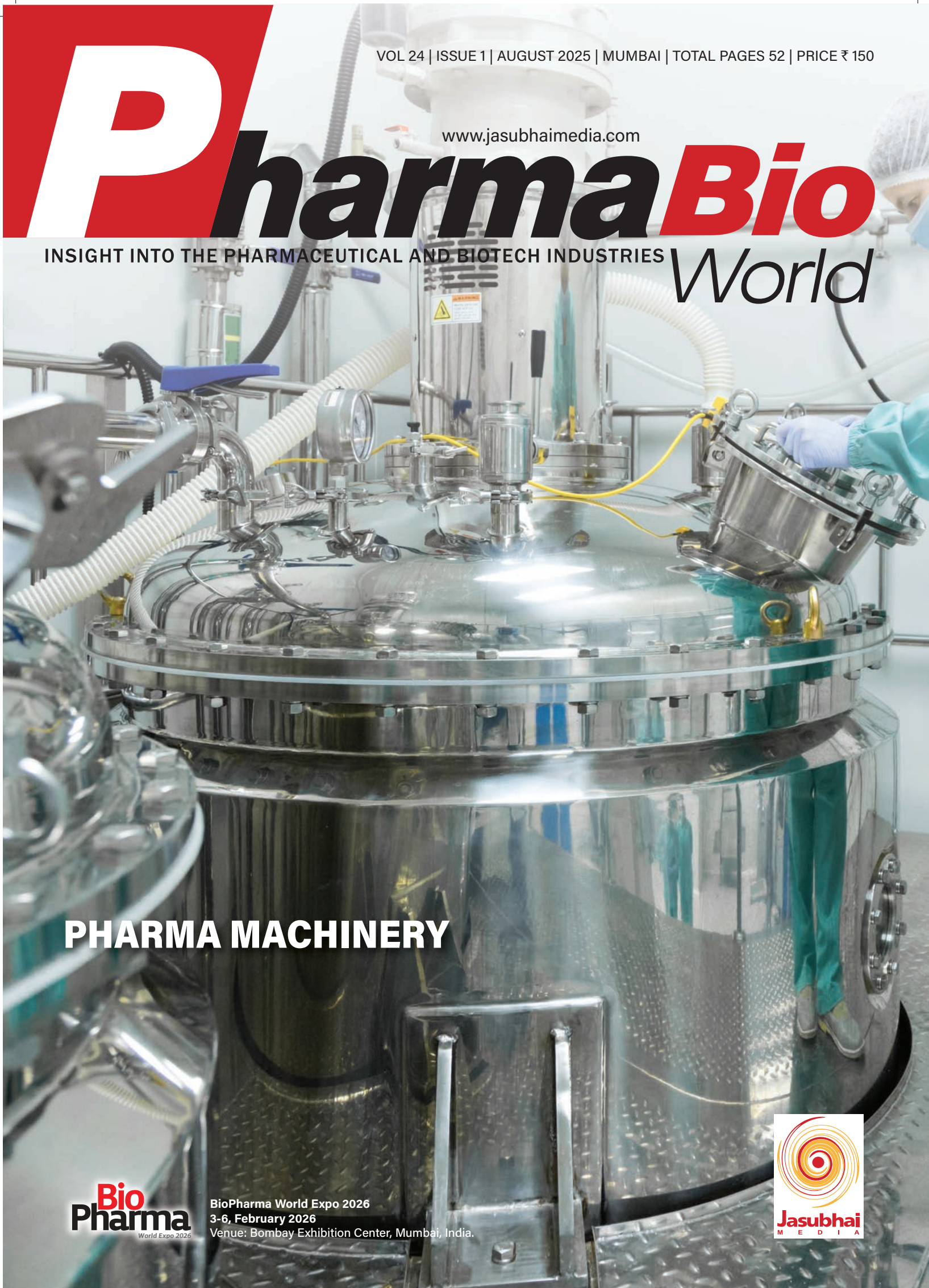


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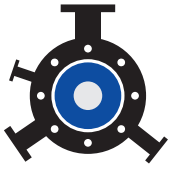
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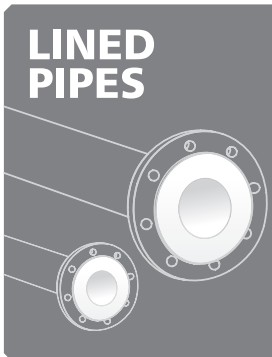
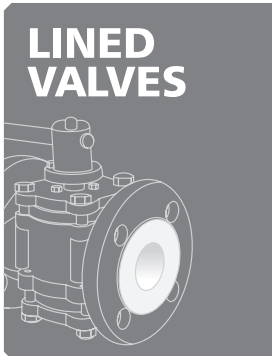
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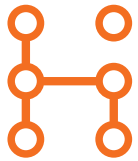
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## AD INDEX

Aeron Composite Limited .....	13
Hitech Applicator .....	2
Horizon Polymer Engineering Pvt. Ltd. ....	3
Mist Resonance Engineering Pvt. Ltd. ....	5
Sealmatic India Ltd. ....	7
Vacuum Drying Technology India LLP .....	11
VEGA India Level and Pressure Measurement Pvt. Ltd. ....	9



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# CONTENTS

## INTERVIEW

**"We are targeting revenue of ₹ 750 crores by FY26." 26**



**Munjal Patel**  
Director  
Lincoln Pharmaceuticals Ltd

**"Rockwell Automation is setting the stage for a transformative future in India" 28**



**Ankur Pancholi**  
Software & Control Business Manager  
Rockwell Automation India

**"We are planning to expand into over 100 countries around the globe" 31**



**Parag Bhatia**  
Director  
Laborate Pharmaceuticals

**"Tubing solutions are the backbone of fluid handling in biopharmaceutical manufacturing." 34**



**Sachin Joshi**  
Co- Founder & MD,  
Pharmnxt Biotech

**"The biopharma sector is undergoing a shift toward advanced therapies like cell and gene therapies" 36**



**Ankush Kapoor**  
Founder & CEO  
Pharmnxt Biotech

## NEWS

08

## PROJECT UPDATES

24

## GUEST COLUMN

**Formulation Development: Why It's So Important in India's Pharma Growth Story 40**



**Sanjeev Jain**  
Managing Director  
Akums Drugs and Pharmaceuticals

## CASE STUDY

**Advanced visualization solution for regulatory compliance & effective data management 22**



## FEATURES

**Regulatory Landscape in Pharma Packaging: The Indian and Global Perspective 37**



**Chakravarthi AVPS**  
AVPS, Global Ambassador,  
World Packaging Organisation (WPO)

**The New Age of Lifesciences: Innovation 44**



**Dr. Satish Wagh**  
Executive Chairman & Whole - Time Director,  
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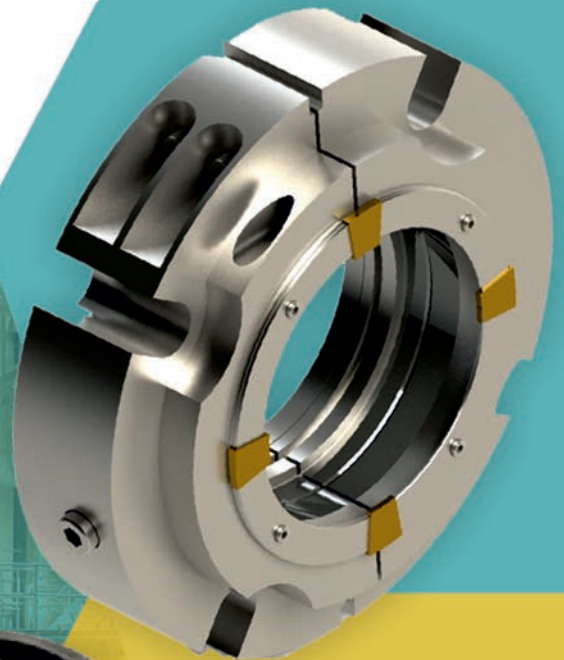
**AMR Surveillance Beyond Big Cities: Why India Needs a Decentralized Approach 47**



**Saransh Chaudhary**  
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## Ajay Kumar Sood chaired 4th review meeting on progress to improving India's regulatory ecosystem for medical products

**New Delhi India:** The fourth follow-up meeting of 24th PM-STIAC meeting on 'Transforming the regulatory ecosystem of the medical products in India' was chaired by Professor. Ajay Kumar Sood, Principal Scientific Adviser (PSA) to the Government of India. The PM-STIAC meeting recommended improving the regulation for medical processes to create a system that ensures transparency, and accountability while promoting innovation in reliable medical products for India and the world.

Dr. Rajeev Raghuvanshi, Drug Controller General of India (DCGI), Central Drugs Standard Control Organisation (CDSCO) updated the progress in priority areas, and informed about the initiatives being undertaken. This included a successful launch of the State Drug regulatory Index on August 12, 2025, where states will be benchmarked based on the performance of state drug regulators through an objective evaluation mechanism. Prof. Sood remarked that such competitive benchmarking would draw all States into the system and significantly raise the overall standard of drug regulation in India.

Dr. Raghuvanshi informed about the release of a comprehensive guidance framework for Subject Expert Committees (SECs) which provides guidelines on application review process. He further informed that the rollout of digital dashboards for tracking and prioritisation has helped reduce processing timelines of applications. For instance, in case of CT-04 applications for Global Clinical Trials for Cell and Gene Therapy (CGTs), the number of days from application submissions to SEC deliberations has decreased significantly, from 226 days in 2022 to 40 days in 2024. Similarly, the approval process for major Post Approval Changes in CGTs has been expedited, with durations of 218 days in 2022 to 98 days in 2024.

Along with the digitisation measures at CDSCO, a digital system with analytics for NSQ (Not of Standard Quality) data, Dual-Use NOC (No Objection Certificate), and digital system of WHO (World Health Organisation) Certificate of Pharmaceutical Product have also been operationalised, creating a harmonised national database and enhancing transparency. Further, in alignment with the global norms, CDSCO has prepared

biosimilar guidance which will facilitate enhanced access of biologics in the country.

Prof. Sood emphasised the importance of defining long-term, quantifiable milestones for India's regulatory system, towards international gold standards including periodic internal audits and measurable targets. He stated that the ongoing transformation is expected to enhance patient safety and domestic capabilities while also giving Indian manufacturers a competitive edge in global markets. Acknowledging the progress, the PSA reiterated that these reforms will strengthen trust in India's regulatory framework, boost predictability and global credibility, and facilitate quicker access to safe, affordable medical products through innovation within the country.

The review was also attended by Dr. Parvinder Maini, Scientific Secretary, Office of PSA; Dr. Sindura Ganapathi, PSA Fellow; Dr. Sangeeta Agarwal, Scientist 'F', Office of PSA; Apoorv Chouhan, Project Manager, One Health PMU from Office of PSA. They were joined by Nikhil Gajraj, Joint Secretary, Department of Health and Family Welfare.

## India's Pharma Exports Surpass USD 30 bn in FY2025 and aim to double by 2030: Rubix Data Sciences

**Mumbai, India:** As trade realignments and tariff tensions redefine global pharma supply chains, India is emerging as a resilient force. With exports touching USD 30.5 billion in FY2025, a 9.3% jump from the previous year, the country is laying the foundation to double its pharmaceutical exports by 2030. In this fast-shifting landscape, Rubix Data Sciences, a leading provider of risk management and monitoring solutions, has released its latest industry report on India's pharmaceutical sector. The report captures how Indian pharma players are navigating uncertainty by doubling down on complex generics, expanding their international presence, and investing in regulatory strength.

India's strength comes at a time of rising external volatility. The United States, which alone accounts for over 32% of India's pharmaceutical exports, is reportedly considering a 200% tariff on pharmaceutical imports. These potential trade shifts carry real implications for India, whose pharma exports are projected to double to USD 65 billion by 2030. But India is not standing still. From strategic acquisitions by Indian CDMOs (Contract Development and Manufacturing Organizations) in

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the US and Europe to the increasing share of complex generics in their product mix, Indian companies are proactively mitigating these risks.

The Rubix report highlights how Indian pharma companies are responding proactively by investing in US-facing manufacturing capabilities, expanding regulatory compliance, and targeting complex generics aligned with upcoming patent expiries. As global pharmaceutical markets brace for a series of high-value drug patent expiries over the next five years, Indian companies are sharpening their focus on complex generics and differentiated products.

The Rubix report further points to a clear shift in strategic priorities among Indian pharma firms, particularly as global risks mount. Companies are enhancing their competitiveness by entering advanced therapeutic areas like oncology, anti-diabetics, and CNS. Many firms are also scaling up their international footprint through partnerships and acquisitions, especially in developed markets, to strengthen supply continuity and regulatory compliance. With 74% of bulk drug imports still coming from China, the push toward diversification both in sourcing and in global customer bases has become a critical lever for long-term resilience.

"The surge in pharma exports this year is encouraging, but it also reflects how Indian manufacturers are recalibrating in response to global uncertainties. From navigating tariff pressures to strengthening regulatory compliance and expanding globally, the sector is showing clear signs of strategic maturity. We believe this momentum will continue as companies focus more on complex generics and strengthen their specialised capabilities. At Rubix, our focus remains on equipping stakeholders with data-driven insights that enable smarter, risk-aware decisions in a rapidly evolving global market," said Mohan Ramaswamy, Co-founder and CEO, Rubix Data Sciences.

## Sun Pharma announces launch of LEQSELVI (deuruxolitinib) in US

**Mumbai, India:** Sun Pharmaceutical Industries Limited announced LEQSELVI (deuruxolitinib) 8 mg tablets is now available to healthcare providers and people living with severe alopecia areata in the U.S. LEQSELVI is indicated for the treatment of adults with severe alopecia areata.<sup>1</sup>

"The launch of LEQSELVI in the U.S. brings an effective, new treatment option for severe alopecia areata to eligible patients and the healthcare providers who treat

them," said Richard Ascroft, CEO, Sun Pharma North America. "As a company committed to launching new therapeutic options which address the unmet needs of patients, adding LEQSELVI to our dermatology portfolio represents a key milestone for the business and an important advancement for the alopecia areata community."

