistent supply-chain pressures and

fast-changing regulatory expectations. Our strategy focuses on resilience, compliance agility, and customer continuity, ensuring our clients can rely on us as a stable, compliant partner even in uncertain conditions.

● **Continuous regulatory monitoring:** Our compliance team actively tracks updates from the FDA, EMA, WHO, and ICH to ensure all equipment design and documentation reflect current global requirements.

● **Design built for audit-readiness:** Every system now features 21 CFR Part 11-compliant software, secure data logging, audit trails, and electronic signatures to meet global data-integrity norms.

● **Comprehensive documentation:** All installations are supported with DQ/IQ/OQ/PQ protocols, calibration traceability, and validation assistance to simplify customer audits.

● **Regional service hubs and remote support:** We've expanded our service network and introduced remote diagnostics to minimise downtime when travel or logistics are disrupted.

● **Digital communication channels:** Customers can now access online support, documentation, and maintenance scheduling to maintain validation and compliance continuity.

Are you announcing any new partnerships, distribution tie-ups, or co-development agreements at CPHI?

At CPHI 2025, Mack Pharmatech Pvt. Ltd. is excited to highlight several strategic collaborations that strengthen our international presence and enhance the support we provide to global pharma and biotech manufacturers. These partnerships reflect our long-term commitment to localised service, digital innovation, and co-development of advanced environmental solutions.

Creating the birthplace of scientific breakthroughs: The GD Waldner story

Adhiraj Patel, CEO, GD Waldner, highlights the company's 100-year legacy of precision and innovation, blending German design excellence with Indian execution to deliver world-class, future-ready laboratories for the nation's scientific and industrial leaders

In the world of pharmaceuticals, life sciences, and advanced research, laboratories are more than just workspaces — they're the birthplace of innovation. Behind every breakthrough stands an environment built for precision, safety, and imagination. For over 100 years the company has been shaping those very environments — crafting laboratories that empower discovery.

Our 100 year journey

As we celebrate a century of scientific proficiency we remain committed to pushing the boundaries of knowledge further to achieve key milestones. Our rich tradition of innovation has left an indelible mark across diverse fields, actively shaping the landscape of scientific discovery.

Post the joint venture with Waldner, Germany, GD Waldner is today a seamless blend of German innovation and Indian execution. Every solution embodies global design excellence, adapted to Indian conditions, compliance requirements, and cost structures. The result —

laboratories that meet international safety and performance standards while responding to the evolving needs of Indian Research and Industry.

Why us

- 100 years of excellence in designing and building world-class lab spaces.

- Comprehensive Design-Build Solutions for Laboratory Furniture, Fume Hoods and MEP services (HVAC, Gas Piping, Electricals, Interiors, BMS and Fire Safety Systems).

- International project experience to offer the best design elements from around the world.

- World-class products and solutions designed in Germany, manufactured and executed in India.

- Unmatched service and faster project turnaround time in India.

- Highly responsive Service Network - experienced technicians equipped with original spare parts.

Serving the nation's knowledge industries



From Pharmaceuticals and Biotechnology to Chemicals, Education, Food and Beverage testing, and Energy (EV), GD Waldner India serves some of the most demanding sectors in the country.

For the pharmaceutical and life-sciences community in particular, the value is clear. As research scales, regulations tighten, and new modalities emerge, the need for safe, modular, and compliant laboratories becomes mission critical. Whether it's a quality-control lab in a manufacturing plant or a high-end R&D centre, GD Waldner ensures every facility is future-ready — in design, infra-

structure, and service.

Engineering for the future

The modern laboratory is evolving faster than ever before. Digital integration, sustainability, and safety are now inseparable from design. GD Waldner India has been at the forefront of this shift, introducing labs that are energy-efficient, adaptable, and intelligently managed.

Their systems integrate seamlessly with building management solutions, optimise airflow to reduce energy consumption, and prioritise ergonomics to enhance productivity. With sustainability becoming a central pillar for the global pharmaceutical industry, GD Waldner's innovation-driven approach offers a tangible way forward — labs that perform better and last longer, with a lighter footprint.

Partnerships that last a lifetime

Perhaps what defines GD Waldner India most is its commitment to partnership. The company's promise extends beyond project delivery — it extends

across the entire lifecycle of a laboratory. Their dedicated service network across India ensures consistent support, quick response times, and ongoing training for teams. This commitment has built long-term relationships with industry leaders — partnerships measured not in years, but in generations of scientific progress.

Conclusion: Precision, possibility and purpose

For nearly a century, GD Waldner has stood for precision, safety, and intelligent design. In India, that legacy continues — not as a distant claim, but as a testament of laboratory installations at the nation's most ambitious industries.

With a legacy of 100 years in serving the scientific community, G.D. Waldner stands as the cornerstone of comprehensive laboratory solutions, driving the entire journey from concept to breakthrough. This legacy is also a testament to our transparent business practices, long-standing partnerships and customer centricity.

GD Waldner unveils 20,000 sq.ft turnkey facility featuring synthesis, analytical, and kilo labs

Elegance meets functionality!

Thrilled to announce the successful completion of a turnkey project of 20,000 sq. ft, Synthesis labs, Analytical labs and Kilo labs which embody efficiency and user centric innovation.

With comprehensive scope covering Lab Design and Build, Civil Interiors, MEP (HVAC, Exhaust, Fire Fighting, GDS, ELV, Data, Clean Room Partitions and BMS) along with the integration of a high volume of Laboratory Furniture and nearly 100 nos. Fume Hoods, these labs set a new gold standard for research and development.



SRICO strengthens collaboration with JULABO

As JULABO's exclusive distributor for temperature control solutions in India, SRICO has become a trusted partner for research institutes, universities, and industry



Narasimha Murthy Bhatta, Director of SRICO (left), and Markus Juchheim, CEO of JULABO, both commit to a long-term partnership that will benefit all research institutes, universities, and industrial customers in India



Narasimha Murthy Bhatta, Director of SRICO (left), and Mark Bitterwolf, JULABO CMO and Director of Sales, during the official signing ceremony of the closer partnership at the SRICO headquarters in Bangalore



SRICO Directors Narasimha Murthy Bhatta (left) and Shalini Rao, together with Mark Bitterwolf, JULABO CMO and Director of Sales, during the official signing ceremony of the closer partnership at the SRICO headquarters in Bangalore

SRICO (Scientific Research Instruments Company), a leading provider of laboratory and research technologies in India, has deepened its long-standing partnership with JULABO, a global leader in temperature control technology. JULABO has acquired a stake in SRICO, reinforcing the relationship and paving the way for stronger and reliable solutions and services for customers across India.

For decades, SRICO has combined premium international technologies with local expertise and service excellence. As JULABO's exclusive distributor for temperature control solutions in India, SRICO has become a trusted partner for research institutes, universities, and industry.

"Our mission has always been to put Indian customers first – by giving them access to the world's best technology, delivered with strong local support. The closer col-



"Our mission has always been to put Indian customers first – by giving them access to the world's best technology, delivered with strong local support. This is about more than business – it is about keeping our promise to help laboratories and industries in India succeed."

Narasimha Murthy Bhatta, Director, SRICO



SRICO Directors Narasimha Murthy Bhatta (fourth from right) and Shalini Rao (fifth from left) together with members of the SRICO team and JULABO CMO and Director of Sales Mark Bitterwolf (third from right), at the official signing ceremony marking the strengthened partnership at SRICO headquarters in Bangalore

laboration with JULABO enables us to offer even more stability, resources, and innovation. This is about more than business – it is about keeping our promise to help laboratories and industries in India succeed," states Narasimha Murthy Bhatta, Director of SRICO.

Markus Juchheim, CEO of JULABO, adds, "We are proud to stand even closer alongside SRICO. Customers in India will benefit from our shared expertise, our joint commitment, and the long-term vision that this partnership represents."

With this enhanced collaboration, SRICO and JULABO reaffirm their joint mission. Murthy concludes, "This step fills us with pride and energy. Together with JULABO, we will expand what we can deliver: cutting-edge solutions, dependable service, and future-proof technologies that empower science and industry across India."

INTERVIEW

We built our business by obsessing over excipients

Shivang Zaveri, Director, Transchem Corporation Pharma; discusses Transchem's approach to excipients, innovation, and market strategy with Express Pharma.

What differentiates Transchem in the excipients space?

We built our business by obsessing over excipients long before they became a crowded category. Our team knows how these materials behave in real formulations because we're constantly working with R&D teams and production folks, not just reading spec sheets. That lets us flag problems early, suggest smarter substitutes, and save customers from wasting batches. This along with our long-standing relationships with global producers and our reputation for clear, rapid responses, and it's no surprise we're the trusted partner in high stakes environments where precision is paramount.

How do you translate global technologies from partners like BASF for the Indian market?

While scientific innovation is universal, its application must be tailored to local realities. At Transchem, we adapt global technologies to meet the specific demands of the Indian market—ensuring product stability under high heat and humidity, navigating regulatory documentation to align with CDSCO requirements, and supporting exporters with compliance for regulated markets. We also facilitate direct engagement between our partners and clients, enabling deep technical conversations while we manage the local context, logistics, and implementation. This collaborative approach ensures that global science delivers real-world impact in India.



For us, innovation isn't a buzzword—it's about solving tomorrow's problems today, and making sure our clients are always one step ahead

How are you using innovation and technology to stay competitive?

We approach innovation as a strategic tool to stay ahead of market shifts. By closely tracking demand patterns, engaging regularly with formulation teams, and

monitoring early signals in supply and regulation, we are able to anticipate changes before they happen. We also collaborate with partner labs to test new grades early, giving us a clear view of what's coming down the pipeline. On the

operational side, we have streamlined our supply chain to ensure predictability and speed. For us, innovation isn't a buzzword—it's about solving tomorrow's problems today, and making sure our clients are always one step ahead.

What regulatory or market challenges do you face, and how are you handling them?

Increasing regulatory complexity and global supply chain volatility are ongoing challenges in our industry. To stay ahead, we have strengthened our internal documentation systems to ensure fast, accurate compliance with evolving standards. On the supply side, we collaborate closely with our principals to secure long-term allocations and maintain strategic inventory buffers within India. These measures help us absorb disruptions and keep timelines predictable. Ultimately, our goal is simple: by managing the volatility internally, we ensure our customers enjoy seamless service and dependable outcomes.

What are your growth drivers and priorities for the next three to five years?

The rise of complex generics, increasing demand for cleaner excipients, and a sharper focus by Indian companies on regulated markets are reshaping the industry. Our growth strategy is built around these shifts. We are deepening technical engagement with customers, expanding our portfolio of functional and high-value excipients, and reinforcing our distribution network to ensure consistent availability. As we scale, we remain committed to the direct, responsive approach that defines our customer relationships—because growth should never come at the cost of agility or trust.

Central Solutions Enterprise (CSE) acquires Metal Chem Industries

Central Solutions Enterprise (CSE) and Metal Chem Equipments (Formerly Metal Chem Industries) have joined forces. They are not just continuing a legacy; they are aiming to maximise it. **Ketur Shah**, Director, CSE provides more insights on this development

Can you brief about CSE background and how Metal Chem became a pivotal addition in their portfolio?

Since its founding in 2009, CSE has been a key provider of solutions for customers across various segments, including pharma, biotech, food & beverage, dairy, and health-care. We achieve this by representing global companies like CGS (US), Ge-citech (France) and Aseptsoft (Aseptconn group company) (Switzerland). Our initial product offerings spanned a wide range, from stainless steel components (tubes & fittings), hoses, diaphragm valves, gaskets, and spare diaphragms to specialised services like Intelligent P&ID software. This software's standout feature is that it transforms standard P&IDs into a digital process design platform thereby reducing manual errors and processing time. Our offerings from products side to providing equipment-side was a natural extension aimed at broadening our customer solutions, which is where Metal Chem will become a critical part of our portfolio.

What was the most compelling factor that led you to join hands with Metal Chem?

Metal Chem has a long legacy serving the industry of providing equipment for sterile solutions since 1982. However, with time and age



Our goal is to position Metal Chem Equipments as one of the market leaders in sterilising equipment within five years, delivering a consistently peaceful and hassle-free experience for every client

catching up with the founder, BN Amrolia - one of the most respected figures in the industry found it challenging to cater to ever growing requirements of sterilising equipment. With no succession in place to take the legacy forward we were excited to get on-board with this association forming Metal Chem Equipments Pvt. Ltd. as Mr. Amrolia wanted the brand Metal Chem to continue to grow as it was a result of his 4 decades of dedication to the industry.

What is the core philosophical or operational 'North Star' for Metal Chem Equipment's mission?

With the association, our primary objective is to continue Metal Chem's commitment and carry its legacy to new heights to serve the industry by supplying equipment such as Autoclaves, Bung processors, Dry Heat Sterilizers, Depyrogenation Tunnels maintaining the same ethos of quality, reliability and customer service as set by Mr. Amrolia. Our 'North Star' would be to supply equipment which operate seamlessly for decades without any issues as it has been in the past.

In terms of manufacturing and quality control, what new processes or certifications have you planned to adopt to ensure the highest global pharma standards?

With the backing of experienced team under the guidance of Mr. Amrolia, we intend to implement operational changes which will help us to deliver equipment faster. Going forward we will be aiming to manufacture equipment meeting global standards such as CE to expand our horizon to global requirements.

Beyond your equipment, what new service offerings?

Metal Chem has supplied 500+ equipment to the industry. We are re-engaging with the client to update our association and also establishing AMC contracts which will provide smooth running of equipment. We are working on developing solutions for remote diagnostics for troubleshooting hence reducing the valuable downtime that customers may face. We will also be focusing on how to integrate AI solutions into our solutions to provide better customer experience.

If you could fast-forward five years, what is the one key achievement that would define the success of this take over?

Our goal is to position Metal Chem Equipments as one of the market leaders in sterilising equipment within five years, delivering a consistently peaceful and hassle-free experience for every client. We want Metal Chem to manufacture in India for the world providing world class equipment.

INTERVIEW

We are positioning ourselves as a leader in creating foundational infrastructure for the modern pharma plant

Dr Kiran Badgujar; Founder & Director discusses how the company is aligning with global pharma trends in AI integration, sustainability, and supply chain resilience, while unveiling its next-generation INFRAS technology, with **Express Pharma**

What key industry trends are visible at CPHI this year, and how is your company positioning itself in response?

The dominant trends at CPHI this year are clearly the integration of AI in pharmaceutical manufacturing, a major push toward sustainability and greener processes, and the critical need for building resilient, transparent supply chains. At Aureole Group, our strategy is directly aligned with these themes. We are positioning ourselves as a leader in creating foundational infrastructure for the modern pharmaceutical plant. Our equipment, including our advanced stability and environmental chambers, is now engineered to be digital-ready, providing the validated, reliable data streams that AI and Pharma 4.0 systems depend on. Aureole is heading towards on the road of consistent improvement and R&D, for example our new INFRAS technology directly addresses sustainability by drastically cutting energy consumption compared to traditional systems. This focus on energy efficiency and robust, qualification-ready equipment helps our partners meet their sustainability goals, strengthen their supply chains with reliable in-house testing capabilities.