With limited treatment options available to people living with severe alopecia areata in the U.S., the need for innovative therapies such as LEQSELVI remains critically important. LEQSELVI demonstrated rapid results in clinical trials with one third of patients regaining almost all of their hair by Week 24. Some patients (3%) achieved 80% or more scalp coverage as fast as 8 weeks.<sup>1</sup>

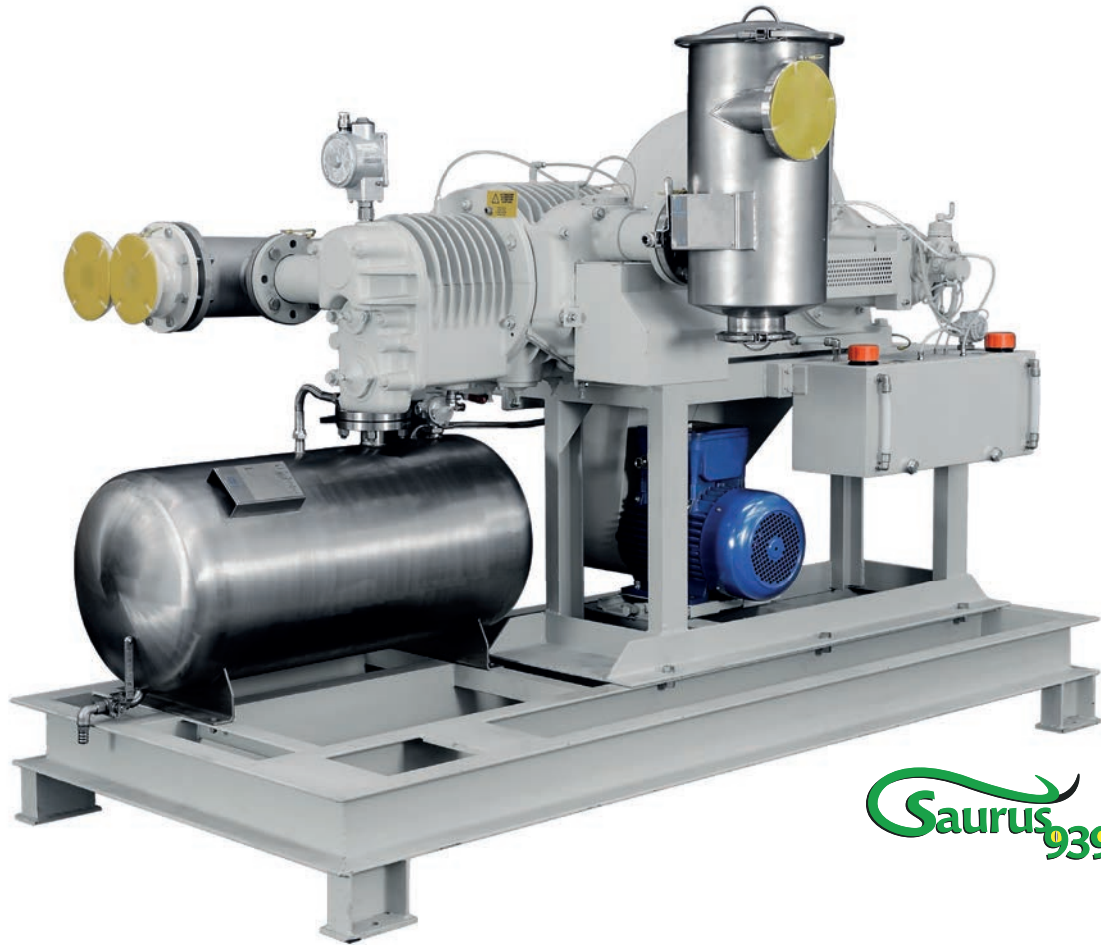
"The clinical evidence for LEQSELVI is truly compelling, demonstrating consistent efficacy," said Arash Mostaghimi, MD, MPA, MPH, FAAD, Vice Chair of Clinical Trials and Innovation and Associate Professor of Dermatology at Brigham and Women's Hospital. "LEQSELVI provides clinicians with an important new treatment that can deliver significant, rapid outcomes for patients with alopecia areata."

The psychosocial impact of alopecia areata can be significant. Many people living with severe alopecia areata face psychological distress, including loss of self-confidence, due to the unpredictable nature of hair loss, underscoring the importance of effective treatment solutions.<sup>2</sup> A medication that works fast is critical for alopecia areata patients.<sup>5</sup> In a recent survey, 83% of patients preferred a treatment with attributes that included speed. Fast regrowth brings back more than just hair.<sup>3,5</sup>

"The availability of LEQSELVI offers hope to our community, delivering a new, effective treatment option for adults living with severe alopecia areata," said Nicole Friedland, President and CEO, National Alopecia Areata Foundation (NAAF). "NAAF is thrilled to see expanded choices and increased opportunities for individuals to find an FDA-approved treatment to address hair loss caused by this autoimmune disease."

LEQSELVI may cause serious side effects including serious infections, malignancies, thrombosis, gastrointestinal perforations, and certain laboratory abnormalities. There also may be an increased risk of mortality and major cardiovascular events. LEQSELVI should not be used in patients who are CYP2C9 poor metabolizers or who are taking moderate or strong CYP2C9 inhibitors. In placebo-controlled trials, the

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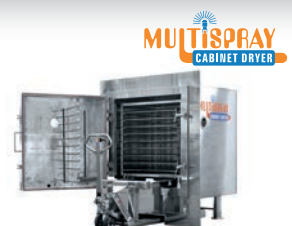
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three most common adverse events were headache (12.4% as compared to 9.4% with placebo), acne (10% as compared to 4.3% with placebo), and nasopharyngitis (8.1% as compared to 6.7% with placebo).

## Biocon Biologics expands Diabetes Portfolio with FDA Approval of Kirsty



Shreehas Tambe, CEO & Managing Director, Biocon Biologics

**Bangalore, India:** Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. announced that the U.S. Food and Drug Administration (FDA) has approved Kirsty™ (Insulin Aspart-xjhz), 100 units/mL as the first and only interchangeable\* biosimilar to NovoLog®

(Insulin Aspart). KIRSTY is a rapid-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. KIRSTY will be available as a single-patient-use prefilled pen for subcutaneous use and a multiple-dose vial for subcutaneous and intravenous use.

The FDA approval of KIRSTY expands Biocon Biologics' biosimilar insulin portfolio, which also includes the first approved interchangeable biosimilar, Semglee® (Insulin Glargine-yfgn Injection). KIRSTY has been available in Europe and Canada since 2022.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd., said: "The FDA approval of Kirsty, the first and only interchangeable biosimilar rapid-acting Insulin Aspart in the U.S., is a significant step forward in our efforts to make insulin more accessible and affordable. It builds on the foundation we laid with Semglee®, reinforcing our commitment to scientific excellence and patient-centric innovation. With Kirsty™, we are expanding treatment choices for people living with diabetes and advancing our ambition to be a global leader in addressing unmet needs in diabetes care."

There are 38.4 million people with diabetes in the United States, approximately 11.6 percent of the total population, with nearly a quarter of them being undiagnosed. An additional 97.6 million Americans have been identified as prediabetic.<sup>1</sup> Sales of Insulin Aspart in the United States were approximately \$1.9 billion in 2024, according to IQVIA.

## Pfizer launches 20-valent Pneumococcal Conjugate Vaccine (PCV20) for Adults in India

**Mumbai, India:** Pfizer announced the launch of its next-generation 20-valent pneumococcal conjugate vaccine (PCV20) for adults in India. With broader serotype coverage, Pfizer's vaccine marks a significant advancement in protection against pneumococcal disease in adults.

Pfizer's vaccine helps protect against clinically relevant 20 serotypes responsible for a majority of invasive and non-invasive pneumococcal disease. It enables timely and proactive protection for all adults, including those living with chronic conditions. PCV20 will be available as a single shot vaccine and those vaccinated with PCV20 may not need a second dose.

Meenakshi Nevatia, Managing Director, Pfizer Ltd., India, said, "We are excited to launch PCV20, our 20-valent pneumococcal conjugate vaccine, in India. We believe this vaccine, with its broad coverage of 20 pneumococcal disease serotypes, will address the increasing need for adult immunization in our country."

Adults over 50 years of age, as well as individuals with comorbidities such as asthma, COPD (Chronic Obstructive Pulmonary Disease), chronic kidney disease, and diabetes, face a higher risk of developing pneumococcal infections, which can result in complications, hospitalization, and even death.

Timely immunization is critical to reducing the risk of severe illness, hospitalization, and mortality caused by pneumococcal disease. Vaccination with PCVs are considered one of the most effective public health tools for reducing the burden of pneumococcal disease.

The introduction of PCV20 in India strengthens Pfizer's longstanding commitment to preventive health and builds on 25 years of leadership in pneumococcal vaccine innovation.

## Cadila Pharmaceuticals Launches Bilacad Dex Syrup

**Ahmedabad, India:** Cadila Pharmaceuticals Limited, one of India's most respected and innovation-driven pharmaceutical companies, has announced the launch of Bilacad Dex Syrup, to address the increasing burden of respiratory and allergy-related conditions with a novel fixed-dose combination of Bilastine, Dextromethorphan, and Phenylephrine.

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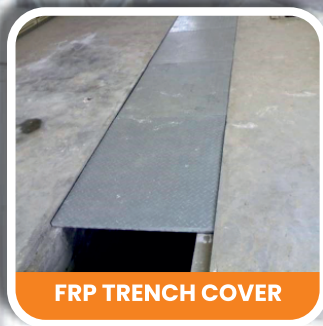
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Bilacad Dex Syrup represents Cadila Pharmaceuticals' strategic expansion into combination therapies that cater to the evolving needs of patients and prescribers seeking efficient multi-symptom relief. It is poised to make a meaningful impact in the ₹4,709 crore Indian cough syrup market.

With growing awareness around the side effects of sedating antihistamines and the need for convenience, Bilacad Dex Syrup aligns with contemporary healthcare preferences. It is designed for oral administration and is indicated for adults and children aged 12 years and above, at a dosage of 10 ml three times daily. The syrup is well tolerated in elderly populations, and its use is not recommended for children under 12 for more than 7 days.

Moreover, Bilacad Dex is especially suitable for professionals, students, and active individuals who seek effective symptom relief without compromising alertness and productivity.

## Rubicon Research Limited completes acquisition of Alkem's Pithampur manufacturing unit

**New Delhi, India:** Rubicon Research Limited has completed the acquisition of Alkem Laboratories' formulations manufacturing facility in Pithampur, Madhya Pradesh in an all-cash deal for ₹149 crores.

The acquired facility, located in the Special Economic Zone at Pithampur, Madhya Pradesh, is equipped to manufacture steroids, hormones, and high-potency products, including immunosuppressants and oncology medications. The facility was inspected by the U.S. Food and Drug Administration (US FDA) in 2022. With a built-up area of more than 16,000 sq. m. and total plot area of more than 1,25,000 sq. m., the site has potential for future expansion.

Besides capacity expansion, the addition of a third formulations manufacturing location strengthens Rubicon's supply chain and adds new manufacturing capabilities for Rubicon in segments like steroids, hormones, and high-potency products.

Parag Sancheti, Chief Executive Officer of Rubicon Research Limited highlighted the importance of this acquisition saying, "This acquisition supports our strategy of expanding our US market presence and complements our development efforts to grow our portfolio of specialty products and drug device combination products. The Pithampur facility increases our ability to manufacture products for regulated markets at scale through a resilient supply chain".

## Glenmark Pharmaceuticals launches TEVIMBRA in India



Alok Malik, President and Business Head - India Formulations, Glenmark Pharma

**Mumbai, India:** Glenmark Pharmaceuticals Ltd a research-led, global pharmaceutical company, launched TEVIMBRA® (tislelizumab) in India following the approval by Central Drugs Standard Control Organization (CDSCO).

TEVIMBRA is a uniquely designed anti-PD-1 monoclonal antibody developed by BeiGene (now BeOne Medicines), a global oncology leader committed to delivering advanced treatments for cancer patients worldwide. It is indicated for the treatment of first-line locally advanced or metastatic non-small cell lung cancer (NSCLC) in combination with chemotherapy and second-line treatment of locally advanced or metastatic NSCLC and esophageal squamous cell carcinoma (ESCC) as monotherapy.

This launch marks Glenmark's first foray into immunoncology in India and is a major milestone in expanding its innovative oncology portfolio. NSCLC is the most common type of lung cancer, representing over 80% of all lung cancer cases. Similarly, ESCC is the most common histological subtype of esophageal cancer in India. TEVIMBRA caters to the needs of this significant patient population by offering a differentiated and proven treatment option for these cancers.

"With the launch of TEVIMBRA, Glenmark is delivering on its commitment to transform cancer care in India by making globally benchmarked immunotherapies more accessible," said Alok Malik, President and Business Head - India Formulations, Glenmark Pharmaceuticals Ltd. "At a time when the cancer burden is rising sharply, we are proud to enable oncologists and patients to access TEVIMBRA, a therapy with proven efficacy

and safety outcomes, strong science, and meaningful impact. Immuno-oncology offers a promising future for the treatment of various types of advanced cancers which are difficult to treat. Our foray in this area marks a significant inflection point in our journey to build a world-class oncology portfolio that is innovative, inclusive and at the same time life-changing for patients."

## Alembic Pharmaceuticals receives USFDA Final approval for Tretinoin Cream

**Mumbai, India:** Alembic Pharmaceuticals Limited announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Tretinoin Cream USP, 0.025%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Retin-A Cream, 0.025%, of Bausch Health US, LLC. Tretinoin cream is indicated for topical application in the treatment of acne vulgaris. Refer label for a detailed indication.

Tretinoin cream USP, 0.025%, has an estimated market size of USD 94 million for twelve months ending June 2025 according to IQVIA.

Alembic has a cumulative total of 224 ANDA approvals (202 final approvals and 22 tentative approvals).

Senores Pharmaceuticals acquires ANDAs from Teva Pharmaceuticals USA

Ahmedabad, India: Senores Pharmaceuticals Limited, through its wholly-owned subsidiary Senores Pharmaceuticals, Inc., USA, has signed an agreement today to acquire two products of USFDA-approved Abbreviated New Drug Applications ("ANDAs") from Teva Pharmaceuticals USA, Inc.

The addressable opportunity of the acquired ANDAs in the USA is ~USD 38 Mn (MAT December 2024)\* as per IQVIA and ~USD 120 Mn (MAT June 2025)# as per the speciality data aggregator Symphony.

The acquisition will be funded through the Initial Public Offer ("IPO") proceeds raised by SPL. This is in line with the objects of the IPO stated in the Red Herring Prospectus.