Our growth strategy for emerging markets is centred on a 'hub-and-spoke' model that combines our world-class manufacturing with strong partnerships

How has CPHI influenced your product or market strategy over time?

CPHI has been immensely influential in shaping our trajectory. Year after year, the conversations and feedback from industry

leaders at the event have reinforced the critical importance of compliance and robust documentation. This has driven us to develop equipment that not only performs exceptionally but also comes with

comprehensive, qualification-ready documentation to simplify and accelerate our clients' validation processes. Furthermore, the global nature of CPHI has directly shaped our market strategy. Engaging with partners from

diverse regions and countries has highlighted the need for adaptable, modular equipment designs and has been the catalyst for our regional distribution and support model. This ensures we can provide timely, effective service globally, a strategy born from understanding the varied needs of the international pharma community present at CPHI.

Which new products, technologies, or solutions are you showcasing at this year's event?

This year, we are incredibly excited to showcase three revolutionary technologies that represent a significant leap forward in environmental control: INFRAS, RHS, and IFC. ● RHS (Rapid Humidification by Sonification) is our new ultrasonic humidification system that use less energy than conventional steam generators by creating a fine, cool mist without heat, allowing for incredibly fast and precise humidity control which leads to 40 per cent less running cost. ● IFC (Infused Fluid Cooling) is our closed-loop cooling technology that uses a chilled fluid reservoir to deliver stable, efficient cooling, drastically reducing compressor cycling and energy waste while eliminating temperature undershoot.

● **INFRAS** is the integrated system that combines both RHS and IFC. It creates a harmonised environment, eliminating the energy-wasting conflict between heating, cooling, and humidification seen in traditional chamber design. This provides unparalleled stability and precision with minimal energy consumption. We will be showcasing these technologies at CPHI with additional features, demonstrating how they provide superior performance than all of our competition in walk-in and reach-in models, alongside our other solutions like ultra-low temperature freezers and BOD incubators.

How have your products evolved to meet current global pharma requirements, be it quality, compliance or cost?

Our products have evolved specifically to meet the stringent demands of the global pharmaceutical industry. To address quality and compliance, we've moved beyond basic performance to focus on precision and data integrity. Our new INFRAS platform, with its IFC and RHS technologies, provides

exceptionally tight control over temperature and humidity, which is critical for meeting ICH stability guidelines. We've also integrated enhanced digital monitoring and 21 CFR Part 11-compliant features to ensure data is secure and traceable for regulatory audits. On the cost front, the energy efficiency of the INFRAS system is a direct response to global pressures to reduce operational expenditures and improve sustainability. By using less energy for humidification and optimising cooling cycles, we are significantly lowering the total running cost for our clients, a key consideration in today's competitive market.

What is your growth strategy in emerging markets, and which regions are your current priorities?

Our growth strategy for emerging markets is centered on a "hub-and-spoke" model that combines our world-class manufacturing with strong partnerships. We manufacture our advanced equipment at our state-of-the-art facility in Nashik, India, and then rely on a network of trained, certified partners for installation,

validation, and crucial lifecycle support. This model is key to our success. Our current priority regions are South Asia, Africa, and



Central Asia. In these markets, having reliable, on-the-ground support is not just a value-add; it's a necessity. Local partners ensure our clients receive responsive service and technical assistance, overcoming logistical challenges and ensuring maximum uptime for their critical processes which is foremost for us since in pharma sector quality and service shapes the brand value of company. This combination of centralised

manufacturing excellence and decentralised support allows us to deliver reliability and peace of mind.

How is your company addressing ongoing challenges like supply chain disruptions and shifting regulatory frameworks?

We address these challenges with a two-pronged approach focusing on operational resilience and forward-looking design. To mitigate supply chain disruptions, we have implemented a multi-vendor sourcing strategy for all critical components, which prevents over-reliance on any single supplier. We also maintain strategic safety stocks for long-lead-time items to buffer against unexpected delays. To navigate shifting regulatory frameworks, our equipment is designed for adaptability. Our modular designs and software which is mostly customisable allows for easier upgrades and service, while our focus on digital traceability ensures our systems are aligned with the principles of Pharma 4.0 and data integrity expectations from global regulators. This proactive approach ensures

our clients are well-prepared for both current and future compliance demands.

Are you announcing any new partnerships, distribution tie-ups, or co-development agreements at CPHI?

CPHI is always a catalyst for new collaborations, and this year is no different. We are in several active discussions to expand our global footprint through new regional distribution partnerships and strategic co-development agreements. These conversations, many of which are initiated or advanced here at the event, are focused on integrating our core technologies into new applications and entering new markets. While we are not making formal announcements at this exact moment, we anticipate finalising several of these agreements in the near future. Any official announcements will be made through our corporate channels and our social media profiles, so we encourage everyone to stay connected with us there, and at last as always, "We are there with you."

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The next-generation of manufacturing: Smarter, faster, greener

Jhankar Dutta, Regional MD – Southern and Eastern Asia, B&R Industrial Automation explains that India's pharma industry stands on the brink of a manufacturing revolution. As automation, digital intelligence, and sustainability converge, the sector is moving from mass production to smart, adaptive and eco-efficient manufacturing

India's pharmaceutical sector is at a defining crossroads. Long regarded as the "pharmacy of the world," the industry has built its reputation on scale and efficiency. But the next phase of growth demands a different playbook — one that prioritises innovation, intelligence, and sustainability.

The transition from capacity-led expansion to capability-driven excellence is ushering in a new era of manufacturing — one that is smarter, faster, and greener.

Efficiency alone no longer defines success. The future lies in precision, agility, and sustainability.

At the same time, global pressures and technological shifts are accelerating the evolution of pharma manufacturing. Regulatory scrutiny is intensifying, while patients increasingly expect personalised therapies and faster delivery. In this new paradigm, manufacturers must produce smaller batches with higher flexibility — while meeting the same rigorous standards of quality, compliance, and cost efficiency. Adopting next-generation automation technologies is no longer optional; it is essential for competitiveness.

The challenges of change

However, this transformation is not without hurdles. Traditional, linear production systems were never designed for today's high-mix, low-volume environments. Frequent product changeovers, short runs, and the need for real-time data expose inefficiencies that can hinder both productivity and profitability.

Another key challenge lies in digitalisation. Integrating intelligence into every stage of production while maintaining com-



Efficiency alone no longer defines success. The future lies in precision, agility, and sustainability

pliance with GAMP and FDA 21 CFR Part 11 regulations demands a cohesive approach. The shift requires more than upgrading machines — it calls for reimagining how data, processes, and people work together.

Technologies enabling the shift

At the heart of this transformation is mechatronic automation — the convergence of mechanics, electronics, and software. This integration allows production systems to adapt instantly to different SKUs, packaging formats, or batch sizes, enabling

precision and flexibility at scale.

Digital connectivity is equally critical. Leveraging open communication standards like OPC UA and MQTT, manufacturers can achieve full transparency from the shop floor to enterprise systems. Predictive maintenance and remote diagnostics further reduce downtime and boost agility.

Proven solutions for a smarter tomorrow

B&R's proven portfolio demonstrates the readiness of next-generation automation and enable the future of Indian pharma to be built on intelligent, adap-

tive and sustainable automation:

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OPC UA FX (Unified Architecture for Field eXchange, UAFX) marks a fundamental shift in industrial connectivity. portfolio includes X20 controllers, bus controllers, industrial PCs, panel PCs and a TSN machine switch

The smarter, faster, greener reality

Across more than 80 countries, B&R's technologies have reduced mechanical wear by 40 per cent, accelerated time-to-market by 30 per cent, and improved productivity through digital intelligence.

India's pharmaceutical sector now can set global benchmarks by merging scientific expertise with advanced automation. The convergence of mechatronic design, data connectivity, and sustainability will define the next chapter of progress — one where every batch is precise, every process efficient, and every facility resilient.

The future of manufacturing is not about producing more — it's about producing smarter, faster and greener.

Delivering precision and sterility at scale

SCHOTT Poonawalla, a ₹1,000+ crore powerhouse, has emerged as a trusted partner in India's injectable packaging landscape



Leadership team, left to right: Rakesh Patel, CHRO, Ashok Saxena, Managing Director, Sangeetha Shenvi, Sr. Vice Presidente Sales and Marketing (standing), Ajith Kumar, Director Operations, Rohit Sarmalkar, CFO

India's pharmaceutical industry is on an upward curve, fuelled by rising demand for vaccines, biologics, and advanced therapies. As focus sharpens on the packaging that protects these critical medicines, SCHOTT Poonawalla (SPPL) emerges as a trusted partner in the country's injectable packaging landscape.

End-to-end solutions

SPPL designs advanced drug containment and delivery solutions for pharmaceutical and biotechnology customers. The company's portfolio features a large range of products including cartridges for auto-injector pens and pre-fillable syringes

for a wide variety of biologics in addition to large quantity of vials and ampoules. The company also provides regulatory services for a diverse base of more than 200 customers including top biotech and pharmaceutical companies, and contract development and manufacturing organisations (CDMOs).

What began as a modest venture over 30 years ago has now evolved into a ₹1000+ crore powerhouse in India's injectable packaging landscape. This leap didn't happen overnight. It was driven by strategic investments in capacity, technology, and advanced inspection systems. With three state-of-the-art, fully

automated manufacturing facilities to introduction of ready-to-use packaging formats, SPPL has led the industry in delivering precision and sterility at scale.

Growth: Future-ready solutions

The company has the largest manufacturing footprint for vials and ampoules. In recent years, they have strategically scaled up their pre-fillable syringes (PFS) and cartridges portfolio, aligning with the rising demand for advanced drug delivery systems in high-growth areas like vaccines, GLP-1 therapies, oncology, and biosimilars.

It has also invested heavily in

high-speed forming lines for PFS and cartridges and sterile processing lines for PFS and continues to invest in state-of-the-art manufacturing lines. With India's pharmaceutical sector booming, these investments are perfectly timed.

"Now more than ever, our pharma partners are relying on SPPL to supply next-generation cutting-edge drug delivery solutions, as they continue to innovate, expand operations and supply complex drugs," says Ashok Saxena, Managing Director, SCHOTT Poonawalla.

Strategic partnerships

Innovation capabilities and pure-play focus on injectables of

its parent company, SCHOTT Pharma, Germany helps bring the best-in-class products to Indian companies. The company's journey has been further accelerated by the recent strategic investment from TPG Growth, alongside SCHOTT Pharma and Serum Institute of India (SII). This partnership brings strategic insight to fuel the company's next phase of growth.

As India continues to cement its role as the pharmacy to the world, SPPL remains proud to be the trusted partner behind that promise, ensuring safe, high-quality injectable packaging that travels from the factory to the hands of patients, consistently and reliably.

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- Reactive extrusion



type	screw diameter (mm)	torque screws (Nm)	screw speed (rpm)	drive power (kW)	L x W x H (approx. mm)
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ZSE 12 HP-PH	12	20	1,000	2	1,500 x 700 x 1,200
ZSE 18 HP-PH	18	71	1,200	7.1	2,290 x 700 x 1,270
ZSE 27 HP-PH	27	268	500 & 1,200	15	3,650 x 1,150 x 1,800
ZSE 40 HP-PH	40	830	400	37	4,000 x 1,400 x 2,100
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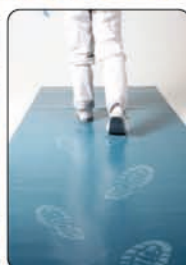
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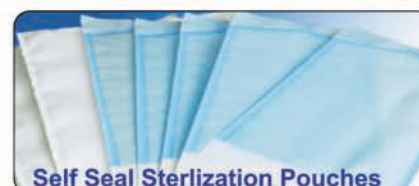
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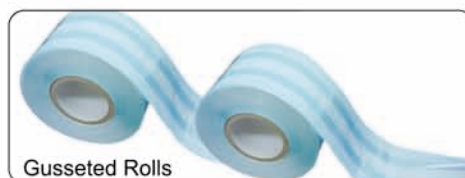
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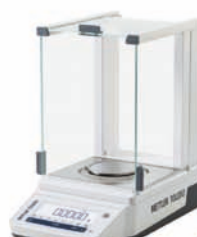
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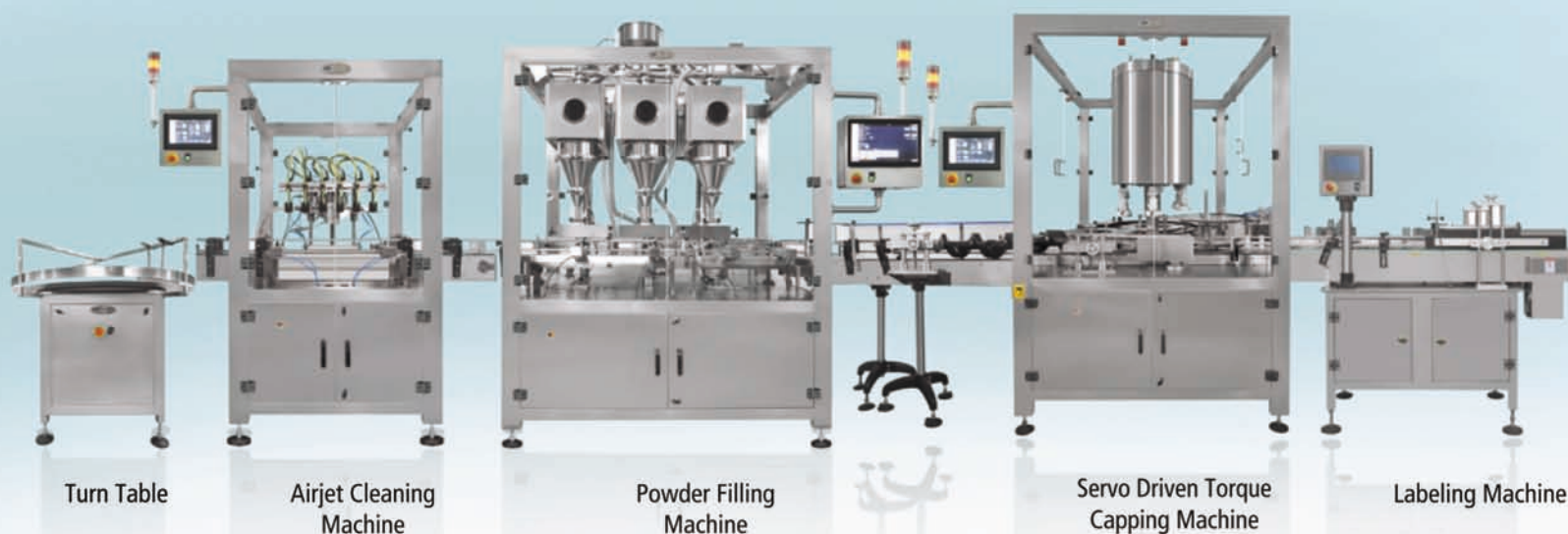
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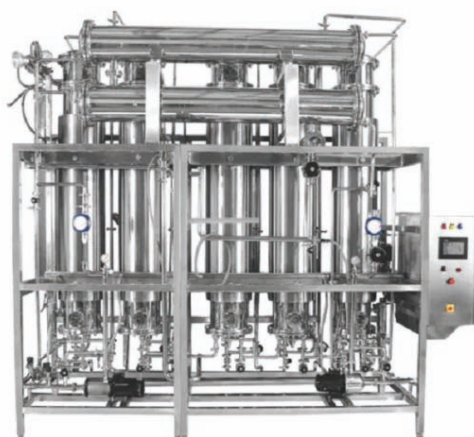
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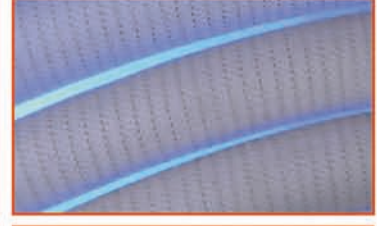
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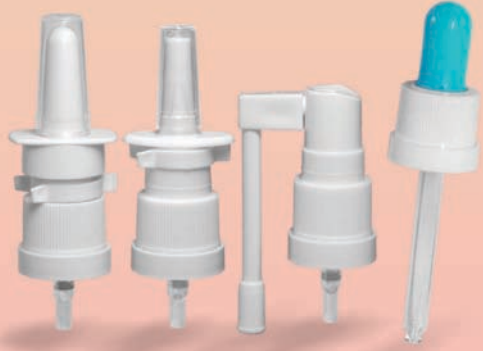
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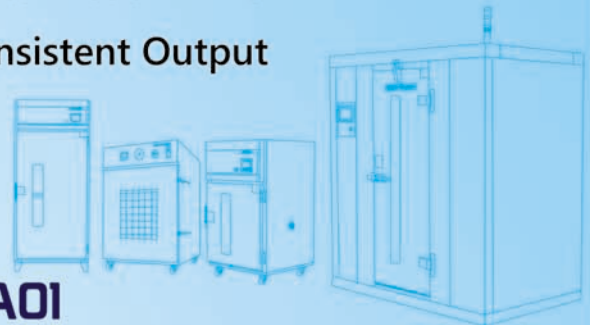
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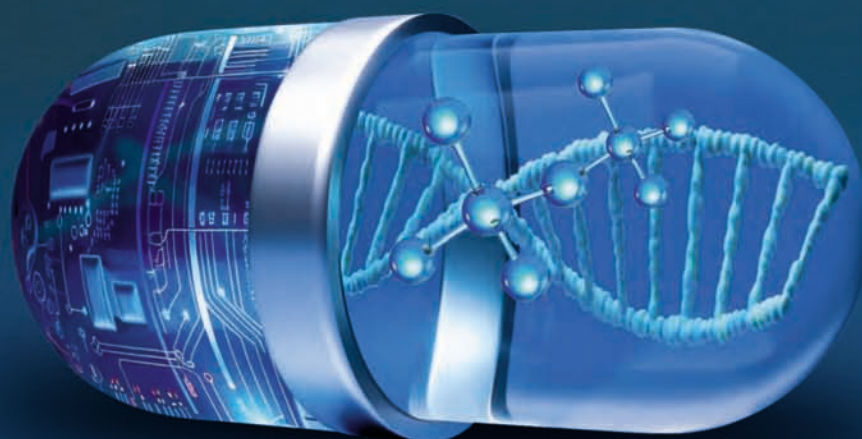