## Divi's Laboratories selects Juniper Networks for Automated Network Infrastructure

**Hyderabad, India:** Juniper Networks, a leader in secure, AI-driven networks, announced that Divi's Laboratories, one of the largest active pharmaceutical ingredients (API) companies globally, has selected Juniper to deliver highly available, ultra-reliable networking solutions across its manufacturing operations, the largest API manufacturing facilities in the world.

Headquartered in Hyderabad, India, Divi's Labs strategically partners with many of the world's leading pharma companies, manufacturing and custom synthesizing APIs for products used in over 95 countries including antidepressants, blood pressure medicine, antihistamines and more. In addition, its nutraceutical division also makes vitamins and beta-carotenes used in supplements, food and beverages sold across the world.

Divi's currently operates two manufacturing sites which run 24/7 near Hyderabad and Visakhapatnam in India, with a third under construction. Collectively, these operations make up the largest API manufacturing facilities globally, with a gross total of 14,500sqm of manufacturing space spread across over 64 buildings in the two sites.

Due to its stringent quality-control processes, Divi's required an ultra-reliable network that could securely transfer data at line rate between its two plants without any packet loss. After experiencing difficulties managing and monitoring its network with their previous legacy solution, it decided to embark on a network refresh with Juniper that would future-proof several operational requirements.

This network refresh would include reliable Power-over-Ethernet (PoE) and PoE+ switching to drive their wireless infrastructure while providing for organizational-wide network visibility, easy onboarding and manageability. Furthermore, Divi's Labs required high-capacity uplinks and multigigabit downlinks to meet growing data exchange needs, as well as the ability to reduce power consumption to meet Divi's sustainability commitments.

Within each site, Divi's Labs utilizes the EX4600 as Core/Distribution switches, while EX3400 and EX2300 switches provide connectivity to critical network resources including Wi-Fi Access Points. In

addition, their data center also fully runs on Juniper gear, driving critical manufacturing processes like formula management, batch tracking, quality control, compliance tracking and even production scheduling.

## PharmNXT brings European Bioprocess Engineering to India with Strategic DTR Acquisition

**New Delhi, India:** In a landmark development for India's biopharmaceutical sector, PharmNXT Biotech has acquired Defined Tubing Routing (DTR), a globally recognised player from Ireland, working in advanced bioprocess tubing solutions. This move enables PharmNXT to access technology solutions related to single-use systems, strengthening its capacity to serve pharmaceutical and biopharma clients with more tailored and technically aligned offerings.

With the addition of DTR's modular tubing systems, capable of supporting bioprocess volumes from 20 L to 500 L and custom spans up to 2.9 meters, PharmNXT significantly expands its engineering capabilities, faster turnaround, enhanced customisation, and stronger compliance. DTR systems are increasingly being adopted in biopharmaceutical manufacturing, especially within single-use technology setups where efficient tubing management is critical. These systems help reduce operational risks by minimizing trip hazards and clearly outlining flow paths, thereby supporting safety and compliance.

"This is a defining moment for the Indian biopharmaceutical sector," said Sachin Joshi, Founder and Managing Director at PharmNXT. "With this acquisition, PharmNXT will introduce an innovative range of new solutions for biopharmaceutical and pharmaceutical customers worldwide. DTR is an innovative solution to address issues related to single-use tubing management. DTR systems are designed to handle single-use tubing in pharmaceutical and biotech/biopharma facilities, ensuring proper routing, reducing errors, and enhancing the overall appearance of the facility.

Ankush Kapoor, Founder and CEO of PharmNXT Biotech, says, "We are really excited about this acquisition, which is highly strategic and complements our manufacturing capabilities in single-use technologies-consumables and process equipment. The addition of DTR systems allows customers to access the full range of solutions in single-use technologies from PharmNXT. David

Walton, the former owner of DTR, brings invaluable industry knowledge, further strengthening our technical leadership. David's extensive experience, expertise, and global customer base in this space will play a pivotal role in accelerating the growth of PharmNXT's end-to-end single-use solutions portfolio in the US, Europe, and Asia."

Former DTR owner, Mr Walton, is going to be a strategic advisor to PharmNXT's leadership team, offering continuity and strategic direction. He added, "I'm excited to be associated with PharmNXT team. Our combined strengths open up new possibilities in R&D and product customization, especially for clients operating in tightly regulated markets. I look forward to contributing to PharmNXT's mission of delivering high-quality, scalable solutions to customers worldwide."

India's pharmaceutical exports crossed \$30 billion in the FY25, driven by low-cost innovation, technical skill, and regulatory adaptability. PharmNXT's acquisition comes at a time when global pharma companies are looking for robust, de-risked supply chains, making India not just a backup but a preferred partner in biotech infrastructure.

## Lilly expands India Presence with inauguration of Hyderabad Site to Accelerate Global Digital Innovation

**Hyderabad, India:** Eli Lilly and Company (India) announced the opening of its new technology and innovation site in Hyderabad; a new strategic hub for advanced digital and technology capabilities that will improve efficiency across Lilly's global operations. By focusing on areas such as artificial intelligence (AI), automation, cloud computing, and software product engineering, the site will contribute to solving some of the world's most pressing health challenges while also creating growth opportunities for local talent.

Located in Gachibowli, Lilly's Hyderabad site spans approximately 220,000 square feet across four floors within the Phoenix Equinox building. Lilly has already onboarded 100 professionals at the Hyderabad facility and plans to expand the headcount to 1,500 over the next few years. The facility was officially inaugurated by Diogo Rau, Executive Vice President and Chief Information and Digital Officer of Eli Lilly and Company, alongside the Hon'ble Chief Minister of Telangana, Shri A. Revanth Reddy, and Shri D. Sridhar Babu, Hon'ble Minister for IT, Electronics & Communications, Industries & Commerce, and Legislative Affairs, Government of Telangana. Sanjay Kumar, IAS, Special

Chief Secretary, Industries and Commerce Department, was also present at the event.

Shri A. Revanth Reddy, Hon'ble Chief Minister of Telangana, said, "We are delighted to welcome Lilly to Hyderabad's growing life sciences ecosystem. The inauguration of this new site further reinforces the city's position as a global hub for healthcare innovation, built on scientific excellence, skilled talent, and international collaboration. The Government of Telangana remains committed to fostering an environment where pioneering companies like Lilly can thrive and deliver meaningful impact both in India and globally."

Shri Sridhar Babu, Hon'ble Minister for Information Technology, Electronics & Communications, Industries & Commerce and Legislative Affairs, Telangana, added, "Hyderabad is rapidly emerging as a global epicentre for digital innovation, and Lilly's new site inauguration is a strong validation of that momentum. This investment reflects the transformative impact of technology on healthcare. Telangana remains committed to enabling future-focused partnerships that drive economic growth and advance digital health solutions for the world."

"The inauguration of our Hyderabad site reflects our long-term commitment to India and our intent to strengthen our presence in the region," said Diogo Rau, Executive Vice President and Chief Information and Digital Officer, Eli Lilly and Company. "This expansion brings together top talent in AI, data science, and engineering to build the digital foundation that will accelerate the discovery and delivery of innovative medicines. Hyderabad offers the perfect blend of deep technical expertise and a spirit of collaboration, making it a natural partner in our mission to make life better for people around the world. The city's legacy of innovation runs deep—from establishing one of India's first medical schools in 1846 to being among the earliest regions to adopt railways in recognition of the power of connectivity. Today, we are proud to build on that history by creating an integrated ecosystem that unites medicine, engineering, and digital innovation to transform how healthcare is delivered."

## **CORONA Remedies appoints Ameetkumar Desai, Bhaskar Iyer, Shirish Belapure, Monica Kanuga on its Board as Independent Directors**

**New Delhi, India:** CORONA Remedies Limited, backed by Sepia Investments Limited, an affiliate of ChrysCapital, has appointed Ameetkumar Hiranyakumar Desai,

Bhaskar Vemban Iyer, Shirish Gundopant Belapure and Monica Hemal Kanuga as Independent Directors to its Board of Directors bringing in diverse expertise and experience.

CORONA Remedies Limited is an India-focused branded pharmaceutical formulation Company engaged in developing, manufacturing and marketing products in women's healthcare, cardio-diabeto, pain management, urology and other therapeutic areas. CORONA Remedies is the second fastest growing Company among the top 30 companies in the Indian Pharmaceutical Market ("IPM") in terms of domestic sales between MAT December 2021 and MAT December 2024 (Source: CRISIL Intelligence Report). The Company has two manufacturing facilities, located in the states of Gujarat and Himachal Pradesh and it is in the process of commissioning a hormone manufacturing facility in Gujarat at Ahmedabad. As of December 31, 2024, it had a workforce of 4470 with two facilities which are spread over an aggregate of 2.83 hectares and have an aggregate installed capacity for formulations of 1,285.44 million units per annum, with a total of 11 production lines.

Welcoming our Independent directors, Mr. Niravkumar Kirtikumar Mehta, Managing Director and CEO of CORONA Remedies, said: "We welcome these distinguished professionals to our Board. Their breadth of experience and strategic insight will support our mission of delivering impactful healthcare solutions and upholding high governance standards."

Ameetkumar Hiranyakumar Desai, said: "I joined the Board of CORONA Remedies, where I will contribute my experience and insights to support the Company's growth and strategic objectives."

Bhaskar Vemban Iyer added, "I joined the Board of CORONA Remedies committed to leveraging my industry insights to drive sustainable growth and build long-term stakeholder value. I will use my industry experience to support the Company's sustainable growth and long-term value creation."

Shirish Gundopant Belapure expressed by stating, I joined the board of "CORONA Remedies and will contribute to its success through operational excellence and innovation providing guidance on key appointments and succession planning, aligned with Company's long-term vision and sustainability."

Monica Hemal Kanuga stated, "I will contribute to the Board of CORONA Remedies, supporting the Company's focus on innovation and patient-centric solutions."

## Laborate Pharmaceuticals Secures EU-GMP Certification

**New Delhi, India:** Laborate Pharmaceuticals, one of India's prominent pharmaceutical manufacturing and exporting companies, recently announced that its manufacturing site in Laborate Pharmaceuticals India Ltd, 111, Paonta Sahib, ( H.P.) has been granted the EU-GMP (European Union - Good Manufacturing Practice) certification from the relevant European regulatory agency.

The certification confirms compliance with the high standards set by the EU for pharmaceutical manufacturers and provides Laborate Pharmaceuticals with new opportunities to export and ship its products to the European Union and other regulated markets. The facility is built for Oral Solid Dosage Form, including Tablets & Capsules, and is fitted with state-of-the-art systems and processes to ensure consistent quality and regulatory compliance.

"This EU-GMP certification provides a clear pathway to our focus on world-class standards of quality and manufacturing to take an unprecedented step to be recognised as the EU-GMP accredited pharmaceutical organisation," said Parag Bhatia, Director, Laborate Pharmaceuticals. "The certification confirms our capability to supply and export quality, safe and effective medicines to millions of people around the world."

Laborate is currently negotiating advanced discussions with clients in Europe and UK for the co-development and supply of finished formulation products targeted to treat various therapeutic diseases. These agreements will play a key role in Laborate's international strategy, pipeline expansion over the next 5 years.

The EU-GMP-certified facility, covering 157,500 square feet, has dedicated areas for 53000. The facility was audited and certified after a detailed investigation of its processes, systems, documentation, and quality management systems.

In fact, the facility certification provides a path to filing regulatory dossiers for multiple products in the EU market. The company intends to file 20 dossiers over the next 5 months to obtain approvals in Europe, UK, Australia and South Africa. The company is also exploring additional certifications via authorities such as GCC, EAEU to enhance its presence in regulated markets.

"We are focused on establishing longer-term

partnerships with global companies that value reliable and scalable manufacturing at a cost-effective and compliant basis," said Parag Bhatia, Director, Laborate Pharmaceuticals.

## Dr. Cyrus S. Poonawalla unveils newly built state-of-the-art Indian Red Cross Society



Dr. Cyrus S. Poonawalla, Chairman, Serum Institute of India

**New Delhi, India:** Dr. Cyrus S. Poonawalla, Chairman, Serum Institute of India (SII), part of Cyrus Poonawalla group and the world's largest vaccine manufacturer, today inaugurated the grand new building of Indian Red Cross Society's Dr. Cyrus Poonawalla School for Hearing Impaired at a new premise at 'Centenary Centre', Lulla Nagar, Pune. The newly built school is equipped with state-of-the-art infrastructure and modern amenities for the hearing-impaired children. The Viloo Poonawalla Foundation (VPF) has given all forms of support to the school since it was established and has helped the school to improve its facilities, resources, and programs, providing students with a better learning environment.

Spread across a wide area, the newly inaugurated school is equipped with high-end technologies and designed in a manner to meet the unique needs of children with hearing impairments, offering a wide array of enhanced services and specialised support. This expansion reflects the school's ongoing commitment of empowering the hearing community through specialised education and improved accessibility tailored to their specific needs. Run by 'The Indian Red Cross Society', Dr. Cyrus Poonawalla School for Hearing Impaired fosters a nurturing and encouraging environment to support inclusive and adaptive learning.

Expressing his delight at the inauguration of the newly built school, Dr. Cyrus S. Poonawalla, Chairman, Serum Institute of India said, "Providing better healthcare and support to children with special needs is a cause

very close to my heart. Today, I feel deeply gratified to inaugurate this new school dedicated for the children with hearing-impairments. As an organization, our goal is to effectively utilize our resources to provide the best preventive solutions to the population, including children. This new building encompassing advanced infrastructure and modern facilities for the hearing-impaired children is a step towards the same direction.”

With Dr. Cyrus S. Poonawalla as the Chief Guest, the inaugural ceremony was attended by Dr Vikram Phatak, Chairman, Indian Red Cross Society, Mr. Mabrin Nanavati, Vice Chairman, Indian Red Cross Society, and Prof R.V. Kulkarni Hon. Secretary, Indian Red Cross Society, Pune, along with members of the SII leadership team and school community.

The School for the Hearing Impaired was established in 1976, with a vision of empowering children with hearing challenges. Over the decades, it has grown into a well-respected institution providing specialised education tailored to the needs of the hearing-impaired students. With a mission to empower the hearing community, the school continues to provide education in an accessible setting.

## Zydus receives final approval from USFDA for Prucalopride tablets

**Ahmedabad, India:** Zydus Lifesciences Limited has received final approval from the United States Food and Drug Administration (USFDA) for Prucalopride Tablets, 1 mg and 2 mg (USRLD: Motegrity® Tablets, 1 mg and 2 mg).

Prucalopride is prescribed for chronic idiopathic constipation (CIC), a condition where the cause of constipation is unknown. It helps stimulate peristalsis, natural muscle contractions in the colon, to promote more regular bowel movements. Prucalopride tablets will be produced at Zydus Lifesciences Ltd (SEZ), Ahmedabad. Prucalopride tablets had annual sales of USD 186.8 mn in the United States (IQVIA MAT June 2025).

The group now has 422 approvals and has so far filed 483\* ANDAs since the commencement of the filing process in FY 2003-04.

## Agilent supports India's Global Biopharma Ambitions with State-of-the-Art Experience Center in Hyderabad

**Hyderabad, India:** Agilent Technologies, a global leader in life sciences, diagnostics, and applied chemical markets, announced the inauguration of its new Biopharma Experience Center in Hyderabad, Telangana. The facility marks a significant investment in India's rapidly growing life sciences ecosystem and reflects Agilent's long-term commitment to advancing biopharmaceutical innovation both locally and globally. The center was inaugurated by Shri Duddila Sridhar Babu, Hon'ble Minister for Information Technology, Electronics, Communications, and Industries, Government of Telangana, in the presence of Agilent President and CEO Padraig McDonnell, along with senior leaders from India's pharmaceutical and biopharma sectors.

The new Agilent Biopharma Experience Center in Hyderabad presents a major opportunity to accelerate the city's leadership in life sciences and healthcare innovation. Designed to support the full drug development journey, the center brings together advanced lab technologies, expert training, and regulatory-ready workflows to help researchers, scientists, and companies develop high-quality, life-saving medicines faster and more efficiently. It offers end-to-end solutions across key modalities such as chromatography, mass spectrometry, cell analysis, and lab informatics, allowing companies to simulate real lab environments, test for quality and compliance, and co-create market-ready solutions tailored to both Indian and global needs.

For Hyderabad's vibrant ecosystem of startups, academic institutions, and skilled professionals, the center unlocks direct access to global expertise, cutting-edge instrumentation, and real-world application environments. It supports faster R&D, hands-on training aligned with international regulatory standards, and stronger collaboration between industry and academia. By addressing critical challenges in biosimilars, biologics, and precision medicine, the facility strengthens Hyderabad's position as a trusted global hub for next-generation drug development, and a key contributor to India's biopharma growth story.

“India is a strategic growth market for Agilent, and Hyderabad is at the forefront of biopharma innovation,” said Padraig McDonnell, CEO, Agilent Technologies.

“Our future will be defined by continued innovation and a relentless focus on our customers. This new center reflects our commitment to delivering integrated solutions that help bring life-changing therapies to market faster and more efficiently. It also reinforces our support for the ‘Make-in-India’ initiative by empowering local innovation, nurturing talent, and enabling scalable, affordable, and sustainable solutions.”

## Sun Pharma Q1 Gross sales up 10%



Dilip Shanghvi, Chairman and Managing Director, Sun Pharma

**Mumbai, India:** Sun Pharmaceutical Industries Limited reported financials for the first quarter ending June 30th, 2025.

The company's Gross sales was at ₹ 137,861 million, growth of 10.1%, while India formulation sales was at ₹ 47,211 million, up 13.9%.

The company's EBITDA stood at ₹ 43,017 million (including other operating revenues), up 19.2%, with resulting EBITDA margin of 31.1%

Dilip Shanghvi, Chairman and Managing Director of the Company, said, “Sun had a strong performance during the quarter, where the overall growth reflects steady progress across all our markets. India continues to show strong momentum, contributing meaningfully to our performance. The U.S. launch of LEQSELVI represents an important step forward, offering a new treatment option for patients with severe alopecia areata. LEQSELVI augments our portfolio in dermatology and adds a growth engine to our Innovative Medicines business.”

## Wockhardt Q1 revenue stood at ₹ 738 Crore

**Mumbai, India:** Wockhardt Limited, the Pharmaceutical and Biotechnology major, reported its 1st Quarter Results for Financial Year 2025-26

The company's Revenue for Q1FY26 is ₹ 738 Crore as compared to ₹ 747 Cr in the previous year and QoQ growth of 1% in EBITDA in Q1FY26, EBITDA for Q1FY26 of ₹ 101 Crore compared to ₹ 100 Crore in the previous year.

Business approach of the Company is to continue the growth momentum with focus on profitability while balancing investments in innovative portfolio comprising Novel Antibiotics and Diabetes Biosimilars to build an organization across various aspects of regulatory, clinical, medical and commercial excellence for pre-launch and launch activities in India and developed markets.

Two pre-NDA meetings with US FDA have been successfully completed and the filing of the New Drug Application (NDA) dossier is targeted in September 2025. In India, the NDA has already been submitted on March 31, 2025.

## OneSource Specialty Pharma Q1 revenue up 12%

**Bangalore, India:** OneSource Specialty Pharma Limited announced its consolidated financial results for the quarter ended June 30, 2025 (Q1FY26).

The company's Revenues stood at ₹3,273 million, up 12% YoY, while EBITDA grew 37% YoY to ₹885 million.

Neeraj Sharma, CEO & MD, OneSource Specialty Pharma Limited speaking on the performance said, “Our Q1 performance has been in line with our expectations. During the quarter, we secured 6 new contracts and received 25 RFPs across all our offerings. In preparation for forthcoming DDC commercial launches, we have undertaken major capacity expansion work in our flagship site. Our unrelenting focus on quality and compliance was once again validated with our flagship site successfully clearing back-to-back inspections from USFDA and ANVISA Brazil paving the way for commercialisation.”

The Board of Directors of the Company, in their meeting, appointed a sub-committee of independent directors to evaluate a strategic transaction for the company's future growth. This investment committee will evaluate the potential acquisition of two USFDA-approved specialty injectable assets of Steriscience Specialities.

## Marksans Pharma Q1 Operating revenue up 5%

**Mumbai, India:** Marksans Pharma Ltd. reported the financial results for the quarter ended on June 30, 2025.

The company's Operating revenue stood at ₹ 620 crore., up by 5% YoY, driven mainly by growth in the US market from new product launches in the gastrointestinal, pain management, and digestive health segments.

The company's Gross profit stood at ₹ 358.2 crore., up by 8.9% YoY, with a gross margin expansion of 209 bps YoY to 57.8%. Gross margin improved with the liquidation of higher-cost inventories and benefits from softening input costs.

Mark Saldanha, Managing Director of the Company said "While Q1FY26 was a seasonally soft quarter, we delivered year-on-year revenue growth of 5%, while gross profit increased by 8.9%. This was supported by successful new product launches in the US markets and the easing of raw material costs. While EBITDA and net profit margins were impacted by ramp-up costs, a one-time ECL provision for the emerging market division, and forex adjustments, these are transient and do not affect the fundamental momentum of our business. We are already seeing encouraging early signs of demand recovery in key markets such as the U.S., U.K., and Australia. With the Goa facility integration nearing completion, we are now sharply focused on scaling capacity, enhancing operational efficiency, and unlocking synergies. Our execution discipline, combined with a robust pipeline and expanding market presence, positions us well to deliver sustainable, long-term value."

## Alkem Q1 reports net profit rise 22%



Dr. Vikas Gupta, CEO, Alkem Laboratories

**Mumbai, India:** Alkem Laboratories Ltd announced its standalone and consolidated financial results for the first quarter ended June 30, 2025.

The company's total Revenue from Operations was ₹33,711 million, with YoY growth of 11.2%, while Net Profit (after Minority

Interest) was ₹6,643 million, YoY growth of 21.8%.

Commenting on the Q1 FY26 results, Dr. Vikas Gupta, CEO of Alkem, said, "Q1 FY26 marked a strong start to the year, with healthy growth across both our domestic and international markets. Our performance was driven by strong topline growth and an improved gross margin, which resulted in a better EBITDA profile. These results reflect the disciplined execution of our strategy, focused investments, and a deliberate pivot toward value-accretive products and markets with a sharper focus on EBITDA. We are strategically accelerating our focus on the non-US business segment by strengthening our presence in high-potential non-US markets and capturing new opportunities that align with our long-term growth ambitions."

## Aurobindo Pharma Q1 Revenue from Operations up 4%

**Hyderabad, India:** Aurobindo Pharma Limited announced its consolidated financial results for the quarter ended June 30, 2025.

The company's Revenue from Operations increased by 4.0% YoY to ₹ 7,868 Crore with growth in Europe and Growth markets, while Net Profit for the period stood at ₹ 824 Crore.

The company has received final approval for 14 ANDAs (including 1 ANDA previously tentatively approved, now receiving the final approval) from the USFDA.

The company's growth Markets revenue increased by 8.8% YoY to ₹ 772 Crore.

Commenting on the Company's performance, K. Nithyananda Reddy, Vice-Chairman and Managing Director of the Company said: "We started the year steadily, with our European business maintaining strong growth momentum and our core US business showing resilience despite temporary challenges from destocking and seasonal dynamics. Our disciplined execution, operational initiatives, and recent US acquisition strengthens our commercial footprint and accelerates growth potential." ■

## ▶ CASE STUDY

# Advanced visualization solution for regulatory compliance & effective data management



NKP Pharma is a leader in pharmaceutical machinery manufacturing, committed to innovation and delivering advanced solutions that meet the evolving demands of the pharmaceutical industry. Established in 1988, NKP launched its first automatic machine for sterile dry powder injectable filling. Today, NKP Pharma is a significant player in India's pharmaceutical packaging machinery sector.

### **Challenges faced by NKP Pharma:**

NKP faced a significant challenge navigating the stringent regulations of the pharmaceutical industry, particularly compliance with USFDA 21 CFR Part 11. These regulations govern electronic records and signatures, protecting data integrity and traceability in pharmaceutical manufacturing.

Traditional IPC-SCADA systems, designed to achieve 21 CFR Part 11 compliance, had become cost prohibitive. For NKP Pharma, implementing the IPC-SCADA solution across all of their machines strained

budgets and passed on high costs to customers. Additionally, the current setup centralized data management with NKP Pharma, leaving customers without direct access to their operational data. This lack of accessibility created a hurdle for customer satisfaction and operational efficiency.

### **Solutions offered by Rockwell Automation:**

NKP sought a cost-effective solution that supported compliance with 21 CFR Part 11 while granting customers access to more of their own data. Turning to Rockwell Automation, NKP Pharma looked to

modernize their systems without compromising quality or compliance.

Rockwell Automation recommended FactoryTalk® Optix™, a next-generation HMI solution designed for advanced visualization and seamless data integration. FactoryTalk® Optix™ simplifies automation and enables real-time insights into machine operations. Its flexibility and user-centric design make it an ideal choice for pharmaceutical manufacturing environments requiring regulatory compliance and robust data management.

NKP Pharma initiated a pilot project to test the solution on their inspection machine. As part of the implementation, the company included 21 CFR Part 11 criteria, such as user-level access control, alarm reporting, and online reporting. This structured experiment with FactoryTalk Optix allowed NKP Pharma to reap the benefits from modernizing their system before deploying it onto other machines on their floor and on customer machines.

#### Results achieved:

The pilot project with FactoryTalk® Optix delivered impressive results. The new HMI solution met compliance requirements while reducing expenses.

"I can proudly say that after implementing FactoryTalk Optix during our pilot phase, we have the cost-effective solution for the market with respect to the costly solution of IPC-SCADA," said, Alpesh Mistry, Vice President of Operations, NKP Pharma.

Following the success with the pilot project, NKP Pharma implemented the FactoryTalk Optix on customer machines with great success. Customers appreciated the improved accessibility and performance, leading to increased orders for machines equipped with the new HMI solution.

The company now plans to integrate FactoryTalk Optix into their filling line machinery and diversify their portfolio with advanced injectable pharma solutions, such as blow-fill-seal machines and cartridge filling machines. ■

#### For more information, visit our website:

<https://www.rockwellautomation.com/en-in/industries/life-sciences.html>) and Email: [RAIndiamarketing@rockwellautomation.com](mailto:RAIndiamarketing@rockwellautomation.com)



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## Cohance Lifesciences announces ₹230 mn Investment in Hyderabad

**Hyderabad, India:** Cohance Lifesciences Limited, a partner of choice for global innovator pharma companies, announced Rs. 230 million investment and significant progress on its new cGMP oligonucleotide building block manufacturing facility in Hyderabad, India. This strategic investment strengthens Cohance's integrated oligonucleotide platform and enhances its position as a preferred partner for emerging modalities.

Cohance brings deep expertise in modified nucleosides and locked nucleic acids (LNA), with a proven track record in complex nucleoside and nucleic acid synthesis at the R&D stage. The new facility will enable the Company to take these high-value chemistries from laboratory scale to full commercial manufacturing, meeting the needs of innovators advancing oligonucleotide-based therapeutics.

Integrated with pilot plant for early-stage synthesis and for non-GMP scale-up, the facility will add fit-for-purpose GMP capacity of up to 700 kg annually, with room for future expansion. This scale, combined with advanced environmental controls including ISO Class 8 clean rooms and RH-controlled areas, is designed to meet the stringent requirements of complex oligonucleotide building block production.

Customer engagements are already underway, with audits planned in the coming quarters. Kilo lab validations and modified nucleotides are in progress, with GMP-grade PMO and LNA amidite validations expected to commence in CY26.

Vivek Sharma, Executive Chairman, Cohance Lifesciences, said: "Oligonucleotides are a fast-emerging therapeutic class, and innovators are seeking integrated, cost-efficient partners with scalable GMP capacity. This facility is a high-impact strategic investment that complements our pilot and scale-up assets, positioning Cohance to deliver with speed, quality, and flexibility while expanding our role in next-generation therapeutics."

This investment follows the Company's recently announced USD 10 million expansion of cGMP bioconjugation capabilities at NJ Bio in the United States. Together, these investments form part of Cohance's planned capacity expansion program across high-growth modalities, enhancing its ability to serve global innovators from early development to commercial supply.

## Celcius Logistics enters Pharma Cold Supply Chain with ₹50 Crore Investment

**Mumbai, India:** Celcius Logistics, India's leading tech-driven 3PL and cold supply chain solutions provider, has announced the launch of Celcius+, a specialised logistics arm dedicated exclusively to the seamless management of the pharmaceutical supply chain. Designed to meet the sector's stringent requirements for temperature control, compliance, and real-time visibility, Celcius+ ensures medicines, vaccines, and other sensitive products are transported with maximum safety and efficiency.