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SaniSure introduces integrated single-use solutions to streamline bioprocessing operations

Mixed4Sure™, One2Fill™, Fill4Sure™, and RC-40™ form a unified ecosystem designed to optimise biopharmaceutical manufacturing efficiency and reliability

In a biopharmaceutical landscape defined by speed, precision, and reliability, SaniSure has emerged as a trusted global partner for single-use technologies. Its integrated solutions help manufacturers simplify operations, accelerate timelines, and reduce contamination risks across every stage of production.

With an expanding portfolio of end-to-end fluid management systems, SaniSure enables customers to bring therapies to market faster through innovations engineered for consistency and performance. Four technologies stand out: Mixed4Sure™, One2Fill™, Fill4Sure™, and RC-40™ — forming a unified ecosystem that is transforming single-use manufacturing.

Mixed4Sure™: Clean mixing for complex challenges

Biopharmaceutical mixing demands homogeneity without compromising sterility or damaging sensitive components. Mixed4Sure™ delivers this balance through a patented low-shear mechanism that ensures uniform blending of media, buffers, and suspensions in a closed, single-use environment.

Eliminating cleaning validation and cross-contamination risk, Mixed4Sure™ supports scalability from R&D to GMP manufacturing in volumes from 10 L to 1,000 L. Integrated sensors for pH, conductivity, and temperature provide real-time process control. The result is faster turnaround and consistent quality — redefining simplicity in bioprocess mixing.

One2Fill™: Automation that simplifies aseptic filling

In fill-finish, accuracy and sterility are paramount. One2Fill™ integrates SaniSure's proprietary tubing, closures, and connectors into a single closed-path system that automates aseptic



liquid filling.

Its flexible configuration allows customisation for both clinical and commercial environments, while gamma-sterilised, quick-connect assemblies shorten changeover time and eliminate operator exposure. The result: reduced contamination risk, improved reproducibility,

and GMP-compliant efficiency for every batch.

Fill4Sure™: Precision meets reliability

Designed for high-value biologics and vaccines, Fill4Sure™ provides controlled, repeatable dispensing with exceptional accuracy. Assemblies are built

from pharma-grade tubing and precision-engineered flow components, ensuring sterility through final closure.

When paired with SaniSure's bag and bottle assemblies, Fill4Sure™ delivers end-to-end confidence — a simple, scalable, and validated solution for manufacturers who demand flawless performance at every fill.

RC-40™: The next generation of reactor containment

Upstream success depends on containment integrity. The RC-40™ Reactor Containment System eliminates the ergonomic and contamination challenges of open bioreactors through a rigid yet lightweight design that enables rapid, sterile connection and disconnection.

Built for flexibility and operator safety, RC-40™ integrates viewing ports and sampling features for real-time monitoring. By replacing stainless-steel cleaning cycles with disposable assemblies, it reduces validation time and total cost of ownership — redefining containment for modern bioprocessing.

A unified ecosystem for end-to-end control

The true power of SaniSure's technology lies in integration. Mixed4Sure™, One2Fill™, Fill4Sure™, and RC-40™ connect seamlessly to cover the entire fluid management cycle:

- Mixing and formulation
- Transfer and storage
- Filling and final packaging
- Containment and process integrity

Standardised connection points and modular designs let manufacturers build customised workflows that reduce assembly time, streamline validation, and maintain sterility from start to finish.

This holistic approach embodies SaniSure's mission — to

simplify single-use systems so customers can focus on advancing life-changing therapies.

Engineering confidence through collaboration

SaniSure's innovation extends beyond its products. Its engineers partner closely with customer teams to design, prototype, and validate assemblies that meet specific process requirements.

From extractables testing to pressure validation and lifecycle documentation, SaniSure ensures every system meets global regulatory expectations. With manufacturing sites in North America, Europe, and Asia, the company offers redundant capacity and localised support to safeguard supply continuity.

Its guiding philosophy, "Engineered for Confidence," reflects an unwavering commitment to reliability, innovation, and customer success.

Driving the future of single-use technology

As the bioprocessing industry embraces flexibility, automation, and sustainability, SaniSure remains at the forefront — pioneering solutions that enable continuous manufacturing and faster time-to-market.

With Mixed4Sure™, One2Fill™, Fill4Sure™, and RC-40™, SaniSure delivers more than products; it provides a pathway to process simplification. Each system helps reduce risk, cut costs, and accelerate the production of critical therapies worldwide.

In an era where every molecule and every batch matters, SaniSure ensures that innovation and reliability go hand in hand — empowering manufacturers to deliver with precision, purity, and purpose.

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Turnkey solutions in aseptic manufacturing

Optima Pharma offers integrated fill-and-finish systems designed and qualified for regulatory compliance, operational efficiency, and ready-to-implement deployment

The pharmaceutical and biotech industries are facing increasingly complex requirements. Regulatory frameworks such as EU GMP Annex 1, evolving product portfolios, and the need for flexible, contamination-free production environments demand a paradigm shift toward integrated system solutions. In this context, turnkey concepts, particularly in aseptic fill-and-finish processes involving isolators and freeze-drying, are gaining strategic importance.

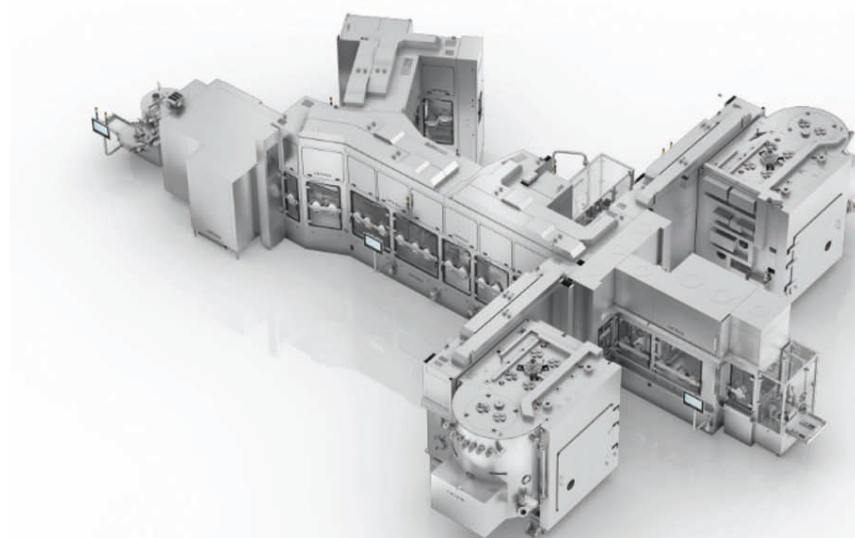
Turnkey in the context of aseptic processing

Turnkey solutions in pharmaceutical manufacturing refer to the delivery of a fully integrated, pre-tested, and qualified system from a single source. This includes the filling line, isolator, and, where applicable, the freeze dryer - designed and developed as a functional unit. Unlike conventional approaches, where components are procured separately and integrated on-site, turnkey systems are engineered holistically, with coordinated mechanical, software, and control interfaces.

This approach significantly reduces project complexity, minimises risk, and shortens the time to production readiness. At the same time, it ensures that the system meets regulatory requirements prior to installation, simplifying qualification and validation processes.

Digital engineering as the foundation for system integration

A key element of modern turnkey solutions is digital engineering. Simulation tools are used early in the project phase to model airflow, temperature distribution, and decontamination cycles using vaporised hydrogen peroxide (VHP). These



OPTIMA MultiUse line with fully integrated isolator and freeze-dryer

Pharma and biotech manufacturers are shifting toward turnkey aseptic systems to meet regulatory and process requirements. Optima Pharma provides fully integrated fill-and-finish solutions, supported by digital engineering, pre-delivery qualification, and lifecycle support

simulations enable precise injector positioning and cycle parameterisation, ensuring compliance with Annex 1 requirements - particularly regarding laminar airflow and product contact surfaces.

The consistency between simulation results and physical smoke studies underscores the reliability of this approach. Potential weaknesses can be identified and resolved early, enhancing system stability and regulatory conformity.

In-house testing and qualification: minimising risk before delivery

Optima Pharma's Comprehensive Scientific Process Engineering (CSPE) concept, implemented at its Schwäbisch Hall facilities, enables extensive testing prior to delivery. This includes verification of cable connections, safety circuits, isolator leak tests, and validation of software functionality across the entire system. The automation architecture, including SCADA

integration, is also reviewed according to defined procedures to ensure readiness for integrated Factory Acceptance Testing (iFAT).

The qualification strategy, known as "leveraging", allows reuse of qualification documentation (IQ/OQ) created at Optima. Only interfaces separated for transport require requalification at the customer's facility. This significantly reduces validation effort and accelerates commissioning.

Project coordination and lifecycle support

A dedicated project manager at Optima oversees all phases - from planning and engineering to installation and lifecycle support. This reduces coordination effort on the customer side and enables faster system implementation in cleanroom environments.

Operator training is delivered through structured programs tailored to specific roles. These include online modules, hands-on instruction at the machine, and certified training - either at Optima or directly on-site. This ensures that production teams are fully prepared from day one.

Continuous innovation and outlook

Turnkey systems are subject to ongoing development. Optima Pharma employs innovative methods such as enzymatic indicators for cycle development, which deliver faster and more precise results. The internal organisation has also been adapted to ensure that experienced experts in filling, containment, and freeze-drying are involved from the moment a project is initiated. The future goal is to deliver fill-and-finish systems that are not only fully qualified but also nearly "ready for media fill" upon arrival. This vision reflects a further reduction in commissioning time and increased operational reliability.

Turnkey solutions are setting new standards in aseptic pharmaceutical manufacturing. By integrating engineering, qualification, and lifecycle support into a consistent process, they offer a reliable path to regulatory compliance and operational efficiency. With over 15 years of experience and two dedicated CSPE centers, Optima Pharma is a proven partner for the implementation of demanding turnkey projects - including for the growing Indian pharmaceutical market.

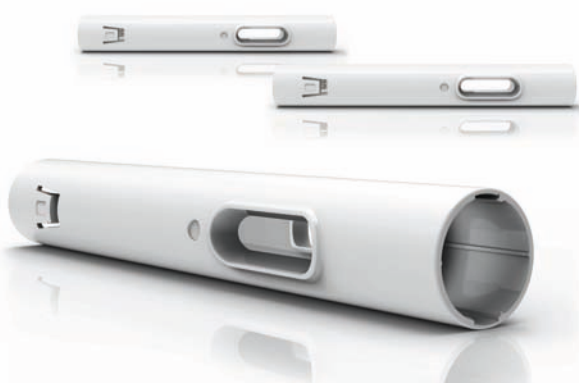
ZAHORANSKY launches Z.SONIC turn mold concept for pen and autoinjector housing production

ZAHORANSKY presents Z.SONIC turn for increased output and reduced cycle times in injector component manufacturing

With Z.SONIC turn, ZAHORANSKY introduces a mold concept that significantly accelerates the large-scale production of housings for pen and autoinjectors while also making it more energy- and space-efficient. Against the backdrop of dynamically growing demand for such injectors – primarily due to the rapidly growing market for GLP-1 medication – Z.SONIC turn offers manufacturers an effective possibility to make the best possible use of their production capacities. Depending on the application, the solution enables cycle times to be reduced by up to 30 per cent, increases output by around a third, and reduces manufacturing costs per part by a good 20 per cent. Sample ROI (return on investment) calculations also show that the investment can be amortised after approximately nine months, which is significantly faster than with conventional molds. Z.SONIC turn was presented to the public for the first time at K 2025 at the NETSTAL booth. The mold concept was part of a production line with the ELION MED injection molding machine and hot halves with servo-electric needle valve control from EWIKON.