In its initial phase, Celcius will invest ₹50 crore to create a dedicated pharma fleet and support infrastructure, with a goal of achieving ₹100 crore in Annual Recurring Revenue (ARR) from this segment within the next 18 months. Of this, ₹35 crore will be allocated towards deploying 100 new reefer vehicles for Celcius+ along key pharmaceutical corridors across India. A further ₹10–15 crore is being earmarked to build a robust pharma courier system tailored to serve high-demand urban and semi-urban markets.

To support this rapid expansion, Celcius will add 30–40 specialised team members with expertise in pharma logistics, operations, and regulatory compliance. Leveraging its advanced technology platform, Celcius+ will offer real-time tracking, continuous temperature monitoring, and AI-enabled route optimisation, ensuring every shipment adheres to the industry's most stringent quality and compliance standards.

Commenting on the launch, Swarup Bose, Founder & CEO at Celcius Logistics, said, "India's pharmaceutical sector is among the fastest growing in the world, yet maintaining product integrity from manufacturer to patient remains a challenge. With Celcius+, we are not only expanding capacity but also setting new benchmarks for wastage reduction, safety, transparency, and operational excellence in pharma logistics. Our investment in this vertical marks the beginning of a focused journey to bridge gaps in pharma distribution with tech-backed, GDP-compliant solutions. This initiative is in line with Celcius Logistics' mission to bridge cold chain gaps, reduce wastage, and enable safe, timely deliveries for life-saving products. We're confident that Celcius+ will help pharmaceutical companies extend their reach safely and efficiently across major cities by year-end."

With this specialized vertical, Celcius plans to partner

with leading pharmaceutical companies and extend its reach to more than 100 cities across India by the end of 2025.

Celcius+ will deliver tech-enabled supply chain solutions tailored for pharmaceutical and healthcare clients, addressing critical challenges such as temperature-sensitive logistics, regulatory adherence, and real-time shipment visibility. The vertical will focus on high-value, sensitive segments including vaccines, biologics, insulin, and specialty medicines, offering services that span primary distribution, secondary distribution, and last-mile pharma courier delivery.

## Medistep Healthcare Eyes ₹16.09 Crore Fundraise

**Mumbai, India:** Medistep Healthcare Limited is set to raise approximately ₹16.09 crore through its upcoming fixed-price Initial Public Offering (IPO), with the primary objective of strengthening its manufacturing infrastructure through the acquisition of advanced plant and machinery.

A significant portion of the IPO proceeds will be allocated toward the acquisition and installation of state-of-the-art equipment at the company's existing manufacturing facility in Kheda, Gujarat. At the core of this investment is a fully automated, high-speed sanitary pad production line, capable of producing up to 500 pads per minute. This integrated line features raw material feeding, embossing, adhesive application, and inline quality inspection within a single, streamlined workflow.

Additionally, the company will commission a twin-shaft ribbon blender with vacuum-sealed hoppers and an integrated volumetric filler from DEF Tech Industries. This system will enable precise and hygienic blending and packaging of energy powder sachets at speeds of up to 200 units per minute. To enhance the secondary packaging process, three modular tri-axis flow-wrap machines will also be installed. These machines are equipped for automatic bag feeding, sealing, date-coding, and stacking, thereby increasing throughput and significantly reducing manual processes.

The capital expenditure also covers plant-floor modifications, utility installations, operator training, and warranty support. All systems are expected to be fully operational and certified within three months of their scheduled delivery in Q4 FY26. This strategic infrastructure upgrade is projected to increase overall manufacturing capacity by approximately 30% over

the next 12 months, markedly improving production efficiency, product quality, and the company's responsiveness to growing market demand.

A portion of the funds will also go toward bolstering working capital to ensure uninterrupted raw material procurement and optimal inventory levels. Remaining proceeds will be used for general corporate purposes and expenses related to the IPO.

"The funds raised will support our next phase of growth by strengthening our manufacturing capabilities and supporting market expansion," said Mr. Girdhari Lal Prajapati, Managing Director of Medistep Healthcare Limited.

## Sai Parenterals Secures ₹50 Crore Equity Investment from Marquee Investors

**Mumbai, India:** Sai Parenterals Limited is pleased to announce the successful completion of a ₹50 crore equity investment round by a group of marquee investors. The capital will support the company's growth plans for establishing its international footprint as it pursues its vision to become a global pharmaceutical company.

Samarsh Capital, Vyom Partners, and funds associated with Blue Lotus Capital led the fundraising round.

Anil Karusala, Managing Director of Sai Parenterals, remarked "We are working diligently to build a world-class pharmaceutical company that adheres to the highest global standards and practices. This equity infusion will allow us to acquire high-potential international assets and intellectual property in regulated markets, expand our product portfolio and geographical presence, and enhance our manufacturing capabilities. We are honoured by the confidence of such professional investors in our company's strategy and future."

Sandeep Shenoy, Managing Partner of Samarsh Capital, commented, "Our investment in Sai Parenterals reflects our confidence in its solid fundamentals, scalable model, and potential to achieve strong growth in the global pharmaceutical sector. Under the visionary leadership of Anil, we expect Sai Parenterals to emerge as a leader in its segment."

Sai Parenterals Limited is an Indian pharmaceutical company with a proven track record in the formulations segment. The company operates across the pharmaceutical value chain, including research & development (R&D), manufacturing, regulatory compliance, marketing, and exports. ■

## “We are targeting revenue of ₹ 750 crores by FY26.”



**Munjal Patel**

Director  
Lincoln Pharmaceuticals Ltd

**Munjal Patel, Director, Lincoln Pharmaceuticals Ltd** spoke about the Pharmaceutical industry and expansion plans globally going ahead. He also emphasized about product launches and new initiatives.

### **What outlook do you see for the Pharma industry going ahead?**

The global pharmaceutical industry is set for sustained growth, fuelled by rising healthcare awareness, aging population, and a shift toward preventive and personalized medicinal awareness.

India, now the world's 4th largest economy, plays a pivotal role in this landscape. As a global leader in production of generic drugs—accounting for 20% of global supply—India's pharma sector is supported by 3,000+ companies and 10,500 manufacturing units. Renowned for cost-efficiency and quality, India exports to over 200 countries, including regulated markets like the US and EU, and supplies around 60% of global

vaccine demand. With strong R&D, a skilled workforce, and global compliance, India is well-positioned for continued domestic and international growth.

### **Brief us about your expansion plans?**

Lincoln Pharmaceuticals is pursuing strategic expansion through new product launches in key therapeutic areas like chronic care, women's health, and ENT department, targeting both domestic and international markets. The company is strengthening its global presence by entering new geographies, especially regulated markets such as the Canada, Australia and EU. Backed by robust R&D and a focus on innovation, we are developing niche and technology-driven formulations. We are also enhancing manufacturing capacity with advanced, globally

compliant facilities, while adopting digital tools to boost operational efficiency. We have also completed the expansion of our Cephalosporin plant in Mehsana, Gujarat, and are aggressively pursuing product registration, with anticipated sales of approximately Rs. 150 crore over the next 2-3 years. These initiatives aim to expand our portfolio and solidify our position in the global pharmaceutical landscape.

#### **What is your focus area going ahead?**

Our focus area moving forward is on extending our international reach. Currently exporting to over 60 countries, we plan to increase this reach to 90 countries within the next 2-3 years. Our major international markets include East and West Africa, Central, North and Latin America, as well as South East Asia. Our recent initiatives include entering the Canadian market and securing approvals from TGA - Australia and EU GMP, which will facilitate further expansion into these regions. Our growth strategy involves registering new products for export, strengthening our market presence in existing and new regions, and leveraging our state-of-the-art manufacturing facilities that comply with international standards.

#### **Brief us about the new product launches?**

To facilitate growth and strengthen our market footprint, we are set to launch a series of innovative, value-driven products across multiple therapeutic segments, wherein new products have been developed to cure various diseases faster and efficiently. These upcoming launches are designed to meet changing needs in both local and global markets, supporting our strategy to expand and improve our product range. Backed by Lincoln's strong R&D capabilities and advanced manufacturing infrastructure, these launches will reinforce our commitment to addressing diverse healthcare challenges while solidifying our presence in key global markets.

#### **What are the new initiatives, the company is coming up with?**

We have completed the expansion of our Cephalosporin plant in Mehsana, Gujarat, which is now commercially operational with domestic sales underway. Plans are in progress to register these products for export. This plant is expected to contribute sales of around ₹ 150 crores in next 3 years. We have also received

WHO-GMP approval for tablets, capsules, and dry-powder suspensions at the facility. Going forward, we are focusing on enhancing our portfolio in Oncology & Hormonal range, alongside our existing acute care offerings.

#### **What percentage of revenue comes from international market?**

In FY25 exports contributed 62.1% of the total business. The company exports to over 60 countries across East & West Africa, Central & North America, Latin America, and Southeast Asia. Recent initiatives include entering the Canadian market and securing approvals from TGA - Australia and EU GMP, which will facilitate further expansion into these regions.

#### **What is your revenue target for FY 26?**

We are targeting revenue of ₹ 750 crores by FY26. The company is looking at roughly 15-18% growth yearly, thereby aiming at ₹ 1000 crore revenue in next three years. This goal will be supported by new product launches, expansion into regulated markets like Canada, Australia and Europe, increased export activities, and scaling up of manufacturing capabilities. The company's focus on R&D and high-margin, value-added formulations is expected to play a key role in achieving this milestone. ■

## “Rockwell Automation is setting the stage for a transformative future in India”



**Ankur Pancholi**

Software & Control Business Manager  
Rockwell Automation India

**Ankur Pancholi, Software & Control Business Manager, Rockwell Automation India** emphasizes about insights on the pharma and biotech manufacturing industry. He also spoke about the changes in the manufacturing sector as against pharma and biotech industry and company's vision going ahead.

**The pharma and biotech manufacturing industry uses methods that are highly process intensive. So, based on your experience of more than three decades in the process automation arena, what are the tips and insights that you would like to offer the Indian pharma and biotech players to ensure that their international market share continues on its upward journey?**

Indian pharma and biotech are poised for global leadership — but sustained growth will depend on how well we blend technology, people, and process. My advice:

- Make quality intrinsic, not just compliant — use digital twins, AI analytics, and closed-loop control to keep every batch within target.
- Connect the plant digitally — integrate MES, LIMS, and ERP for real-time visibility from raw material to release.
- Marry productivity with sustainability — deploy IoT for energy efficiency, water recovery, and green chemistry tracking.
- Invest in people — reskill experienced operators in advanced automation and data analytics.

- Think beyond audits — automate compliance to exceed global regulatory expectations.

The differentiator will be agility — adopting Industry 4.0 not just as a technology upgrade, but as a cultural shift. Done right, it will secure and accelerate India's global market share

**It is common knowledge that managing and overcoming the international pharma/biotech regulatory hurdles is a high-budget activity. How can pharma/biotech business owners meet the stringent global regulatory standards without impacting their bottom lines and yet maintain the highest quality?**

From my experience in process automation, three strategies stand out:

- Automate compliance at the source. Build systems that generate compliant data, audit trails, and electronic batch records in real time. This reduces manual documentation costs, eliminates errors, and shortens audit preparation time.
- Use predictive and preventive quality tools. AI-driven analytics can detect anomalies early, allowing corrective action before deviations occur. This avoids costly batch rejections and reduces the need for last-minute firefighting.
- Leverage modular and scalable automation. Instead of overhauling entire plants, adopt scalable digital solutions — like PAT (Process Analytical Technology), IoT-enabled monitoring, and cloud-based validation systems — that can be integrated step-by-step, spreading investment over time while steadily improving compliance readiness.

The goal is to shift from a 'cost of compliance' mindset to a 'return on compliance' mindset — where every rupee spent strengthens both regulatory standing and operational efficiency. By aligning automation investments with both quality and productivity outcomes, pharma and biotech companies can protect their bottom line while meeting, and even exceeding, the world's toughest standards.

**Has the Indian pharma and biotech industry embraced IPC-SCADA, CMMS, cGMP, GAMP 5, etc. in a big way? If so, then have these standards and systems made it easier for pharma/biotech**

**companies to face the increasing unannounced inspection audits conducted by FDA, MHRA, EMA, etc. at Indian locations?**

Over the past decade, Indian pharma and biotech manufacturers have significantly increased adoption of standards and systems like IPC-SCADA, CMMS, cGMP, and GAMP 5. This shift is not just about ticking compliance boxes; it's about building a robust, data-driven operational backbone.

- IPC-SCADA systems now deliver continuous process monitoring with real-time alarms, enabling immediate corrective action and reducing the likelihood of deviations that could raise red flags during inspections.
- CMMS platforms have streamlined preventive maintenance, ensuring that equipment is audit-ready and downtime is minimized — a key factor in demonstrating control to inspectors.
- cGMP and GAMP 5 frameworks have elevated documentation and validation practices, ensuring that every process change, software update, or equipment modification is traceable, validated, and compliant.

The impact on unannounced inspections has been clear: plants with integrated automation and compliance systems are able to present validated data instantly, demonstrate continuous control, and provide transparent audit trails — all of which create confidence with regulators like FDA, MHRA, and EMA.

However, technology alone isn't enough. The companies that perform best in these surprise audits have also invested in training operators and managers to understand not just 'how' to use these systems, but 'why' compliance matters. This cultural readiness, combined with advanced automation, is what truly turns inspections from a stress point into an opportunity to showcase excellence.

**How important is network security in regulated industries like pharma and biotech?**

In today's regulated pharma and biotech landscape, network security has moved far beyond being an IT afterthought — it is now a foundational element of quality, compliance, and operational resilience. Every batch record, every process parameter, every validated system depends on the integrity of the network that

carries it. A single breach can cascade into data manipulation, production halts, loss of intellectual property, and irreparable damage to global credibility. That's why cybersecurity must be engineered into the plant's DNA, woven into the same GxP mindset that governs safety, validation, and product quality.

**Advanced process automation features that enable serialisation is creating an impact beyond the shop floor by helping to combat counterfeit medicines and pilferage. Are there any other similar path breaking trends that is changing the landscape of pharma and biotech manufacturing?**

While serialization has been a breakthrough for combating counterfeits and pilferage, other disruptive trends are reshaping pharma and biotech manufacturing. Continuous manufacturing is shortening lead times, AI-driven PAT is preventing deviations in real time, digital twins are enabling virtual process optimization, edge AI is enhancing compliance monitoring, and blockchain is delivering full supply chain transparency. These aren't just tech upgrades — they are redefining how quality, compliance, and efficiency work together in the global marketplace.