Rotate, remove, re-inject – without any loss of time

At the heart of Z.SONIC turn is an advanced indexing technology that shifts part of the residual cooling away from the mold and makes part removal cycle-neutral. While the mold remains closed, an integrated rotary unit takes over the positioning for removal. At the same time, the



The end product: housings for autoinjectors and pens

next shot is already starting. In the application shown at the trade fair – a four-cavity mold for autoinjector housings – a cycle time of around twelve seconds was achieved. The compact design also re-

duces the mass of the mold by around 1,000 kilograms compared to conventional solutions. This shortens heating times, reduces the energy required, and simplifies the design, as complex relative

movements are no longer necessary. “Many visitors told us that Z.SONIC turn was the most innovative application at the trade fair for them. They were particularly impressed by the seamless interaction between the machine, mold, and automation,” says Simon Hug, Head of Global Account Development at ZAHORANSKY.

Higher output, lower unit costs, smaller footprint

The advantages are immediately reflected in the key figures: Compared to a conventional mold concept, the annual output in a sample calculation increases from approximately 8.5 million to over 12.8 million parts, while unit costs decrease by 23 per cent. Despite a higher initial investment, the payback period is reduced to around nine months. At the same time, the compact, lighter design takes up less space and energy – a plus, especially in cost-intensive clean rooms. With Z.SONIC turn, ZAHORANSKY delivers a future-proof, scalable solution for manufacturers of pen and auto-injectors who want to quickly expand their capacities while increasing overall equipment effectiveness. “Our approach is to focus on smart technologies rather than on more and more cavities. With Z.SONIC turn, we are demonstrating what ZAHORANSKY stands for: innovation in action, consistently geared towards performance and quality,” summarises Simon Hug.

Background information ZAHORANSKY

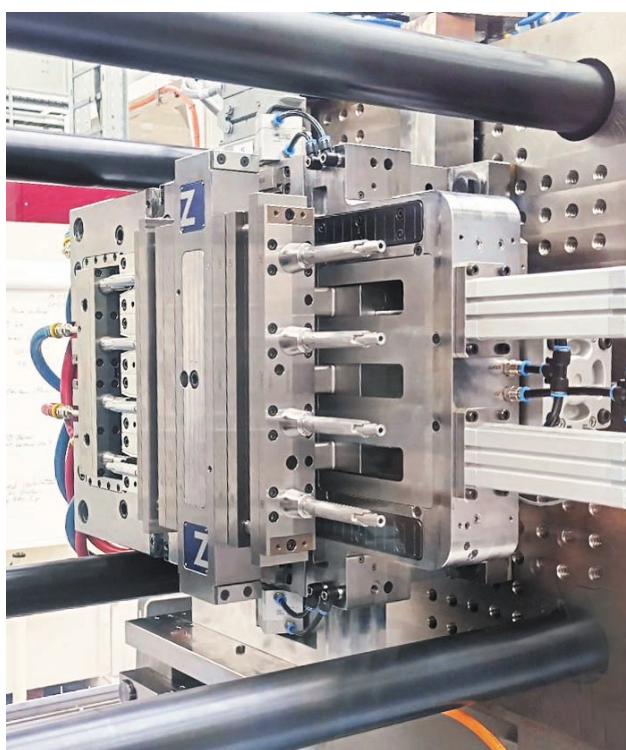
ZAHORANSKY AG is known for cutting-edge technology in

machine engineering and mold making for over 120 years and is today an internationally active technology provider which is 100 per cent family owned. Based on decades of experience combined with foresight and a culture of innovation, ZAHORANSKY is a full-service provider and technology partner for companies in the brush industry, medical technology and other sectors. Market-leading manufacturers of oral care and cosmetic products, producers of household and industrial brushes as well as pharmaceutical companies worldwide rely on the comprehensive consulting, development and service expertise of ZAHORANSKY.

One of the company's proven strengths: on request, ZAHORANSKY provides customers with complete solutions from a single source for the manufacture of complex plastic, hybrid and glass replacement products. This includes injection molds, upstream and downstream automation solutions and quality control as well as the integration of injection molding machines and other system components for turnkey, fully automated production lines. About 690 people are employed at our headquarters in Germany and the sites in Spain, China, India, Japan, Brazil and the USA.



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Innovative mold concept from ZAHORANSKY – the Z.SONIC turn

Flexotherm Heating Tapes & Cords

Tempo's Flexotherm heating tapes and cords provide a safe, flexible, and efficient solution for maintaining solvent temperature across a wide range of industrial processes

Typical applications of heating tapes and cords in industrial solvent handling

Handling and processing solvents in industrial environments requires precise temperature management. Many solvents are sensitive to fluctuations—too cold, and they may thicken or crystallise; too hot, and they may degrade or evaporate. Tempo's Flexotherm™ heating tapes and cords provide a safe, flexible, and efficient solution for maintaining solvent temperature across a wide range of industrial processes.

Why tempo heating tapes and cords?

Unlike bulky heating systems, Tempo heating cords and tapes are thin, robust, and easy to

Unlike bulky heating systems, Tempo heating cords and tapes are thin, robust, and easy to wrap around drums, pipes, valves, or vessels

wrap around drums, pipes, valves, or vessels. They deliver uniform heating, reduce the risk of cold spots, and can be paired with Tempo's digital or thermostatic controllers for precise monitoring and safe operation.

Typical applications in solvent handling

1. Drum and container heating: Solvents stored in poly or metal drums can become viscous at low temperatures. Tempo drum heating jackets and tapes keep contents at the

right viscosity for safe pumping, mixing, or decanting.

2. Pipeline and transfer line heat tracing: Solvent transfer lines are prone to cooling and blockages. Flexotherm™ heat tracing cords maintain consistent flow and prevent condensation or freezing.

3. Valve and flange heating: Critical fittings often act as cold spots. Tempo heating tapes eliminate these risks, ensuring solvents move smoothly through the system.

4. Reactor and vessel heating: In chemical processing, Tempo

customized heating solutions wrap neatly around reactors, tanks, or vessels to deliver controlled, uniform heating.

5. Laboratory solvent applications: From Soxhlet extractors to heating mantles, Tempo lab heating products support safe solvent extraction, distillation, and analysis.

6. Gas cylinder warming: For solvent-related gases such as SF₆, propane, or nitrogen, Tempo cylinder warmers improve pressure stability and minimise losses due to condensation.

Advantages with Tempo solutions

- **Viscosity control:** Prevents thickening, crystallisation, or freezing of solvents.
- **Energy efficiency:** Localised heating ensures minimal energy loss.
- **Safety:** Avoids leaks and blockages from cold solvent lines.
- **Flexibility:** Easy to install on pipelines, drums, reactors, or valves.

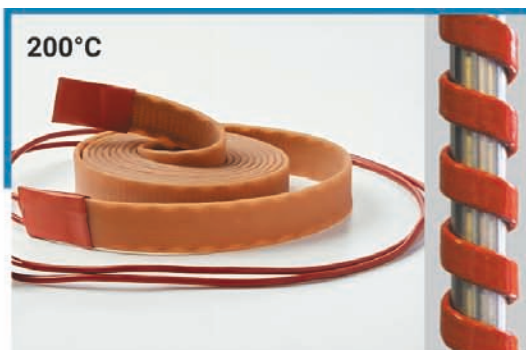
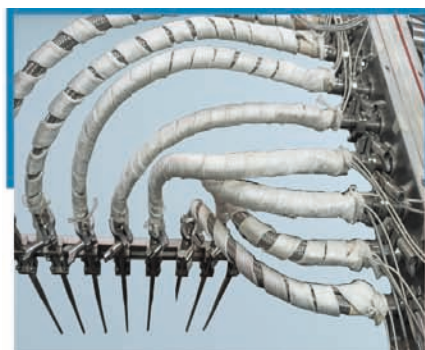
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Empowering pharmaceutical manufacturing with advanced process solutions by GOMA

With over three decades of engineering expertise, GOMA has expanded its footprint from dairy and food processing to the pharmaceutical and biotech sectors, catering to both formulation and sterile processing applications

The pharmaceutical industry is evolving rapidly, with increasing demand for precision, compliance, and automation in manufacturing processes. As India continues to strengthen its position as the global pharma hub, the need for reliable, hygienic, and technologically advanced process systems has become paramount. GOMA Process Technology Pvt. Ltd., a part of the GOMA Group, stands at the forefront of this transformation — delivering world-class pharmaceutical and biopharma process solutions designed for efficiency, scalability, and regulatory excellence.

Driving innovation in pharma manufacturing

With over three decades of engineering expertise, GOMA has expanded its footprint from dairy and food processing to the pharmaceutical and biotech sectors, catering to both formulation and sterile processing applications. The company's integrated capabilities encompass design, fabrication, automation, installation, and validation — offering turnkey solutions tailored to GMP and international quality standards.

GOMA's expertise in the pharmaceutical sector

GOMA's deep understanding of pharmaceutical process requirements positions it as a trusted partner for leading pharma and biopharma companies. The company specialises in delivering equipment and systems that meet the highest standards of sterility, precision, and compliance, ensuring seamless operation across all production stages — from

formulation to final product.

Key highlights of GOMA's pharmaceutical expertise include:

- **Regulatory-compliant design:** All systems are engineered in adherence to cGMP, US-FDA, and WHO-GMP standards.



infrastructure — enabling consistent product quality, higher throughput, and shorter validation timelines.

Comprehensive product portfolio

High pressure homogenizers (10-20000 LPH Upto 2000 Bar): Designed for precise particle size reduction and uniform emulsification, ensuring consistency in suspensions, emulsions, and lipid-based formulations.

High shear mixing tank: Facilitates rapid mixing, emulsifying, and dissolving operations, ideal for creams, lotions, oral liquids, and sterile solutions.

Evaporators and spray dryer: Engineered for controlled concentration and drying processes, ensuring stable, pure, and uniform end products with optimised energy use.

CIP/SIP system: Automated cleaning and sterilisation systems for maintaining hygiene, minimising downtime, and ensuring contamination-free operation.

Emulsion plant: Complete system for producing stable emulsions used in ointments, lotions, and oral suspensions, offering consistent droplet size and texture.

Liquid/syrup oral processing plant: Comprehensive setup for manufacturing oral liquids and syrups, equipped with controlled mixing, heating, and filtration features.

Ointment/cream processing plant: Designed for precise homogenization and uniform blending of semi-solid formulations under hygienic and controlled conditions.

Injectable sterile manufacturing vessel: Specialised for aseptic formulations, maintaining sterility and integrity during the entire production process.

Reactors: Versatile and robust, suitable for chemical synthesis, reactions, and temperature-sensitive formulations under GMP conditions.

Collection/fermentation tanks: Optimised for microbial growth and fermentation processes, ensuring temperature, pH, and oxygen control for biopharma applications.

PHE/THE (Plate & Tube Heat Exchangers): Efficient heat transfer systems used for



- **Automation and validation:** PLC and SCADA-controlled systems ensuring traceability, data integrity, and 21 CFR Part 11 compliance.

- **Custom engineering:** Tailor-made designs for R&D, pilot, and commercial production setups.

- **Aseptic manufacturing competence:** Specialised in sterile processing lines for injectables, oral formulations, and biopharmaceuticals.

- **Process efficiency and sustainability:** Equipment designed to reduce energy consumption, optimise yield, and minimise product loss.

With a strong in-house design and automation team, GOMA ensures every solution integrates seamlessly into the client's existing production



controlled heating and cooling across sterile and non-sterile processes.

Turnkey solutions with product and service piping: End-to-end integrated setups including product transfer, utility piping, and automation—ensuring streamlined process flow and operational efficiency.

Each solution is built with pharma-grade stainless steel, precision instrumentation, and PLC-based automation for data integrity and compliance with FDA, EU-GMP, and WHO standards.

Supporting businesses with scalable and compliant solutions

GOMA's systems are designed to help pharmaceutical manufacturers optimise productivity, reduce process variability, and achieve higher yields — all while maintaining the highest standards of sterility and safety. The company's engineering expertise enables customisation for both pilot-scale R&D setups and large-scale commercial facilities, ensuring flexibility at every stage of production.

By integrating automation, hygienic design, and validation-ready documentation, GOMA empowers pharmaceutical companies to accelerate production cycles, ensure reproducibility, and minimise down-



time — crucial factors in a highly regulated industry.

GOMA: Partnering in pharmaceutical excellence

As the pharmaceutical sector continues to advance toward precision-based and sustainable manufacturing, GOMA remains committed to supporting this evolution through continuous innovation, process optimisation, and technology advancement. By combining engineering excellence with domain expertise, GOMA is enabling India's pharmaceutical ecosystem to achieve global manufacturing standards with confidence.

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Pharma manufacturing faces renewed focus on humidity control and HVAC compliance

Leading HVAC solution providers, such as Bry-Air, have responded to these industry needs with systems specifically designed for pharma validation environment

Environmental control remains one of the most scrutinized areas in pharmaceutical manufacturing, especially as global regulators increase their focus on HVAC system validation. Whether in a tablet coating suite or a sterile filling room, maintaining tight control over temperature and humidity is essential, not only for product quality but also for regulatory compliance under GMP, WHO, and ISO 14644 guidelines.

Recent high-profile recalls and warning letters have underscored just how critical precise humidity control has become. In 2023, U.S. based drugmaker in the tourist state of Goa in western India recalled over 7 million bottles after complaints of foul odor led investigators to uncover water stagnation and hygiene lapses at its Goa plant.

That same year, a leading pharma brand received a U.S. FDA warning letter for allowing relative humidity to exceed limits during softgel production without sufficient corrective action.

Relative humidity (RH) control, in particular, plays a critical role in ensuring product stability and preventing microbial

contamination. Yet, achieving consistent RH, especially across large cleanroom environments, remains technically complex. Qualification protocols such as IQ, OQ, and PQ often expose weaknesses in system design or calibration. Engineers are under pressure to demonstrate uniformity, precision, and traceability.

Modern desiccant dehumidification systems have begun closing this gap. Engineered for pharma environments, these systems can deliver RH levels as low as 20% or dew points reaching -40°C, enabling manufacturers to meet stringent validation targets. Some solutions also integrate with building manage-

ment systems and provide automated traceability logs, streamlining both audit readiness and ongoing compliance.

In a recent example, a WHO GMP-compliant packaging suite required RH control at 25% $\pm$ 3% across varying seasonal conditions. A desiccant dehumidifier system—validated across IQ,

OQ, and PQ phases—was able to meet this specification consistently, while also reducing RH variance to within $\pm$ 2%.

Leading HVAC solution providers, such as Bry-Air, have responded to these industry needs with systems specifically designed for pharmaceutical validation environments.



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As India celebrates its 75th Independence Day, Express Pharma recalls some trials and triumphs which led to its rise as the Pharmacy of the world.

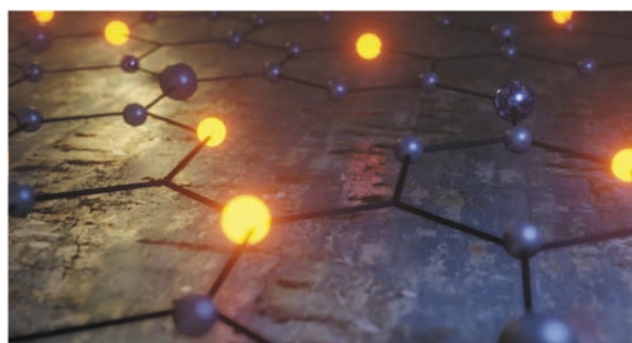
From batteries to biosensors: Conductive polymers make the jump to commercial applications

Hina Goyal, Information Scientist, ACSI India, shares how conductive polymers — a revolutionary class of organic materials that combine the electrical properties of metals and semiconductors with the flexibility of conventional polymers — are transforming research and commercial applications in biomedicine and beyond

Conductive polymers represent a revolutionary class of organic materials that have transformed our understanding of polymeric systems. These materials combine the electrical properties of metals and semiconductors with the mechanical flexibility and processing advantages of conventional polymers. Prior to the 1970s, polymers were universally considered to be electrical insulators. However, the pioneering work of Hideki Shirakawa, Alan MacDiarmid, and Alan Heeger revealed that polyacetylene doped with bromine demonstrated conductivity one million times higher than its pristine form. This earned them the Nobel Prize in Chemistry in 2000 and marked the beginning of the conductive polymer era.

Today, this technology is used in commercial applications with important advances happening in biomedicine. We analysed the CAS Content Collection™, the largest human-curated repository of scientific information, and found publications relating to conductive polymers have increased steadily in the last 30 years (see Figure 1).

The consistent dominance of journal articles throughout the timeline demonstrates sustained



fundamental research interest, while the robust patent activity reflects significant industry investment and commercial viability. Noteworthy is the balanced ecosystem between academic research and commercial development, with journal articles comprising 59 per cent and patent families representing a substantial 41 per cent of total publications. This indicates an exceptional translation from laboratory discoveries to market-ready applications.

Let's take a closer look at how innovations in the formulation and processing of these materials are changing biomedicine and beyond:

Conductive polymers in energy storage systems and more

The fundamental structure of

conductive polymers consists of a conjugated carbon backbone with alternating single (s) and double (p) bonds, where the highly delocalised, polarised, and electron-dense p-bonds are responsible for their remarkable electrical and optical behavior. Key parameters affecting the physical properties of conductive polymers include conjugation length, degree of crystallinity, and intra- and inter-chain interactions, with these materials exhibiting crystalline and partially amorphous characteristics.

A critical factor in enhancing their conductivity is doping, which introduces additional charge carriers, either electrons (n-type) or holes (p-type), into the polymer matrix. This process generates quasi-particles that facilitate charge transport along and between polymer chains, dramatically increasing electrical conductivity. Doping also modifies the electronic structure and can influence the polymer's morphology, stability, and optical properties, making it an essential tool for tuning conductive polymers for applications in organic electronics, sensors, and energy storage devices.

Major conductive polymers that have gained significant attention include polyaniline (PANI), polypyrrole (PPy), polythiophene (PT), poly(3,4-ethyl-

enedioxythiophene) (PEDOT), polyacetylene (PA), poly(p-phenylene) (PPP), poly(p-phenylene vinylene) (PPV), polyfluorene (PF), polyfuran (Pfu), polyindole (PIN), and polycarbazole (PCz) (see Figure 2).

These materials offer substantial advantages over their inorganic counterparts, including chemical diversity, low density, mechanical flexibility, and corrosion resistance. They have controllable morphology and

ous processability and stable dispersion. Other notable conductive polymers include PT and its derivative Poly(3-hexylthiophene) (P3HT), which are central to organic electronics, especially in organic solar cells and organic field-effect transistors (OFETs) due to favorable charge transport properties.

PPV is primarily utilised in light-emitting technologies due to its semiconducting and electroluminescent properties.

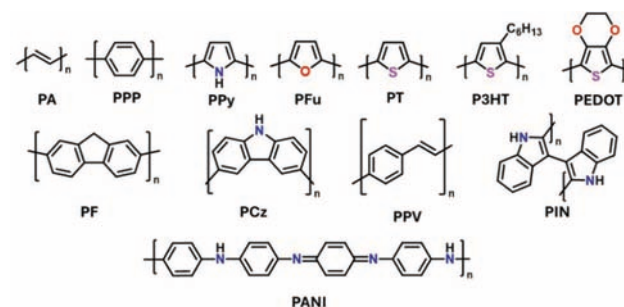


Figure 2: Chemical structures of most frequently used conductive polymers. See list of abbreviations, below, for reference

tunable conductivity to tailor their properties, and they feature self-healing capabilities, environmental stability, and cost-effectiveness.

Based on publication trends in the CAS Content Collection, it's clear that conductive polymers are used across many applications (see Figure 3). PANI, PPy, and PEDOT are the most studied and applied conductive polymers. These materials are integral to fields such as energy storage and conversion, chemical and biological sensing, protective coatings, and optoelectronics, owing to their tunable electrical properties, biocompatibility, and ease of processing.

PEDOT, particularly in its doped form PEDOT:PSS, is widely used in flexible electronics and transparent conductive films, benefiting from its aque-

Meanwhile, PPP, a rigid-rod polymer, finds applications in high-performance engineering, including aerospace, medical devices, and advanced display technologies, where mechanical strength and optical performance are critical. PA is renowned for its tunable electrical conductivity and ease of processing. Its applications span organic solar cells and OFETs, making it a key material in flexible, next-generation electronics.

If we compare journal publications to patents, we see that certain fields are more commercially mature than others (see Figure 4). Sensing applications lead in academic research but show only moderate patent activity, indicating potential challenges in translating research into commercial products. In contrast, energy storage

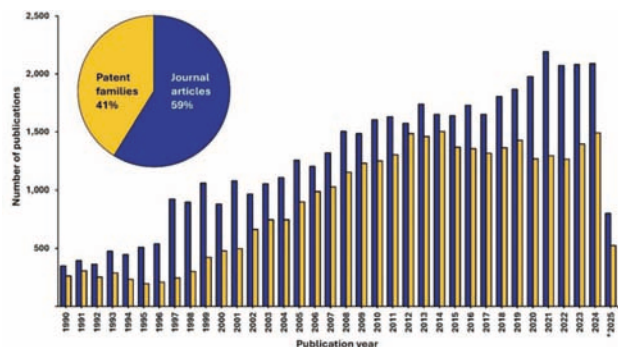


Figure 1: Publication trends in the field of conductive polymers. Source: CAS Content Collection. Note: data for 2025 is partial through May

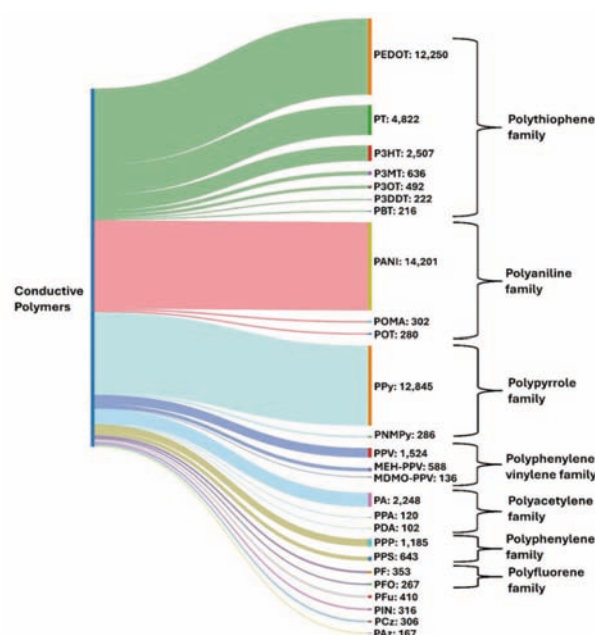


Figure 3: Number of documents for the most common conductive polymers. Source: CAS Content Collection. See list of abbreviations, below, for reference

applications, comprising supercapacitors, batteries, and solar cells, exhibit a strong alignment between research articles and patents, reflecting active commercial development.

Batteries and supercapacitors exhibit robust patent activity that reflects ongoing industrial investment. Other commercially mature applications include OLEDs and EMI shielding, where patent activity nearly matches or balances research output, demonstrating established market viability. Meanwhile, applications such as flexible electronics, wearables, and electrochromic devices remain in early commercialisation stages, despite growing research interest. Overall, the data

indicates that while conductive polymers have found their strongest commercial footing in energy storage and traditional electronics fields, significant untapped opportunities exist in other areas.

Conductive polymer breakthroughs in biomedical applications

One of the most promising frontiers for conducting polymers lies in the biomedical field, where their unique combination of electrical conductivity, mechanical flexibility, and biocompatibility enables numerous innovative applications, such as biosensing, neural interfaces, artificial muscles, tissue engineering, and drug delivery. Recent

advances in conductive polymer formulation and processing now allow these materials to be injected into tissues or printed onto ultra-thin, elastic substrates, enabling seamless integration with living tissue. This breakthrough supports a new generation of bio-integrated electronics for applications such as in vivo biosignal recording, targeted neural stimulation, and closed-loop therapeutic systems.

Their soft, flexible nature eliminates the need for rigid packaging or invasive surgery, while also enabling localised drug release and wireless, passive sensing powered by body heat or motion. These innovations position conductive polymers as key materials for minimally invasive, intelligent biomedical devices.

The publication trend for conductive polymers in biomedical applications reveals a field that has undergone explosive growth (see Figure 5). Notably, the overall distribution shows 67 per cent journal articles versus 32 per cent patent families, indicating a research-dominated field with substantial commercialisation potential. This trend shows that conductive polymers in the biomedical field have transitioned from a niche research focus to a key application area poised for commercial investment.

We further analysed document trends for key biomedical applications of conductive polymers (see Figure 6A). Biosensors lead the field, showing the highest volume of academic and patent activity, reflecting strong research interest and commercial maturity driven by the demand for real-time, sensitive biomarker monitoring.

Bioelectrical stimulation and neural interfaces follow, where conductive polymers enable advanced electrodes and implants that integrate with tissue for applications like neural stimulation, cochlear implants, and retinal prosthetics.

Artificial muscles and implantable prosthetics exhibit a high patent-to-journal ratio, suggesting strong commercialisation potential. This may be attributed to how conductive polymers closely mimic natural muscle movements and facilitate intuitive, brain-controlled prosthetics through seamless neural integration.

Drug and gene delivery is an

emerging area where conductive polymers allow electrically triggered, localised therapeutic release. While antimicrobial coatings have fewer journal articles, their high patent-to-journal ratio suggests significant commercial potential, as conductive polymers provide active surfaces that disrupt microbial growth and reduce infection risks on implants and medical devices. Lastly, tissue engineering remains in early research stages, with conductive polymers used in scaffolds to stimulate cell growth and regeneration.

Overall, the data illustrates a clear progression from mature,

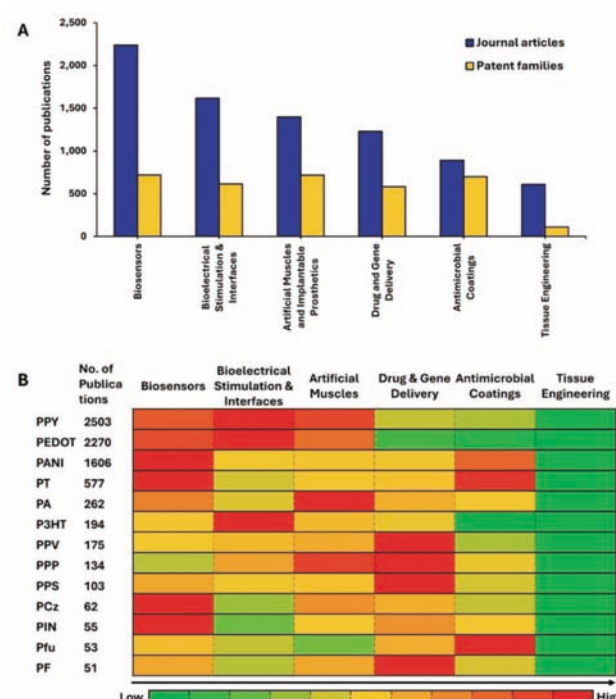


Figure 6: (A) Number of journal articles and patent families for conductive polymers in the biomedical field. (B) Heat map of the most frequently used conductive polymers across biomedical applications. Source: CAS Content Collection. See list of abbreviations, below, for reference

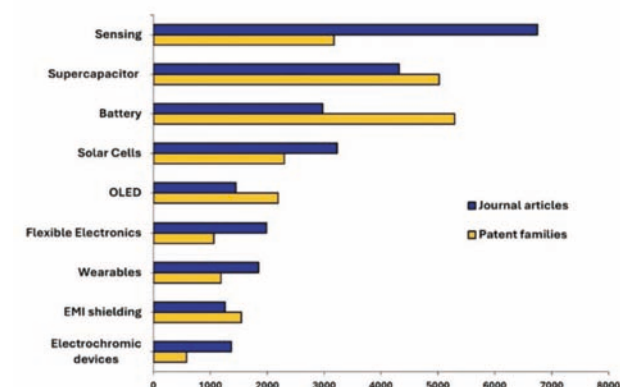


Figure 4: Number of journal articles and patent families for conductive polymer applications. Source: CAS Content Collection

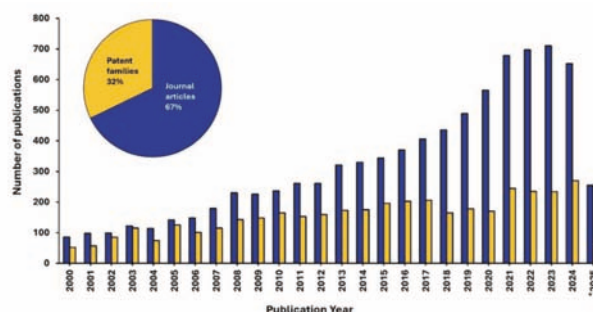


Figure 5: Publication trends in biomedical applications of conductive polymers. Source: CAS Content Collection. Note: data for 2025 is partial through May

commercially viable applications like biosensors to emerging research areas like tissue engineering, highlighting the expanding role of conductive polymers in biomedicine.

The heat map in Figure 6B illustrates the most used conductive polymers in various biomedical applications. PPy demonstrates exceptional versatility, showing high activity across biosensors, bioelectrical stimulation, and artificial muscles, making it a true workhorse

polymer for diverse biomedical applications. Similarly, PEDOT exhibits strong performance in biosensing and bioelectrical applications, reflecting its excellent electrochemical properties and biocompatibility that make it suitable for interfacing with biological systems.