**AI/ML has already changed the service industry in many unimaginable ways. Have you also witnessed comparable changes in the manufacturing sector vis-à-vis the pharma and biotech industry?**

AI/ML is no longer just an R&D or service industry tool — it's now transforming pharma and biotech manufacturing. Predictive quality models analyze historical and real-time data to flag deviations before they occur, reducing batch rejections. Machine learning optimizes processes in real time, improving yields and ensuring compliance. AI-powered digital twins simulate process changes, speeding up validation and scale-up without disrupting production.

**Rockwell Automation has been in India for more than four decades now. Moving forward, what is the company's vision for the next four decades?**

Having served Indian industry for over 40 years, Rockwell Automation is setting the stage for a transformative future in India — one built on smart manufacturing, sustainability, and local innovation.

- India as a critical growth market: The dynamic market and economic potential make India a focus for our future growth.
- Commitment to supporting Indian manufacturing: Building and enabling the ecosystem (OEMs, partners) that will lift the quality of manufacturing. Supporting the 'Make in India' initiative, our technologies and solutions empower Indian manufacturers to improve the productivity, sustainability and global competitiveness. We also design and manufacture many of our own products in India and recently announced our plans to build a new factory in Chennai, Tamil Nadu.
- India as a talent hub: India is a key talent hub for Rockwell. We employ skilled professionals across hardware and software design and manufacturing as well as consulting and executive positions. These employees contribute to our success globally. ■

## “We are planning to expand into over 100 countries around the globe”



**Parag Bhatia**

Director  
Laborate Pharmaceuticals

**Parag Bhatia, Director, Laborate Pharmaceuticals** talks about the company's expansion plans globally. He also emphasized about the company's challenges, partnerships and product launches.

### **What does receiving the EU-GMP certification mean for Laborate Pharmaceuticals at this stage of its growth?**

Laborate is currently exporting to 55 countries around the globe. We have a massive presence across African, Middle Eastern, Latin, and Southeast Asian countries, and getting the certification of EU-GMP will expand Laborate's horizon to over 100 countries in the coming 3–4 years. Our focus with EU-GMP is that this certification is a testament to the quality of the products we manufacture. It certifies that Laborate is one of the renowned quality manufacturers in the country. On the quality front, we are certified to be among the best in the country, and this certificate will enable our growth projection to over 100 countries around the globe.

### **Can you elaborate on the capabilities and infrastructure of the Paonta Sahib facility that helped secure the certification?**

There is zero man-touch involved in the entire process, it is fully automatic. All machines are in place to ensure zero contamination so that every medicine is made in the safest way possible, with no contamination from one room to another or from one product to another. All processes follow a unilateral flow model. Every room is equipped with MAL and PAL facilities, online particle counters, weight checkers, and track-and-trace systems. The facility also has huge blenders, including a 2,500-litre blender suite. Laborate operates on an economies-of-scale model to enable high-quality production at lower costs, making quality medicines affordable across the globe.



finer details cannot be disclosed at this moment. We will share them after commercialisation begins. Our target is to start commercialisation before the end of this financial year, and registration and tech transfer projects are already underway. We are expecting significant growth in the EU and UK markets soon.

**What role will this facility play in achieving the projected \$100 million in international revenue over the next five years? What is the growth target?**

**How does this certification impact Laborate's plans for international expansion, especially in regulated markets like the EU and UK?**

We are planning to expand into over 100 countries around the globe. This certification will not only help us enter the European and UK markets but also multiple Southeast Asian countries like the Philippines, Vietnam, Singapore, and Malaysia, as well as countries such as Australia, New Zealand in the APEC region, Canada, North America, South Africa, Peru, Bolivia, and Guatemala. We are also expanding our base in the UK in a CMO/CDMO model (Contract Manufacturing/Contract Development Manufacturing Organisation) in the UK and European nations including Hungary, France, and Germany.

What types of products will be manufactured at this certified facility, and which therapeutic areas are being prioritised?

We have been certified for the general OSD (oral solid dosage) sector, meaning general tablets and capsules. We will manufacture products across various therapeutic segments including, but not limited to, cardiovascular, diabetic, hypertension, analgesics, gastro, and anti-allergic products.

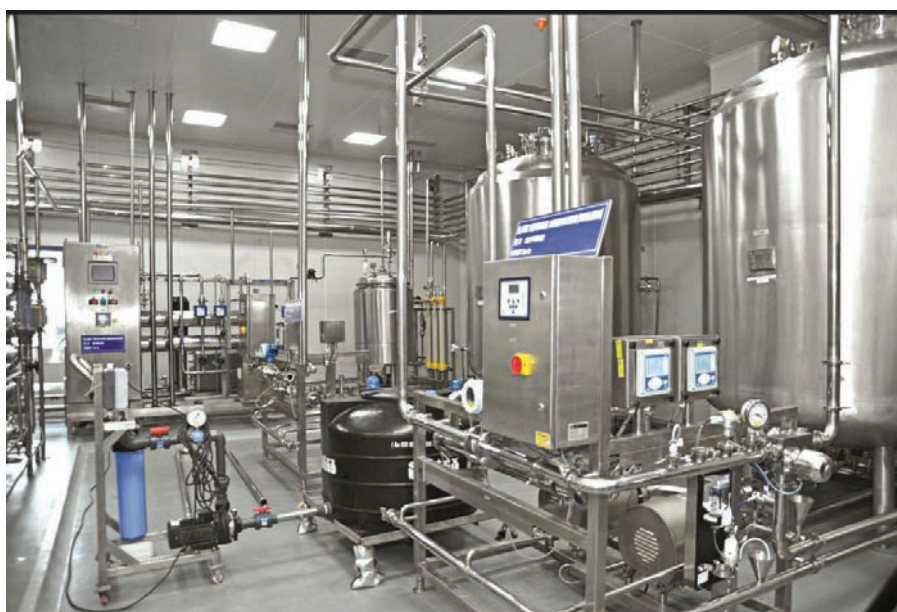
**Brief us about your talks with EU and UK partners? Can you share more on the nature or scale of these partnerships?**

We are already in talks with a lot of European and UK clients and have signed some deals. However, the

Currently, our international business stands at around USD45 million, and we expect to double this in the next five years. This facility will be the centre point of this growth, as we are also getting Eurasian GMP approval for expansion into CIS regions like Russia, Kazakhstan, and Kyrgyzstan. Additionally, there is an injectable and ophthalmic facility within this site that will soon receive EU approval. Preservative-free ophthalmic formulas are in high demand, and we will cater to this for the European region.

**Can you go through the process of obtaining EU-GMP certification and what were the key challenges and milestones?**

The process begins with developing a product and filing a dossier. After filing, the documents are evaluated, including the site master file and all manufacturing unit documents, which are pre-evaluated before the audit. Once the basic fee structure is completed, auditors are





invited to India for inspection. The biggest challenge for the European and UK markets, as well as other regulated markets, is the time it takes to get the facility and products approved. As a businessman, you are incurring costs regularly, but timelines are long and inspection dates are not easy to secure.

How many regulatory dossiers do you plan to file, and for which geographies?

We have around 20 product dossiers in progress. In the initial phase for the European market, we will file in Hungary and the UK. We will also file in South Africa, Australia, New Zealand, GCC nations, and some Latin American countries.

**Beyond the EU, are you exploring certifications from other regulatory bodies such as GCC or EAEU? What's the strategy there?**

Yes, we have our audit inspection for Eurasian GMP in November. Based on EU certification, we are applying for GCC approval in Saudi Arabia. We are also working on WHO pre-qualification for anti-malarial drugs.

**How is Laborate positioning itself as a long-term partner for global pharmaceutical companies?**

Laborate is in a strong position, with over 40 years of experience manufacturing more than 1,500 products for emerging markets. Our large blender capacity and high production volumes allow us to operate on an economies-of-scale model. We specialise in volumetric products that require technical expertise, including difficult-to-manufacture molecules that may fail dissolution or other tests. We are technically strong in resolving these challenges. We also focus on high-volume products where economies of scale are critical, enabling us to help global pharmaceutical companies grow and source quality medicines at affordable prices ■

## “Tubing solutions are the backbone of fluid handling in biopharmaceutical manufacturing.”



**Sachin Joshi**  
Co- Founder & MD,  
Pharmnxt Biotech

### **How will DTR’s modular tubing solutions integrate with India’s ongoing push for self-reliance in biopharmaceutical manufacturing?**

Tubing solutions are the backbone of fluid handling in biopharmaceutical manufacturing. DTR, short for Defined Tubing Routing, is a modular system designed to manage single use tubing in cGMP environments. It uses extruded and injection molded plastic components to clearly define and secure tubing paths. That means fewer trip hazards, easier visibility of flow paths, and a neater facility aesthetic. It’s about functionality combined with operator safety and compliance.

The acquisition of DTR, originally an Ireland-based innovator, gives us direct access to proven, advanced single-use tubing technology. The DTR system handles process volumes from 20 L up to 500 L and supports custom spans up to 2.9 meters. This bolsters our engineering capabilities, letting us offer faster turnaround on facility setup and retrofits, greater

customization, improved safety, and enhanced client confidence.

This move accelerates India’s resilience in the global supply chain, strengthening sovereignty over critical components and reducing dependency on foreign vendors. With DTR under the PharmNXT roof, we’re stepping onto the global stage with products made in India that match international standards. That’s how you turn self-reliance into competitive advantage.

### **What challenges do DTR’s systems resolve, and how are those relevant to the Indian context?**

Single-use tubing gained prominence because it slashes cleaning validation time and contamination risk. But it also introduces a very real mess of challenges. DTR addresses several of these with precision. It reduces human error by offering 12 colour options, enabling clear colour coding of tubing routes. In operational terms, this reduces misrouting or incorrect connections by a measurable percent. Pragmatically,

if misconnection incidents drop from even 5 to 1 per 1000 operations, the downstream savings in batch rejects and downtime become substantial additionally DTR also helps in

- **Improved Safety:** DTR eliminates trip hazards caused by loose tubing and reduces the risk of errors by clearly defining tubing pathways.
- **Enhanced Aesthetics:** The organized tubing routes create a cleaner and more professional look for the facility.
- **Flexibility:** The system can be adapted to different tubing sizes and can be modified for product changeovers.
- **Visual Identification:** Color-coded components can be used to differentiate between different tubing lines, minimizing the risk of incorrect connections.

DTR supports tubing up to 2.9 meters using clips and portable mounting panels to eliminate dips and maintain consistent flow. In systems operating at around 2 bar pressure, even a slight sag of half a meter in tubing can cut flow by 10–15%, leading to blockages or pressure drops that directly reduce throughput. Flexibility is another one of its benefits, since a modular DTR system can be reconfigured in hours or days, compared to stainless-steel rerouting that might take weeks of engineering and validation.

In India's biopharma sector, all these benefits translate into lowering error rates even among less experienced staff, and cuts in capital costs which improves speed in product changeovers. This is a major advantage in a market where batch cycles are shrinking from weeks to days. This system also strengthens compliance, which is a growing priority under India's tightened post-2020 regulatory regime.

**What global expansion plans does PharmNXT have post this acquisition?**

This acquisition is our gateway to the global market. By integrating DTR's existing international clientele with our capabilities, PharmNXT now has direct access to new customers and ecosystems. This creates an immediate opportunity to expand into high-growth

markets such as South Korea and Europe, where demand for advanced biomanufacturing solutions is rising. David Walton, the previous owner is going to be strategic advisor to PharmNXT's leadership team, offering continuity and strategic direction on DTR and also help in accessing the global companies through his network developed over 3 decades of his tenure.

Equally important, the products we design and manufacture in India can now be promoted through DTR's global network. This means we're not only strengthening our domestic footprint but also positioning PharmNXT as a credible global partner in single-use technologies and modular bioprocessing solutions. In essence, this deal transforms to a company with both local impact and international reach. ■

## “The biopharma sector is undergoing a shift toward advanced therapies like cell and gene therapies”



**Ankush Kapoor**  
Founder & CEO  
Pharmnxt Biotech

### What does this acquisition signal about India's evolution within the biopharma sector?

To understand the broader significance, you have to first look at India's bioeconomy. In just a decade, India's bioeconomy has skyrocketed from about USD 10 billion in 2014 to USD 165.7 billion in 2024 at a CAGR of 17.9% over the last four years. Now the sector is projected to nearly double to USD 300 billion by 2030. A bioeconomy of this scale is sure to become a cornerstone of the Viksit Bharat vision.

We believe that India's ambition to be the “pharmacy of the world” rests on the shoulders of its thousands of emerging startups, which are building homegrown strengths in biologics, biosimilars, vaccines, and advanced manufacturing techniques. The government's support ecosystem, including the National Biopharma Mission, BioE3 policy, and PLI schemes, has nurtured a remarkable rise from roughly 50 biotech startups a decade ago to nearly 11,000 today.

We see ourselves builders of the infrastructure that supports this growth. Acquiring DTR brings critical modular tooling like fluid-handling systems essential in biologics and cell-based manufacturing into the Indian fold. This would help us build supply-chain resilience by reducing dependency on imports. This is a foot in step for our emerging domestic innovation, regulatory confidence, and scalability. Our DTR acquisition is a marker of India stepping up as a global biomanufacturing architect, underpinning the goal of Viksit Bharat with home-grown engineering strength.

### How does this deal affect India's standing in the global biomanufacturing value chain?

India has long been known as the “pharmacy of the world,” supplying 20% of global generic pharmaceuticals

by volume and over 50% of all vaccines globally. However, the supply chain risks that came to the fore during the COVID wave, has increasingly alerted the global community about supply chain resilience. Hence global biomanufacturers are now openly prioritizing “China-plus-one” solution in interest of de-risked, resilient supply chains.

The acquisition of DTR significantly enhances India's capability to offer single-use tubing systems, which are crucial for biologics and advanced therapies, right here at home. This reduces reliance on imports and insulates us from geopolitical or logistical shocks. We also gain engineering sovereignty through this deal. It also broadens our product portfolio and opens doors to international clients who demand high-compliance, single-use systems with greater flexibility.

### What are your investment plans?

Keeping in view the evolving trends in global therapeutics, we are open to further investments that bring cutting-edge technologies into the Indian market. The biopharma sector is undergoing a shift toward advanced therapies like cell and gene therapies, mRNA platforms, and next-generation biologics, and we see a strong opportunity to localize these capabilities.