PANI and PT show a unique application profile, with strong representation in biosensors but notably high activity in antimicrobial coatings, suggesting that their inherent antimicrobial properties make them valuable for infection-control applications. Additionally, PFu is also used in antimicrobial coatings, further highlighting the role of inherent antimicrobial characteristics in guiding application choices. PA is predominantly used in artificial muscles due to its ability to undergo shape changes in response to stimulation. Moreover, polymers such as PPV, PPP, PPS, and PF are primarily employed in drug and

gene delivery applications.

The data suggests that successful biomedical applications of conductive polymers often depend on matching specific polymer properties to application requirements, with some polymers serving as versatile platforms while others excel in specialised niches.

Challenges and future directions of conductive polymers

Despite their promising potential in various biomedical applications, conductive polymers face several critical challenges that are hindering more widespread use. A major concern is their biocompatibility, as many conductive polymers like PPy and PANI can trigger immune responses or degrade into toxic byproducts within the body. Additionally, their mechanical rigidity often doesn't match the soft, elastic nature of biological tissues, leading to poor integration

and potential device failure.

Conductive polymers can also suffer from environmental and electrical instability, particularly in the moist, ion-rich conditions of the human body, which can compromise long-term performance. Their electrical conductivity, while significant, still falls short compared to traditional metals, and maintaining stable doping levels remains a challenge. Furthermore, processing difficulties, such as poor solubility and challenges in forming uniform, and miniaturised structures, complicate biomedical device fabrication.

To address these limitations, researchers are developing composite systems by hybridising conductive polymers with biocompatible materials or nanostructures, aiming to enhance their mechanical flexibility, conductivity, and overall stability for safe and effective biomedical use. Continued research efforts are likely to result in more

breakthroughs that overcome challenges associated with biocompatibility, and conductive polymers may become an important feature of the biomedical field. Already well-established in energy storage and conversion applications, these remarkable materials may soon be in clinical settings as well.

Abbreviations used above include: PEDOT, Poly(3,4-ethylenedioxythiophene); PT, Polythiophene; P3HT, Poly(3-hexylthiophene); P3MT, Poly(3-methylthiophene); P3OT, Poly(3-octylthiophene); P3DDT, Poly(3-dodecylthiophene); PBT, Poly(2,2'-bithiophene); PANI, Polyaniline; POMA, Poly(2-methoxyaniline); POT, Poly(o-toluidine); PPy, Polypyrrole; PN-MPy, Poly(N-methylpyrrole); PPV, Poly(p-phenylene vinylene); MEH-PPV, Poly(2-methoxy-5-(2-ethylhexyloxy)-1,4-phenylenevinylene); MDMO-PPV, Poly(2-methoxy-5-(3,7-dimethyloctyloxy)-1,4-

phenylenevinylene); PA, Polyacetylene; PPA, Poly(phenylacetylene); PDA, Poly(diacetylene); PPP, Poly(p-phenylene); PPS, Poly(phenylene sulfide); PF, polyfluorene; PFO, Poly(9,9-dioctylfluorene); Pfu, Polyfuran; PIN, Polyindole; PCz, Polycarbazole; and PAz, Polyazulene.



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NEEDLES, PENS AND PRESSURE
THE GLP-1 CHALLENGE

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

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JULABO introduces Green Edition Refrigerated Circulators using natural refrigerants for sustainable lab cooling

JULABO launches its Green Edition range of refrigerated circulators designed to support laboratories in reducing carbon emissions, improving energy efficiency, and aligning with global environmental regulations

GREEN your lab, sustainable cooling with natural refrigerant

Labs today face mounting pressure to cut carbon emissions, save energy, and adopt greener habits. A key but frequently ignored source of harm is the cooling gear that keeps experiments on track. Responding to this need, JULABO—now a world authority in temperature management—unveils its Green Edition Refrigerated Circulators, marrying top performance with bold sustainability.

A visible commitment to a greener lab

JULABOs Green Edition circulators combine sleek, energy-wise technology with a standout green exterior, clearly marking your lab as a place that cares about the planet. They deliver a future-ready approach without los-

ing the precision or reliability you depend on every day. Whatever your workload—routine tasks, big projects, or anything in between—a Green Edition model is ready to step in:

1. JULABO CORIO CD Refrigerated / Heating Circulator—basic but bulletproof for everyday lab chores

2. JULABO CORIO CP Refrigerated / Heating Circulator—a robust upgrade that tackles a wider range of duties

3. JULABO DYNEO DD Refrigerated / Heating Circulator—highly adaptable for fast-paced, changeable setups

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unit that fits your setup perfectly.

Natural refrigerants for a healthier planet

Many common synthetic refrigerants cool machines well, but their Global Warming Potential is off the charts and damages the climate. JULABOs new refrigerated circula-

tors use natural coolants, cutting greenhouse gases. This greener move lines up with tightening rules like the EU F-Gas Regulation, keeping your plant compliant today and ready for tomorrow's laws.

Smarter energy use, substantial savings

Energy efficiency sits at the heart of a sustainable lab, and JULABO circulators are built with that goal in mind.

Their design includes:

1. Speed-controlled compressors and fans
2. Electronic expansion valves
3. Adaptive energy modulation that matches real demand. With these upgrades, models that cool at 800 W or above trim power use by as much as 70 percent.

The payoff is lower utility bills, a smaller carbon foot-

print, and a faster payback on your purchase.

Fast payback, long-term value

Yes, green gear may cost a little more at checkout, yet JULABOs circulators often clear that hurdle purely through cheaper electricity. For labs living on tight budgets and strict rules, that's a clear win: smoother operations and lighter overhead.

Final thought

Sustainability isn't just nice to have anymore; it has become an urgent must-do. JULABOs intelligent green refrigerated circulators help labs run perfectly while still doing their share for a cleaner planet. Let your cooling system join the growing team that works for both science and the environment.

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Pharma Technology Review
Making sense of specialisation

A TALE OF GRIT AND GLORY

As India celebrates its 75th Independence Day, Express Pharma recalls some trials and triumphs which led to the rise of the Pharmacy of the world.

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

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

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

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

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



state of controlled integrity, even under varying operational demands.

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

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

Prime Clean Reset is suitable for clean rooms up to ISO Class 5, offering an unparalleled air permeability rate of less than $12 \text{ m}^3/\text{m}^2 \text{ h}$ at $\pm 50 \text{ Pa}$. This ensures that even in the most sensitive environments, the door effectively maintains the critical pressure differen-

tials required to prevent contamination, thereby safeguarding your processes and products.

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

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



petitive edge in highly regulated markets.

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

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

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

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

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

- **Efficient Operation:** The doors offer high efficiency and low permeability values, compliant with EN 12426 and EN 12427 standards, ensuring $< 12 \text{ m}^3/\text{m}^2 \text{ h}$ $\pm 50 \text{ Pa}$.

- **Durable Control Device En-**

closure: The control device enclosure is made of Stainless-Steel SS 316, ensuring durability and resistance to corrosion.

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

For further information on our high-speed doors offering, contact:

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Romaco begins local format part production in India

The Noack N 950E blister packaging machine with Indian-produced format parts to debut at CPHI & PMEC India 2025, followed by installation at the Romaco India Experience Centre in Hyderabad

At CPHI & PMEC India in Delhi, Romaco will be exhibiting the Noack N 950E blister packaging machine, equipped for the first time with format parts from India. This marks the launch of format part production in India for Romaco Noack's blister packaging machines. The new strategic realignment will enable Romaco to dramatically shorten delivery times for format part production. After the trade fair, the N 950E will be ready for use as a test machine at the Romaco India Experience Centre.

Pharmaceutical machinery manufacturer Romaco is bolstering its presence in India and ensuring close proximity to customers by localising format part production for its Noack 900 blister packaging machine series. Users will benefit from shorter delivery times of these locally produced format parts, which will satisfy the same quality criteria as their European counterparts. Furthermore, the resulting reduction in transport mileage will have a positive impact on the carbon footprint of these machine components, which aligns perfectly with Romaco's sustainability strategy.

Since it was founded in 2019, the Sales & Service Centre Romaco India in Mumbai has enjoyed continuous growth. The official opening of the Romaco India Experience Centre in Hyderabad was a key highlight last year. This state-of-the-art customer and training centre also houses a processing laboratory, which pools Romaco's expertise in granulating, tableting and coating pharmaceutical solids.

The localisation of format part production heralds another significant milestone in the expansion of Romaco's position on the Indian market. This move will also boost sales of new machines – an area in which proximity to



N 950E blister packaging machine by Romaco Noack

customers is all-important. Following the presentation of the Noack N 950E at CPHI & PMEC India, the blister packaging machine will be made available to users and prospects at the

Experience Centre in Hyderabad. Here, the machine can be used for running in and testing new formats, as well as for foil tests and operator training sessions. It will also be possible to adjust existing formats locally in future.

Assembly of the N 950E also took place in Asia – at the Romaco plant in China. By expanding Romaco's production site in Changsha and localising format part production in India, Romaco will meet the requirements of its local customers and demonstrate its strong commitment to the Asian markets.

Romaco Noack N 950E blister packaging machine

The N 950E is an ultra-flexible, easy-to-use blister packaging machine with rotary sealing for the high-speed segment. The blisters can be conveyed both longitudinally and crosswise, with the machine achieving a maximum output of 500 blisters a minute. It has a compact design in which the individual stations, such as sealing, coding, perforation and die-cutting, are configured in a way that saves space. Therefore, the N 950E only takes up a very small footprint in the pri-



Romaco India Experience Centre based in Hyderabad

mary packaging cleanroom, enabling space to be used to the max. All machine components are also easy to access, simplifying machine retooling and cleaning. What's more, the use of servo technology ensures fast and reproducible format changes and reliable machine operation with high-quality end products. As a result, the N 950E meets all the requirements for outstanding OEE values, which can easily be read and evaluated on the HMI. The blister packaging machine can handle all sealable films – including sustainable mono-materials of PET, PP, PE and paper – and is equally capable of manufacturing aluminium-aluminium blisters. With its ingenious heating and cooling systems at the forming station and rotary sealing system, the machine can cope with all types of products and packaging materials. Configuration of the product feeding unit is also extremely flexible and takes place either with dedicated feeding, using a brush-box feeder or manually. Furthermore, the Romaco Noack N

950E blister packaging machine is compatible with different transfer systems to the downstream cartoners, such as the Romaco Promatic PC 4201 continuous motion cartoner.

One stop solutions by Romaco

At CPHI & PMEC India, the Romaco Noack N 950E blister packaging machine will also be joined by the VENTILUS® Lab fluid bed processor from Innojet and the KTP IX compaction simulator from Kilian – two laboratory all-rounders for R&D in the field of granulation and tableting.

On show from 25 to 27 November 2025 at CPHI & PMEC India, Delhi NCR, Greater Noida, India Expo Centre, Stand 10.C03.

Romaco Group

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

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

Romaco operates from six production sites worldwide, with a broad portfolio comprised of seven established product brands. Noack and Siebler (Karlsruhe, Germany)

supply blister, heat-sealing and rigid tube filling machines. Macofar (Bologna, Italy) markets technologies for filling sterile and non-sterile powders and liquids. Promatic (also Bologna, Italy) specialises in cartoners, track & trace systems and case packers. Kilian (Cologne, Germany) is a leading manufacturer of tablet presses. Innojet (Steinen, Germany) is in the business of granulating and coating fine solid particles. Tecpharm (Barcelona, Spain) offers tablet coating technologies.

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

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

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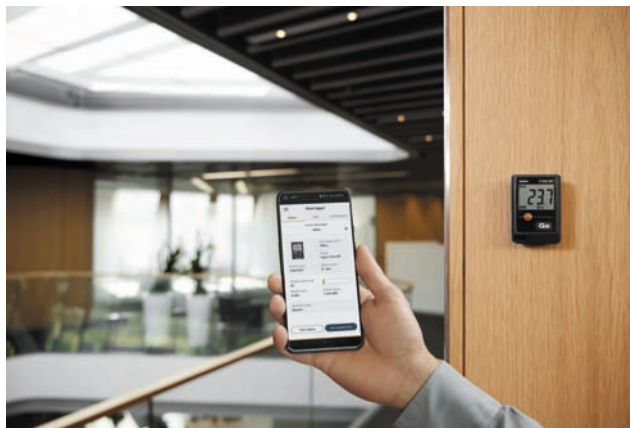
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NEW testo 174 Mini Dataloggers: Revolutionising indoor climate monitoring

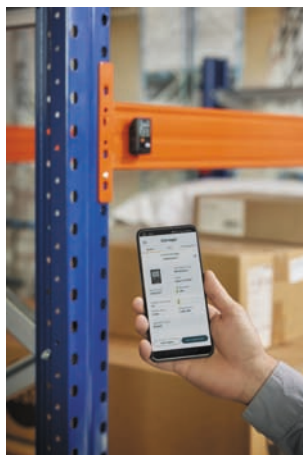
These loggers are designed to meet stringent quality assurance requirements and simplify compliance with regulatory standards

Testo, a leader in measurement technology, introduces the new testo 174 BT (BT is Bluetooth enabled) series mini data loggers, designed to optimise indoor climate monitoring and ensure precise temperature and humidity control. The range offers smart, intuitive features that save time, reduce costs and provide hassle-free digital documentation for a wide range of industries, including food production, pharmaceuticals, and industrial sectors.



Innovative features for enhanced efficiency

The new testo 174 mini data loggers come in multiple models: testo 174 H BT, testo 174 T BT, testo 174 H, and testo 174 T. These loggers support Bluetooth and USB-C connectivity, providing seamless integration with mobile devices or PC software for easy data access and management. These loggers are designed to meet stringent quality assurance requirements and simplify compliance with regulatory standards.



Bluetooth-enabled data loggers: convenient and efficient

The testo 174 H BT (for temperature and humidity) and testo 174 T BT (temperature only) are equipped with Bluetooth, allowing for convenient wireless monitoring. Users can easily configure, record and evaluate measurement data using the free Testo Smart App. The app connects directly to the loggers from up to 30 meters away, enabling real-time data retrieval without the need to remove the device from its monitoring location. This wireless functionality ensures more efficient operations and significant time savings.

With automatic data backup, even if the battery is replaced, all previously recorded data remains intact. The Testo Smart App allows for seamless excel exports, as well as the generation of professional PDF reports with signature and comment functionality. These features eliminate the need for manual record-keeping, reducing the risk of human error and ensuring paperless documentation.

Both Bluetooth models are HACCP certified, ensuring they meet food safety standards, and the testo 174 T BT also holds NSF certification and complies with EN 12830, making them ideal for industries that require stringent

monitoring, such as food production and pharmaceuticals.

USB-C data loggers: Simplified data acquisition

For users who prefer traditional PC-based data management, the testo 174 H (temperature and humidity) and testo 174 T (temperature only) models with USB-C offer an intuitive solution. These loggers feature a large measurement range, from -30 °C to +70 °C for the Testo 174 T and -20 °C to +70 °C for the Testo 174 H, ensuring precise readings for a wide variety of applications.

With a data storage capacity of up to 16,000 readings, these devices can operate for

extended periods, ensuring continuous monitoring. The data can be easily accessed and analysed using the ComSoft Basic software, included with the devices, for fast configuration and readout. ComSoft Professional offers advanced features for batch programming, data analysis, and report generation, making it easier to handle complex quality assurance tasks.

Like the Bluetooth models, these USB-C loggers also meet HACCP standards and EN

need for constant monitoring.

● **HACCP and NSF certification:** Compliance with international standards ensures reliable product safety in food, pharmaceutical and industrial environments.

● **User-friendly software:** The free Testo Smart App and ComSoft software make data management simple and efficient.

Whether you're ensuring the quality of temperature-sensitive goods or maintaining optimal indoor climates, the testo 174 series mini data loggers provide a reliable, efficient, and intuitive solution for all your measurement needs.

Service and calibration

Located at our Head Office in Pune, Testo India has a high quality NABL accredited service & calibration lab. Instruments of any brand/make can be calibrated and serviced locally maintaining international standards. All calibrations are traceable to highly accurate international standards of the PTB Germany.

Testo undertakes calibration jobs for temperature: contact as well as non-contact, humidity, pressure, air velocity, RPM, sound, flue gas & dew point instruments of any brand/make.

Testo India

Testo India Pvt. Ltd. is a 100 per cent subsidiary of Testo SE & Co. KGaA (headquartered in Titisee, Germany) which was established in 2006 and has shown phenomenal growth over the last 18 years with its head office in Pune, & a PAN India network.

Courtesy: Testo India Pvt. Ltd.
For more info: Write to info@testo.in or visit www.testo.com

12830 requirements and the testo 174 T is NSF certified, ensuring reliable product safety in sensitive industries.

Why choose testo 174 Mini Data Loggers?

● **Time and cost efficiency:** Digital documentation and easy data retrieval reduce manual labour and the risk of human error, saving time and costs.

● **Wireless connectivity:** Bluetooth-enabled models offer convenient data readout via the Testo Smart App, streamlining processes.

● **Large data storage:** With up to 16,000 readings, these loggers support extended measurement periods without the

Ami Polymer launches IMAFLEXELL™ Film for bioprocessing applications

Suresh Rathod, Assistant Manager – Business Development at Ami Polymer Pvt. Ltd., explains how IMAFLEXELL™ Film provides enhanced barrier integrity, mechanical strength, and regulatory compliance for single-use bioprocessing systems.

What Makes IMAFLEX-ELL™ Film Unique
Ami Polymer Pvt Ltd. has engineered Imaflexell™ Film, a next-generation multi-layer barrier film, to redefine safety, reliability, and performance in bioprocessing applications. Designed and produced in an ISO 9001 and ISO 15378 certified cleanroom, the film delivers superior barrier and mechanical properties essential for critical biopharmaceutical processes.

and ICH Q3D-compliant extractable studies confirm no detectable volatile, semi-volatile, or non-volatile organic compounds.

- **Biocompatibility and Safety:** Fully compliant with USP <85>, <87>, <88>, <661> and ISO 10993 series. Tests confirm non-cytotoxic, non-haemolytic, non-irritant, and non-sensitizing characteristics.
- **Gamma Sterilization Compatible:** Stable across 25–40

cision with regulatory assurance, Imaflexell™ Film minimizes process risks and ensures biopharmaceutical consistency from development to commercial scale.

Applications across Bioprocessing
Imaflexell™ Film's versatility allows seamless integration across the entire single-use workflow — from 50 mL lab-scale bags to 2000 L produc-

sampling.

- **3D Cube-Style Bags:** Designed for large-scale liquid storage, media preparation, and buffer handling.
- **Custom Assemblies:** Available with porting, connectors, and manifolds for specific process needs.

Typical Applications:

- Media and buffer storage
- Intermediate product collection

- Cell culture and fermentation processes

Each film configuration is pre-irradiated and ready to use, ensuring sterility and convenience for GMP environments.

Certifications & Quality Assurance
Imaflexell™ Film is validated under stringent regulatory and quality standards to meet global biopharmaceutical expectations.

At the core of its innovation lies a five-layer co-extruded structure that provides unmatched balance between flexibility, strength, and barrier protection			
Layer	Material	Function	Thickness
Outer Layer	LDPE (Low-Density Polyethylene)	Mechanical strength & abrasion resistance	50 µm
Tie Layer 1	Adhesive polymer	Bonds outer and barrier layers	10 µm
Core Barrier Layer	EVOH (Ethylene Vinyl Alcohol)	Oxygen and gas barrier	20 µm
Tie Layer 2	Adhesive polymer	Bonds inner and barrier layers	10 µm
Inner Contact Layer	ULDPE (Ultra-Low-Density Polyethylene)	Chemical inertness & fluid compatibility	230 µm

This advanced 320 µm film composition ensures low gas permeability, high puncture resistance, and exceptional chemical compatibility, making it ideal for demanding liquid-handling systems.

Why It Matters
In bioprocessing, maintaining sterility and chemical stability of sensitive media is critical. Imaflexell™ Film directly addresses key challenges faced in single-use technologies (SUT):

- **Superior Barrier Properties:** EVOH core layer provides exceptional resistance to oxygen, carbon dioxide, and moisture—preserving product integrity and extending shelf life.
- **Mechanical Resilience:** High tensile strength (up to 15 MPa) and elongation (>500%) ensure durability even under stress and cold conditions (below -60°C).
- **Low Extractable and Leachable:** Extensive BPOG

Key product features at a glance	
Feature	Description
Film Type	5-Layer Co-extruded Barrier Film
Total Thickness	320 µm ±10 µm
Sterilisation Compatibility	Gamma (25–40 kGy), ETO, e-Beam
Gas Barrier	O2: 0.05 cm³/m²·24h; CO2: <0.5 cm³/m²·24h
Water Vapour Transmission	0.5 g/m²·24h
Mechanical Strength	Puncture resistance: 34 N; Tensile: 13–15 MPa
Transparency	Haze: <4.3%; Clarity: >87%
Temperature Resistance	Withstands below -60°C
Biocompatibility	USP Class VI, Non-toxic, Non-cytotoxic
Extractable	No detectable VOC, SVOC, NVOC, or metals above LOQ
Applications	Media/Buffer Storage, Sampling, Mixing, Bioreactor Bags

kGy irradiation range without degradation in clarity, strength, or barrier performance.

By combining scientific pre-

tion-scale systems. Its configurations include:

- **2D Pillow-Style Bags:** Ideal for small-volume storage and

- Aseptic transfer and sampling
- Bioreactor and mixing bag assemblies

Regulatory Compliance Includes:

- USP Standards: <85>, <87>, <88> (Class VI), <661>, <788>
- ISO Standards: 10993-4, 10993-5, 10993-10, 10993-23, 11137-1
- ASTM Tests: D882 (Tensile), D3985 (O2 Transmission), F1249 (Water Vapour), F2476 (CO2 Transmission), D1003 (Transparency)
- ICH Q3D (R2): Elemental Impurities
- BPOG: Extractable and leachable compliance

Additional approvals:

- FDA 21 CFR 177.1520
- REACH & RoHS compliant
- BPA-free, Phthalate-free
- No TSE/BSE risk (no animal-derived components)

Each roll undergoes traceable labelling, double-bag packaging, and gamma-validated sterility assurance, ensuring full compliance for pharmaceutical and biologics manufacturing.



Written By: Suresh Rathod
Designation: Assistant Manager – Business Development

PRUV® -The original Sodium Stearyl Fumarate

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

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

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

Common lubricants used in drug development

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

A. Fatty acid esters: Fatty acid esters, including glyceride esters (glyceryl monostearate, glyceryl tribehenate, and glyceryl dibehenate), sugar esters (sorbitan monostearate and sucrose monopalmitate) and alcohol ester of stearic alcohol with fumaric acid, including sodium stearyl fumarate are often used as lubricants. In particular, sodium stearyl fumarate and glyceryl dibehenate are effective lubricants to replace magnesium stearate when the latter hampers dissolution and has chemical incompatibility issues. Relative to magnesium stearate, sodium stearyl fumarate has similar lubrication efficiency with a higher optimal concentration (around 2%,

w/w). In addition, the use of sodium stearyl fumarate does not affect compressibility^[1].

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

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

D. Inorganic materials and polymers: Inorganic materials and polymers are also used as lubricants when magnesium stearate cannot be used. In terms of inorganic materials, talc (a hydrated magnesium silicate ($Mg_3Si_4O_{10}(OH)_2$), is often used as a lubricant or as a glidant in formulations. Talc provides some essential lubricity for pharma operations because of its hydrophobicity and weakly bonded sheet structure^{[1][6]}.

Mechanism of lubrication:

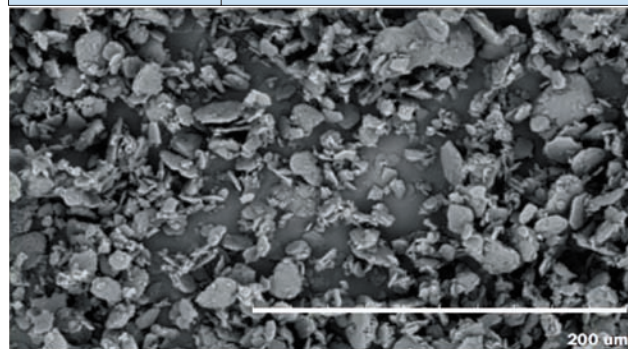
There are four lubrication mechanisms:^[1]

1. Hydrodynamic lubrication,

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

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

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



SEM Picture of PRUV®

For boundary lubrication, a lubricant typically forms layers/film between surfaces or at interfaces to reduce friction, where the penetration of the lubricant into surface asperities

occurs. Structurally, the lubricants commonly used for boundary lubrication are long chain molecules with active end-groups. The typical end-groups include:

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

Considerations for selecting a lubricant

There are many factors to be considered for selecting an appropriate lubricant for preparing solid dosage forms, including low shear strength, being able to form a durable layer covering the surface/particles, non-toxic, chemically compatible with APIs and other components in the formulation, low batch-to-batch variability, and

consideration when selecting a lubricant because both of these two parameters greatly affect the performance of pharma products and processes.^{[1][6]}

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

PRUV® (Sodium Stearyl Fumarate) characteristics:

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

How PRUV® works?

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

Applications of PRUV®

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

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

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

In this study, the effect of different lubricants on Acetaminophen formulation was studied. Acetaminophen API blended with PROSOLV SMCC HD 90 for 15 min and afterwards blended with sieved lubricants for three minutes. Different lubricants like PRUV,

Magnesium stearate, stearic acid and sodium stearate are used. Tablets were compressed to 800 mg weight. tablet.

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

PRUV® helps to avoid API incompatibilities and enhances API stability. With a few exceptions, PRUV® can be applied to any formulation for lubrication,

particularly those in which API stability or tablet taste is compromised due to magnesium stearate. Magnesium cation (Mg²⁺) is electrophilic, it interacts with the free electrons of an API and forms insoluble salts. This is one of the many causes of API incompatibility with magnesium stearate.^[4]

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

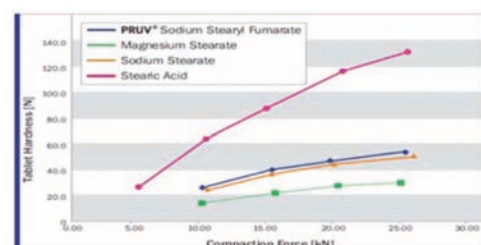
PRUV® was carefully designed to consistently deliver the following functional characteristics:

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

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

Tablet Hardness/Compactability

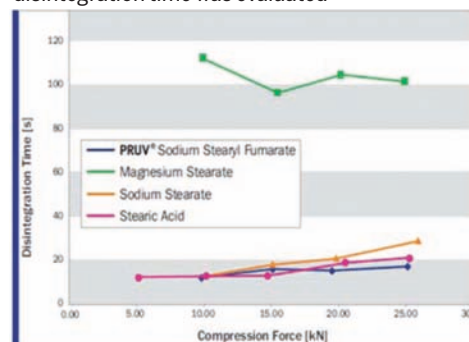
In this study, the effect of different lubricant on tablet hardness was evaluated



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

Disintegration time

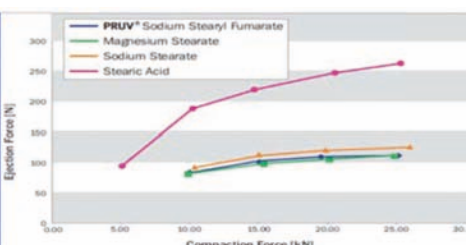
In this study, the effect of different lubricant on disintegration time was evaluated



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

Lubrication efficiency

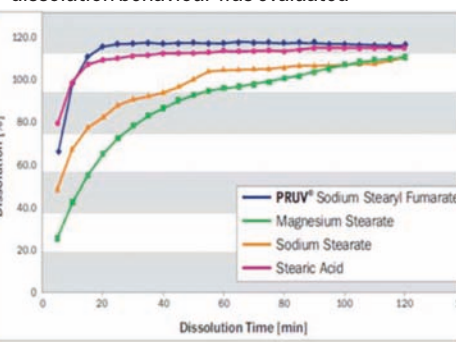
In this study, the effect of lubrication efficiency of different lubricants was evaluated



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

Dissolution behaviour

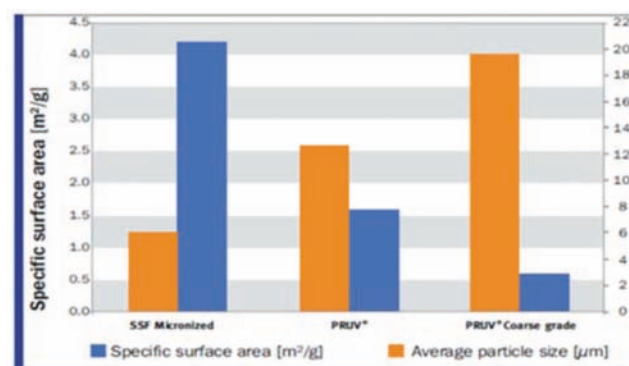
In this study, the effect of different lubricants on dissolution behaviour was evaluated



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

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

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



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

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

Conclusion:

Beyond tablet lubrication properties of PRUV®:

It shows:

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

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

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

PRUV® Sodium Stearyl Fumarate complies with Ph.Eur., NF and JPE. It has the ideal particle size and specific surface area to offer a perfect balance between all functionality

aspects. It is the preferred choice over magnesium stearate in terms of improving disintegration time and dissolution.

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

Regulatory status of PRUV®:

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

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QR Code:

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



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Prashant Bhangdiya, Technical Manager, Pharma Business Unit, Rettenmaier India, is responsible for the JRS Pharma's Excipients Business in South India, East India and Bangladesh, including but not limited to, supporting the business development team, customer service and logistics team.

He completed M Pharmacy from Poona College of Pharmacy, Pune (Bharati vidyapeeth). He has also completed Diploma in Intellectual Property (IP) rights from Symbiosis International, Pune.