Our recent acquisition of DTR is a first step, but not the last. We remain open to both organic growth and strategic acquisitions, particularly those that strengthen India's supply chain resilience and enhance our role in the global biomanufacturing value chain. Every investment decision is guided by two priorities: improving patient access to world-class therapies in India and building long-term self-reliance within the country's bioeconomy. ■

## Regulatory Landscape in Pharma Packaging: The Indian and Global Perspective

Pharmaceutical packaging plays a pivotal role in ensuring the safety, efficacy, and quality of medicinal products. The regulatory landscape for pharma packaging is shaped by a complex interplay of national and international standards designed to protect public health, enhance product traceability, and combat counterfeiting.

Chakravarthi AVPS, Global Ambassador, World Packaging Organisation witnessed how evolving regulations present both challenges and growth opportunities for manufacturers, packagers, and exporters for Indian pharmaceutical industry.

### The Importance of Pharmaceutical Packaging Regulations

The primary purpose of pharma packaging is to protect medicinal products from environmental, physical, chemical, and biological hazards during storage and transportation. Effective packaging ensures the integrity and safety of medications, aids in accurate dosing, prevents tampering and counterfeiting, and supports patient compliance. It also addresses sustainability concerns by minimizing environmental impact through recyclable and biodegradable materials.

Packaging failures are not just about commercial losses but can undermine patient safety and public trust. Regulatory frameworks thus impose strict guidelines for the selection of packaging materials, manufacturing processes, testing, labeling, and waste management—all meant to guarantee that medicines reach patients as intended.

### The Indian Regulatory Framework

#### Central Regulatory Authority: CDSCO

India's pharmaceutical sector is regulated primarily by the Central Drugs Standard Control Organisation (CDSCO), which operates under the Ministry of Health

& Family Welfare. CDSCO sets out comprehensive rules for packaging, serialization (traceability), labeling, and environmental safety. The Drugs and Cosmetics Act, 1940 and subsequent rules form the backbone of India's legal requirements, supplemented by various notifications and guidelines to address contemporary challenges.

#### Key Indian Standards and Requirements

- **Material Compatibility and Safety:** Indian regulations require packaging materials to be chemically inert and non-reactive, preventing any interaction with the drug. This includes the in-depth assessment of extractables and leachables—substances that could migrate from packaging into the medicine.
- **Sterility and Integrity:** Packages for sterile products (parenterals, ophthalmic, etc.) must maintain sterility throughout their shelf life. Tamper-evident features are now mandated for many formulations to ensure pack integrity and patient safety.
- **Labeling Norms:** The packaging must display the generic/brand name, batch number, expiry date, manufacturer details, dosage instructions,

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and warnings. Compliance with both English and regional language requirements is often necessary for domestic products.

- **Serialization and Traceability:** For exported medicines, Indian law requires serialization—assigning unique codes to packs for digital tracking, an essential tool to fight counterfeiting and enable recalls.
- **Sustainability:** Indian authorities increasingly emphasize sustainability, with notifications on the use of recyclable plastics, PET bottles, and the management of packaging waste to limit environmental impact.

### Compliance Challenges

Indian manufacturers must comply with not only local standards but also those of importing countries, especially for exports to the US, EU, and other strict regulatory regimes. Adapting to evolving regulations incurs considerable operational costs and demands continuous technological upgrades.

### The Global Regulatory Landscape

#### Major International Regulatory Bodies

- Food and Drug Administration (FDA) – USA
- European Medicines Agency (EMA) – EU
- Medicines and Healthcare Products Regulatory Agency (MHRA) – UK
- Pharmaceuticals and Medical Devices Agency (PMDA) – Japan
- World Health Organization (WHO) – International standards

Each agency has its own requirements, but there is a significant convergence in principles concerning safety, efficacy, and patient-centricity.

#### Core Global Regulatory Principles

- **Tamper-Evident & Child-Resistant Packaging:** Mandated in most advanced regulatory markets to protect consumers from tampering and accidental poisoning.

- **Labeling and Instructions:** Packaging must clearly state drug names, ingredients, dosage, warnings, storage, and manufacturer information.

- **Material Standards:** The US Pharmacopoeia (USP), European Pharmacopoeia (Ph. Eur.), and international standards such as ISO and ASTM define material quality, compatibility, and test protocols—including leachables, extractables, and packaging-system integrity.

- **Serialization and Anti-Counterfeiting:** The Falsified Medicines Directive (EU-FMD) in Europe, Drug Supply Chain Security Act (US-DSCSA), and others require traceability from manufacturer to end consumer, leveraging unique barcodes and tamper-proof features.

- **Stability Testing:** Regulatory bodies require evidence that packaging preserves drug stability under defined environmental conditions over the entire shelf life.

### WHO and Harmonization

WHO provides international guidelines for packaging, stability, bioequivalence, and model regulatory standards. International collaboration has led to partial harmonization of regulatory approaches, making it somewhat easier for multinational companies and exporters like those in India to align with global expectations.

### Indian Perspective: Opportunities and Innovations

#### Fast-Growing Market Dynamics

India's pharmaceutical packaging market is expanding rapidly due to increased generic drug production, rising healthcare awareness, and demand for improved patient adherence. The growth of chronic diseases and export orientation make compliance with international packaging standards a commercial necessity.

#### Export Compliance: A Key Driver

Indian companies must continuously upgrade their packaging processes to meet not only CDSCO but also international regulations. The EU-FMD mandate,

for example, has driven significant investment in serialization, tamper-evident seals, and digital traceability.

#### Technological Innovation

- **Smart Packaging:** Incorporation of QR codes, RFID, and blockchain for enhanced traceability and communication.
- **Sustainable Materials:** Shift towards bio-based and recyclable packaging in response to both regulatory pressure and consumer demand.
- **Patient-Centric Designs:** Ergonomic blister packs, dose-dispensing aids, and clear labeling to aid compliance, especially in the elderly and pediatric populations.

#### Environment and Waste Management

India has introduced rules for the recycling and responsible disposal of plastic and PET pharma packaging—further aligned with EU directives. Extended Producer Responsibility (EPR) and eco-design are now buzzwords in the Indian regulatory lexicon.

#### Emerging Regulatory Trends

- **Global Convergence:** International regulatory agencies increasingly adopt harmonized standards to ease trade barriers.
- **Serialization and Digital Traceability:** Becoming the global gold standard to fight counterfeiting and improve patient safety.
- **Sustainability Mandates:** Regulations are evolving to set minimum benchmarks for recyclability, carbon footprint, and environmental influence of packaging.
- **Risk-Based Quality Management:** Agencies increasingly expect pharmaceutical companies to adopt a lifecycle approach, employing risk management and continuous improvement throughout packaging development and manufacturing.

#### Conclusion

The Indian pharmaceutical packaging sector operates in a regulatory environment that blends domestic rules with global standards. The interplay of stringent guidelines, emerging technologies, and rising export ambitions pushes Indian firms toward robust compliance and innovation. The regulatory landscape, though complex, acts as a catalyst for progress ensuring that medicines remain safe, effective, and accessible, both within India and across global markets.

For industry professionals, a deep understanding of both Indian and global regulatory frameworks and a readiness to adapt to continual change is essential for driving growth and safeguarding patient health in the evolving world of pharmaceuticals. ■

#### Author



**Chakravarthi AVPS**  
AVPS, Global Ambassador,  
World Packaging Organisation (WPO)

## Formulation Development: Why It's So Important in India's Pharma Growth Story

When people talk about India's rise as the "pharmacy of the world," the image that often comes to mind is rows of blister packs, vats of active pharmaceutical ingredients (APIs) and container ships leaving Indian ports bound for global markets. India is a dominant producer of generics and APIs. Beneath the more visible layers of bulk manufacture and API supply sits a technical, creative and commercially critical function such as formulation development.

**Sanjeev Jain, MD, Akums Drugs and Pharmaceuticals** emphasizes about the formulation development and how it plays a role in India's Pharma growth.



**Sanjeev Jain**

Managing Director  
Akums Drugs and Pharmaceuticals

**A**t Akums, and across the Indian pharmaceutical ecosystem, formulation development is the bridge that converts molecules into medicines that are safe, stable, effective, manufacturable at scale, and acceptable to patients. It is also a strategic lever for export competitiveness, regulatory acceptance, and margin improvement — all of which matter deeply to India's pharma growth story.

### **What we mean by formulation development**

Formulation development is the science and engineering of turning an API into a dosage form —

tablets, capsules, injectables (sterile), topical creams, syrups, oral liquids, and more — that delivers the required drug exposure with predictable performance. It encompasses pre-formulation studies (physical and chemical profiling of the API), excipient selection and compatibility, stability and shelf-life studies, process development (how to manufacture consistently), scale-up, and dossier preparation for regulatory submissions and market approvals. Good formulation development reduces failures in later stages, shortens time-to-market, lowers manufacturing costs, and ensures regulatory robustness.

## Why formulation matters strategically for India

### Enables value capture beyond APIs and raw volumes

India has long been a powerhouse in producing APIs and off-patent generics at competitive prices. But value accrues not only from producing inputs — it accrues from delivering finished, differentiated products with robust quality attributes and patient-friendly features (e.g., taste-masked suspensions, fixed-dose combinations, modified-release tablets). Superior formulation design lets Indian manufacturers move up the value chain from commodity suppliers to **contract development and manufacturing organizations (CDMOs)** and differentiated generic suppliers that command better margins and deeper market access. The India CDMO market itself is materializing as a multibillion-dollar opportunity — recent market analyses estimate the India CDMO market at several billion USD in 2024 with strong mid-single-digit to double-digit CAGRs projected forward.

A molecule that behaves in a lab does not always behave in a 100,000-tablet-a-day production line. Formulation scientists' de-risk that transition: they characterize powder flow, identify critical material attributes, choose excipients that ensure processability, and design processes that are robust to variability. This reduces batch failures, rejects, and costly regulatory remediation. In an environment where global buyers increasingly demand reliability and just-in-time supply, formulation development is a risk-mitigation imperative.

### Critical for exports and regulatory acceptance

Export volumes are only half the story: global regulators evaluate dossiers, quality systems, and product performance. Formulation development must anticipate international regulatory expectations. India's pharma exports in FY 2023–24 were significant — Pharmexcil reports export receipts in the range of roughly USD 27–28 billion for the financial year — and sustained export growth depends on dossier quality, robust stability data, and manufacturing controls. Failures in formulation or quality can damage credibility (we've seen heightened regulatory scrutiny in recent years), whereas well-documented formulation development programs open doors, including to new markets.

## Enables market differentiation and patient-centric features

Patients and prescribers increasingly value palatability, dosing convenience, experience, and adherence—factors that directly impact treatment outcomes. Medicines that are unpleasant to take or require multiple daily doses can lead to missed treatments and lower efficacy. Formulation-led innovations address these challenges: taste-masked paediatric syrups, once-daily modified-release tablets, and fixed-dose combinations simplify regimens, enhance patient experience, and improve adherence.

For Indian manufacturers targeting regulated markets and institutional tenders, these attributes offer a significant competitive advantage beyond price. In global and institutional procurement, decision-makers increasingly consider patient-centric features, Compliance and ease of use alongside cost. Products that simplify dosing, enhance patient comfort, or support adherence are more likely to be preferred by prescribers and procurement bodies.

By focusing on formulation excellence, Indian pharma companies can differentiate themselves, strengthen credibility in international markets, and position their products as high-value solutions—shifting the competition from purely cost-driven to quality- and patient-driven metrics.

### Data points that show why now is the moment

Several market signals show that India's timing is favourable to leverage formulation development capability:

- Domestic market size and growth potential. Recent industry estimates put India's pharmaceutical market at over USD 60 billion in 2024, with projections to grow substantially through 2030 and beyond as healthcare access and per-capita consumption increase. A larger domestic market creates a testbed for new formulations and the commercial scale needed to justify investment.
- Export strength and trajectory. India's pharma exports were valued at roughly USD 27.8 billion in FY 2023–24, showing low-double-digit growth; exports to the U.S., UK and growing share into African and Latin American markets underscore

both scale and reach. Every exported finished product requires robust formulation development and regulatory documentation.

- Rising CDMO opportunity. India's CDMO market is rapidly expanding (estimates vary by source and segmentation) — market research houses have valued it in the multi-billion USD range for 2024 with a strong CAGR projected to 2030. Many global innovators and generics companies are outsourcing formulation and development work to India, attracted by cost, expertise, and manufacturing depth. This creates demand for high-quality formulation development services.
- Regulatory tightness as a spur to quality. After high-profile quality incidents and subsequent inspections, regulators in India and abroad have sharpened their focus on manufacturing processes and dossier completeness. This has made formulation development — including stability protocols, impurity profiling and process controls — non-negotiable. Regulatory enforcement creates both urgency and opportunity for companies that invest in rigorous development practices.

### **Where formulation development delivers outsized impact**

#### **Faster approvals and improved dossier acceptance**

Regulatory dossiers are judged on the quality of data and the rationale behind formulation and process choices. Thoughtful development packages with clear critical-to-quality (CTQ) attributes, risk assessments, and bridging studies reduce cycles during review and inspection. For exporters, this is especially important for markets with specific local requirements (e.g., stability testing across climatic zones, labelling, and local regulations). When we prepare dossiers at Akums, we design stability protocols, analytical methods, and control strategies with the likely regulator (and market) in mind.

#### **Cost optimization across the product lifecycle**

Good formulation work doesn't just ensure performance — it optimizes cost. Excipient choices, yield improvement, reduction in steps, and enabling continuous process enhancements can all reduce

cost-per-dose. That means Indian firms can sustain competitiveness even as prices compress globally.

#### **Readiness for complex and niche dosage forms**

While large volumes of oral solids still dominate, specialty dosage forms like sterile injectables, topical nanoemulsions, or ophthalmic products require specialized formulation skills. Building capability in these areas opens new market segments and higher-value contracts, both domestically and in exports.