He has over 10 years of experience in the field of formulation development and pharma excipients.



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Virosil Pharma: A revolutionary, eco-friendly fumigant

Virosil Pharma has proved to be effective in controlling aerial bacteria and fungus present in sterile rooms. The area becomes completely sterile within 60 minutes of spraying without causing any irritation to the eyes, nose and skin - unlike conventionally used formulations

ABSTRACT

In the past years, the pharma and healthcare industry has witnessed tremendous growth and there have been tie-ups with a number of multinational-als for production and R&D facilities to be nurtured in India. Organisations are applying for ISO standards and upgrading themselves to the latest norms related to health and hygiene.

Microbial contamination and pollution play a significant role in the pharmaceutical industries. Control of microbes has always been the biggest challenge to these industries. A load of microbes are present in areas such as production, storage/packaging, R&D, Q.A/Q.C., filling etc. They are present everywhere in the air, surface, water, instruments, linens etc.

Hence the disinfectant used should be so precise that it should not only take care of the microbial contamination but also be user and eco-friendly. Virosil Pharma meets all the required standards for the pharmaceutical industry.

ABOUT US

Sanosil Biotech, a Mumbai-based company, has launched a range of multipurpose disinfectants which are eco-friendly, chlorine-free and completely biodegradable and have applications in the pharma and healthcare industry as well as in the food processing industry. It is manufactured in India in technical collaboration with SANOSIL AG of Switzerland. SANOSIL AG in Switzerland is the patent holder and has joint venture agreements in more than 15 countries such as France, Italy, Spain, Holland, Norway, South Africa, Australia, Saudi Arabia, Oman, the UAE, etc. The product is being used in various countries by reputed institutions and has been thoroughly tested under

strict regulations imposed by European Health bodies.

PRODUCT DESCRIPTION

Virosil Pharma is a multicomponent fumigant and disinfectant. The oxidizing agent used is hydrogen peroxide, which is bonded with stabilizing agents to form a complex solution. A long-lasting effect is ensured by the addition of silver, which acts as a catalyst in trace amounts. The bactericidal effect of silver is based on the fact that the monovalent silver

ion Ag⁺ binds very firmly to bacterial proteins by a covalent or co-ordinate bond, and thus inactivates or precipitates these.

◆ Its effectiveness against bacteria, viruses, amoebae, fungi and algae; i.e. its extremely wide range of application makes it easy to handle for the end user; i.e. only one product is needed, where so far 2, 3 or various products were necessary.

◆ Owing to the good stability of the product, a long storage



ADVANTAGES

- # Eco-friendly - It is totally biodegradable since (H₂O₂) breaks down into water & oxygen
- # Chlorine free
- # Non-toxic (no irritation to skin or eyes)
- # No effect on pH
- # Non carcinogenic and non mutagenic
- # Excellently rinseable with no remains

PROPERTIES

- # Can easily be dosed
- # Does not foam
- # Decomposes into water and oxygen
- # It is excellently rinseable with no remains
- # Treats any other material with consideration

USFDA DRAFT GUIDELINES

Clean Area Classification	Microbial limit Cfu / 10 cu.ft.	Microbial limit Cfu / 10 cu.m.
100	< 1a	< 3a
1000	< 2	< 7
10,000	< 5	< 18
100,000	<25	<88

a = samples from class 100 environments should normally yield no microbiological contaminants

WHO 2002 MICROBIAL LIMITS

Grade	Max. no. of microorganisms permitted / m ³
A	Less than 1
B	5
C	100
D	500

EU GMP 2002

Grade	Air sample cfu / cu.m.	Settle plates (90mm) cfu / 4 hours	Contact plate 55mm cfu / plate	Glove print Cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

time can be guaranteed. As the product remains stable at high water/air temperatures, and as its effectiveness is even increased at high temperatures. ◆ Due to its long-term effectiveness and pronounced characteristics to prevent recontamination, this product is perfectly suited for disinfection of drinking water and wells.

◆ Virosil Pharma is ecologically harmless. Its principal constituent - hydrogen peroxide - does not pollute waste wa-

ter, because it breaks down into water and oxygen (H₂O and O₂), i.e. it produces no noxious by-products.

◆ The two basic substances (H₂O₂ and Ag) enhance their advantages (*synergism). The bactericidal effect comes into action quicker and more intensively than if either substance was used on its own.

Fumigation with Virosil Pharma, the perfect Salternative to Formalin

Fumigation is one of the most

important factors associated with pharma industries, it plays a vital role in maintaining the sterility of areas and is directly related to production.

Sanosil Biotech is the first company to pioneer the novel concept of eco-friendly fumigation. The company has great respect for human health and the environment. The CEO, Dev Gupta, an MBA from the Bentley Graduate School of Business, Boston, has been actively marketing the brand nationally. According to Gupta, "Virosil Pharma has simplified the lives of so many people who work in the pharmaceutical industry as they are guaranteed sterility with the minimum risk exposure". As there was a high risk to the staff involved in the use of Formaldehyde/Glutaraldehyde for sterilization and disinfection.

Owing to the stringent integrated micro contamination control and biosafety requirements, it is desirable to have micro-contamination control procedures and methods that could be monitored, evaluated and assessed periodically, which are convenient, cost-effective and safe.

A glimpse at the standards put down by various would monitoring agencies would help an individual or an organization help decide on choosing the most appropriate control procedure/methods. The important microbial limits which have been prescribed by various agencies is as follows:

To meet those requirements aerial disinfection (fumigation) with formaldehyde was the most convenient method. With the regulatory having restricted the use of formaldehyde and also putting into place the monitoring levels of formaldehyde after fumigation makes it a procedure with its own limitations.

Formaldehyde is a known carcinogen (IARC & NTP). Formalin is toxic by inhalation, toxic if swallowed, may be fatal if swallowed, causes eye burns, may cause blindness, strong sensitizer, causes irritation to skin, eyes, and respiratory tract. Repeated or prolonged exposure increases the cancer risk.

COMPARISON	
VIROSIL PHARMA	FORMALIN
Eco-friendly, Non-toxic	Highly toxic
Room gets sterilized within 1 hour after fumigation	Requires overnight fumigation
Requires no de-fumigation	Requires de-fumigation
Person can be present during fumigation	Causes skin, eye irritation even after next day of fumigation
Time Saving	Time consuming
Multiple Applications	Application restricted

Virosil Pharma has been a direct alternative to Formalin Fumigation. Virosil Pharma has proved to be effective in controlling aerial bacteria and fungus present in sterile rooms. The area becomes completely sterile within 60 minutes of spraying without causing any irritation to the eyes, nose and skin - unlike conventionally used formulations. Virosil Pharma can even be successfully used in AHU which are responsible for optimal and steady air exchange in production facility, of which the ducts, air shafts, humidifier, filters, etc. are often contaminated with loads of bacterial and bio-films.

The main aim of Virosil Pharma is to increase productivity by cutting down disinfection time while at the same time providing a totally microbe-free environment.

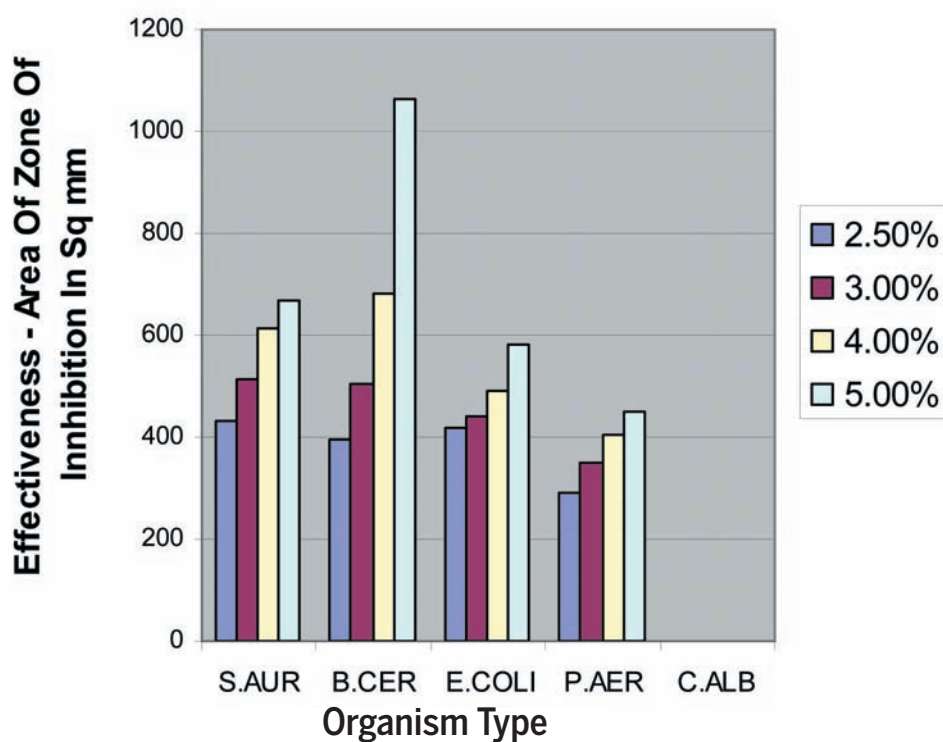
Virosil Pharma is also very effective in disinfection of all critical surfaces that come in contact with pharma products. There is no requirement to re-wash equipment and surfaces disinfected with Virosil Pharma since it is H₂O₂ based and decomposes into water and oxygen.

Virosil Pharma has been tested by several reputed and renowned institutions in India with respect to its disinfection and fumigation applications in Pharmaceutical Industry

Because of all these factors, Virosil Pharma has attained maximum satisfaction of the customers in controlling the microbial contamination in their respective applications. The introduction of an eco-friendly, non-carcinogenic and totally biodegradable versatile product, like Virosil Pharma,

A GRAPHICAL VIEW ON DISINFECTANT EVALUATION DATA - VIROSIL PHARMA

Disinfectant Effectiveness Evaluation Data Virosil Pharma



	S.AUR	B.CER	E.COLI	PAER	C.ALB
2.50%	429.83	397.4	418.15	289.38	0
3.00%	514.44	502.4	440.92	349.48	0
4.00%	615.44	683.14	490.625	404.5	0
5.00%	669.32	1063.07	580.77	452.16	0

has not only brought an end to the era of conventional biocides but has completely solved the disinfection requirements which these healthcare industries were prone to.

Targets

Sanosil Biotech is marketing this disinfectant under the 'Virosil Pharma' brand name and is targeting the entire industrial belt of India. The com-

pany has already set up a distribution and infrastructure network having establishments in Maharashtra, M.P., Hyderabad, Chennai and Delhi.



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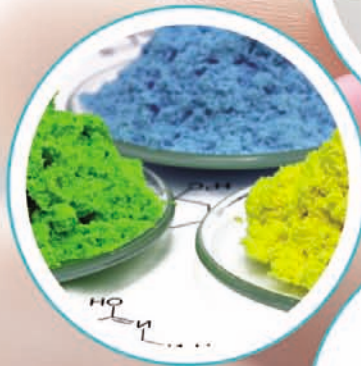
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Dispersible Tablet | Chewable Tablet



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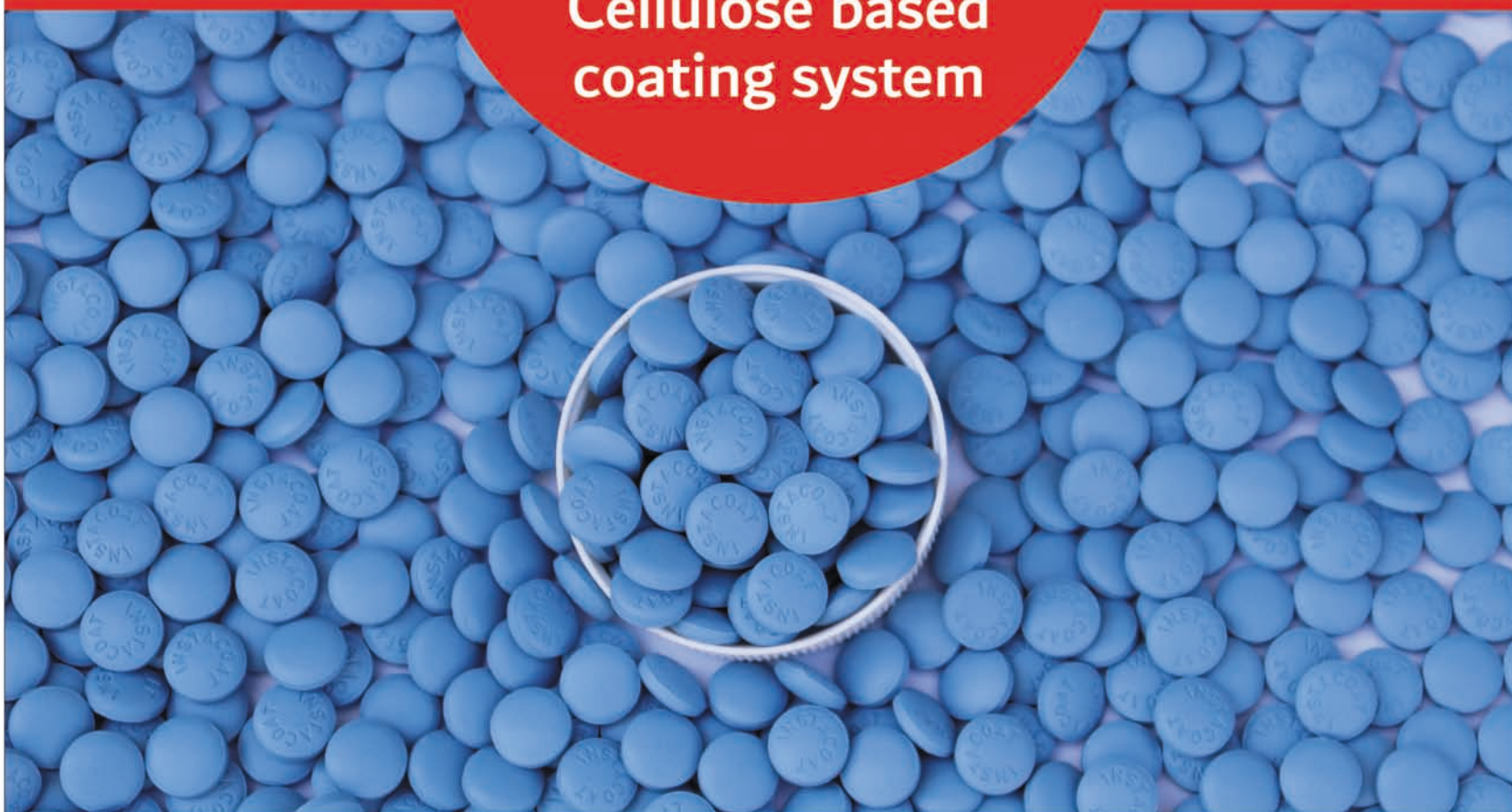
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