#### **Supporting India's CDMO & CRDMO ambitions**

As global pharma firms diversify manufacturing footprints, India is well placed to expand its role as a contract development and manufacturing hub. Strong formulation development capability is core to that promise: global partners outsource not only manufacturing but also development work. India's CDMO market trajectory — supported by favourable cost structures and skilled talent — will be shaped by how quickly Indian players can deliver development quality at global standards. Practical levers for industry and policy to accelerate formulation-enabled growth

#### **Invest in human capital and specialized skill sets**

Formulation science is inherently multidisciplinary — drawing on polymer chemistry, physical pharmacy, process engineering, and analytical science. To remain globally competitive, India must invest in developing this expertise through industry-academia partnerships, structured upskilling programs, and specialized training in areas such as QbD (Quality by Design), PAT (Process Analytical Technology), and stability science. Equally critical are advances in process development, enhanced analytical methodologies, chemical analysis, and adoption of automation to ensure precision, scalability, and compliance with international standards. Building capabilities in these areas will not only strengthen India's formulation bench strength but also create a workforce equipped to deliver innovation, efficiency, and regulatory confidence in global markets

#### **Harmonize regulatory pathways and promote reliance mechanisms**

International regulatory reliance and harmonization shorten approval cycles. Brazil's Anvisa, for instance,

has been active in issuing guidance on regulatory reliance and procedural streamlining — an indicator of how international regulators are evolving. When Indian companies anticipate and align with such global regulatory trends, they gain smoother access to diverse markets. The reference to ANVISA is not intended to single out a particular regulatory authority, but rather to illustrate how global regulators are increasingly moving toward collaborative, reliance-based frameworks. This shift reflects a broader trend in international regulatory science, where agencies leverage each other's evaluations to enhance efficiency and harmonization.

### **Invest in analytical and stability capacity**

Robust analytical methods and sufficiently capacious stability chambers (covering climatic zones) are often the bottleneck in bringing formulations to market. Firms should prioritize investment in validated methods, impurity profiling capabilities and expanded real-time/accelerated stability testing capacity.

### **Challenges — and how formulation development helps solve them**

India's pharma sector faces familiar challenges: dependence on certain raw material geographies, the need to meet increasingly stringent regulatory standards, and margin pressures in commoditized generics. Formulation development is not a silver bullet, but it is a practical hedge:

- **Quality incidents:** Better pre-formulation characterization and control strategies reduce the likelihood of quality lapses and recalls.
- **Regulatory friction:** Well-documented formulation rationale and comprehensive stability/analytical data ease reviews and inspections.
- **Price competition:** Product differentiation through formulation (modified-release, combination products, patient-centric forms) shifts competition away from purely price-based comparison.

### **A note on sustainability and patient access**

Formulation development can and should align with sustainability goals. Process optimization reduces waste, solvent use and energy consumption. Designing

stable products with less cold-chain dependence (wherever clinically appropriate) improves access to medicines in remote or resource-constrained geographies. Patient-centric formulation design also enables better adherence and therapeutic outcomes — a public health good that supports long-term market sustainability.

### **Formulation development as a strategic capability**

If India's pharma narrative is to evolve from being the "world's pharmacy" to becoming a global development and manufacturing powerhouse, formulation development will be one of the decisive capabilities. It connects science to commerce: guaranteeing product performance, enabling regulatory acceptance across jurisdictions, optimizing cost structures, and unlocking higher-value market segments. For companies like Akums — fortunate to operate large, multidisciplinary manufacturing and development footprints — investing in formulation science is not optional; it is a strategic imperative.

As India pursues initiatives to broaden its manufacturing base, attract global outsourcing work, and climb the value chain, formulation development will keep delivering returns in the form of export resilience, higher margins, regulatory trust, and — most importantly — better medicines for patients at scale. Policymakers, industry leaders and academic institutions must coordinate to build the skills, infrastructure and regulatory alignment needed to accelerate this transformation. When that happens, the benefits will be felt across patients, healthcare systems, and the national economy — and formulation development will quietly have powered much of the progress. ■

## The New Age of Lifesciences: Innovation

The Lifescience's sector has always carried a unique dual responsibility: advancing human health while meeting some of the most demanding regulatory, ethical, and operational standards of any industry. In recent years, this responsibility has only deepened. Science is moving at unprecedented speed, patients are more informed than ever, and regulators across the globe are aligning frameworks that raise both the opportunity and the accountability of our work.

**Dr. Satish Wagh, Executive Chairman & Whole - Time Director, Supriya Lifescience Ltd** emphasized about the lifescience sector and regulation in lifesciences. He also spoke about the artificial intelligence transforming drug discovery and manufacturing.

**H**aving witnessed the evolution of this sector for decades, Our greatest challenge today is not one of ideas but of execution. We do not suffer from a lack of innovation, policies, or visions. What we need is the discipline to transform frameworks into practice, data into decisions, and scientific breakthroughs into reliable, affordable therapies that reach patients at the right time. The question before us in 2025 is how to make the lifesciences engine work faster, cleaner, and closer to those who need it most.

### Data and Technology

Much has been written about artificial intelligence transforming drug discovery and manufacturing. Yet the hard reality is that very few organizations have AI-ready data. Earlier this year, in January 2025, the US Food and Drug Administration released detailed guidance on the use of AI to support regulatory decision-making. Rather than encouraging blanket adoption, it focused on a very practical principle: credibility in context. That means AI tools must be assessed the same way we assess assays or methods, defined purpose, known inputs, validation against agreed criteria, and monitoring for drift over time.

For companies in the lifesciences segment, the practical takeaway is simple. Data cannot remain a by-product of operations; it must be treated like

a regulated material. Just as we test, qualify, and document raw materials, we must ensure our data is complete, accurate, and auditable. Without that foundation, AI becomes more of a compliance risk than a business advantage.

### Regulation: From Barrier to Enabler

Regulation in lifesciences is no longer the hurdle it was once perceived to be. Around the world, agencies are steadily shifting towards a more adaptive and science-driven approach. Clearer guidelines, harmonised standards, and structured pathways for accelerated approvals are now shaping the way therapies are developed and delivered. What stands out is that these frameworks continue to demand the highest levels of quality and safety, while creating room for innovation to progress at pace. For the industry, this change means regulatory alignment must be viewed not as a box-ticking exercise but as an integral part of strategy from the very beginning. When science and regulation move together, the entire ecosystem functions with greater confidence and reliability.

### The Digital Backbone

For a long time, the lifesciences industry was seen as cautious in embracing digital solutions. That perception is changing rapidly. Today, digital



systems are becoming an essential part of everyday operations across the value chain, spanning research, development, manufacturing, and quality management.

In production, digital tools are strengthening process controls and supporting real-time decision-making. Quality functions are steadily moving away from paper-heavy practices, with electronic batch records and automated workflows reducing errors and ensuring stronger compliance. The shift is not about adopting the most advanced technologies overnight but about building a solid foundation of reliable data. Companies that still depend on fragmented spreadsheets and manual entries must first focus on closing these basic gaps. Once data integrity and core systems such as LIMS, MES, and QMS are firmly in place, more advanced analytics and automation can add genuine value and earn the trust of regulators and partners alike.

### **Sustainability and Responsibility**

In late 2024, the World Health Organization called on the pharmaceutical industry to decarbonize its footprint, marking a turning point where sustainability moved from being a CSR talking point to a regulatory and procurement priority. For the lifesciences sector, this shift is reshaping the way processes are designed, materials are sourced, and costs are managed. Companies can no longer depend on resource-heavy methods, solvent use must pivot to greener alternatives with closed-loop recovery, salt-heavy reactions

need rethinking through biocatalysis or telescoping approaches, and energy-intensive operations must increasingly rely on electrified heating or renewable sources. With rising environmental pressures, practices like green chemistry, solvent recovery, and energy-efficient manufacturing are no longer differentiators but basic expectations. The reality is clear: the cheapest kilogram is no longer the one with the lowest raw material cost,

but the one with the cleanest lifecycle footprint, and those who act on this now will set the competitive standard for the future.

### **Shifting Value from Capacity to Capability**

Over the past few years, companies have invested heavily in building biomanufacturing facilities across the globe. However, with the rise of diverse treatment methods and smaller batch sizes, having more floor space is no longer the real advantage. The real strength now lies in specialized expertise, such as method development, comparability studies, advanced analytical testing, and regulatory guidance. For businesses, the focus is moving from being “capacity-rich” to being “capability-rich.” Those who combine technical know-how with flexible processes and strong regulatory insight will be better placed to lead the future.

### **People: The Cornerstone of Change**

In lifesciences, the real edge doesn't come from machines or labs alone, it comes from people. A workforce that can shift between small molecules, biologics, or aseptic fills is essential, and so are experts who can bridge development, analytics, and regulation. On the ground, it's the supervisors, engineers, and writers who keep things moving and compliant. That's why investing in people, through training, cross-learning, and a culture of openness, delivers the biggest impact. At the end of the day, progress in lifesciences is powered by human

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judgment and adaptability.

### Pharma's Growing Integration with Devices and Diagnostics

In lifesciences, the line between pharmaceuticals, medical devices, and diagnostics is becoming less defined. For pharma, this convergence means that treatments will increasingly be supported by diagnostic tools and innovative delivery systems. To stay relevant, companies must strengthen their understanding not only of drug development but also of technology and design, ensuring that medicines are part of a more connected healthcare solution.

### Partnerships that scale trust

The final piece of the puzzle is partnerships. The lifesciences ecosystem is shifting from isolated excellence to ecosystem excellence. Whether it is an API manufacturer ensuring backward integration, a CDMO taking over complex processes, or a CRO running hybrid trials, the future belongs to networks that share more than purchase orders. True partnerships share

platforms - common data definitions, interoperable change-control systems, and aligned roadmaps. When companies and their partners plan at a platform level, every product transfer, every regulatory filing, and every supply chain decision becomes smoother and more reliable.

The lifesciences segment in 2025 is not suffering from a shortage of ambition. What it needs is a culture of applied craft, disciplined processes, credible models, auditable data, and partnerships that compound strengths rather than duplicate weaknesses.

Regulators have provided clarity on AI adoption, continuous manufacturing, bioequivalence standards, serialization, and sustainability. For the API sector, the focus now is on building consistent quality, strengthening supply security, and adopting greener, more efficient production methods. These shifts are not just about compliance, they are about shaping a resilient and globally competitive pharma manufacturing base. ■

### Author



#### Dr. Satish Wagh

Executive Chairman & Whole - Time Director,  
Supriya Lifescience

## AMR Surveillance Beyond Big Cities: Why India Needs a Decentralized Approach

The invisible war against antimicrobial resistance (AMR) is being fought on uneven terrain. While metropolitan hospitals generate reams of surveillance data, India's rural heartland—where 65% of the country's population lives according to the Economic Survey 2022-23—remains largely invisible to our AMR monitoring systems. This blind spot isn't merely a statistical inconvenience; it's a strategic vulnerability that could undermine our entire national response to one of humanity's gravest health threats.

**President - Global Critical Care, Venus Remedies, and CEO, Venus Medicine Research Centre (VMRC)** speaks about the antimicrobial resistance (AMR) and highlights government initiatives that underscore the growing strategic importance of surveillance. He also emphasizes how digital transformation is offering unprecedented opportunities to democratize sophisticated surveillance capabilities

**A**ccording to the WHO, AMR claims at least 700,000 lives globally each year, with projections suggesting this could spiral to 10 million annually by 2050 if current trends persists. In India, where antibiotic misuse spans healthcare, agriculture, and livestock sectors, the stakes couldn't be higher.

The Metropolitan Myopia: Progress Without Equity India's National AMR Surveillance Network (NARS-Net) represents genuine progress—60 state medical college laboratories now submit monthly data to the National Centre for Disease Control using standardized WHONET software. Since enrolling in WHO's Global AMR Surveillance System (GLASS) in 2017, India has published annual surveillance reports that paint an increasingly detailed picture of high levels of resistance patterns in *E. coli* and *K. pneumoniae* to

third-generation cephalosporins and carbapenems.

Yet this urban-centric lens distorts our understanding of AMR's true burden. The WHO's 2025 global survey to track antimicrobial resistance, launched in May 2025, explicitly emphasizes multisectoral approaches that transcend traditional healthcare boundaries—a recognition that resistance emerges wherever antibiotics are used, not just where they're monitored.

### Rural Revelations: What We're Missing

The urgency for decentralized surveillance crystallized through a groundbreaking 2024 ICMR study in rural Odisha that tracked multidrug-resistant organisms across 50 villages in Tigiria block, covering 74,639 people served by two Community Health Centres, four Primary Health Centres, and 14 sub-centres. The findings revealed alarming rates of MRSA and

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carbapenem-resistant Enterobacteriaceae carriage in communities with virtually no baseline surveillance infrastructure.

This isn't an Odisha anomaly—it's a national pattern.

In India, the data on AMR that is being collated and archived appears to be too little and too patchy to be fully representative to make meaningful assessment and intervention, as per the Vision 2035 Public Health Surveillance In India report release by NITI Aayog in 2023.

The fragmentation masks resistance trends in precisely those areas where antibiotic stewardship is weakest and resistance pressure highest. While there have been many pilot projects implemented to enhance the existing surveillance system such as influenza surveillance supported by the WHO, these largely remain as 'research driven' pilots, with limited resources and willingness by governments to scale these up.

### **Beyond Infrastructure: Reimagining Surveillance Architecture**

Decentralized regional laboratories represent more than geographical expansion—they embody a philosophical shift toward precision public health. These facilities wouldn't merely replicate urban surveillance models; they'd capture resistance patterns shaped by local agricultural practices, traditional medicine integration, and community antibiotic-seeking behaviors that metropolitan systems routinely miss.

Research published in *Frontiers in Public Health* underscores that strengthening AMR surveillance requires addressing laboratory capacity gaps, standardizing protocols, and developing robust data management systems specifically designed for peripheral healthcare settings. The challenge extends beyond equipment to human resources, career pathways, and sustainable financing models that make rural microbiology positions attractive rather than punitive.

### **GASAR: Industry-Academia Synergy in Action**

At Venus Remedies, our Genetic Assessment and

Surveillance of Antimicrobial Resistance (GASAR) initiative demonstrates how industry resources can complement public health efforts. As the first Indian pharmaceutical company to join Vivli's AMR Register, we've committed to sharing surveillance data transparently, contributing to global collaborative research efforts.

GASAR's extensive clinical isolate library serves dual purposes: informing resistance trend analysis and facilitating therapeutic innovation assessment. Our recent collaboration with AdjuTec Pharma to evaluate their APC-148 platform technology against multidrug-resistant bacterial strains exemplifies how surveillance data can accelerate solution development. We have in-licensed MET-X, an innovative metallo-beta-lactamase (MBL) inhibitor, to address India's high rates of carbapenem resistance. Going forward, GASAR's national surveillance network would be helpful in tracking emerging resistance patterns and monitor MET-X's impact, supporting targeted stewardship and therapy optimization.

Most critically, GASAR reveals sharp regional variations in resistance patterns across India—variations that underscore the futility of one-size-fits-all national guidelines and the urgent need for hyperlocal surveillance data to inform targeted interventions.

### **Digital Transformation: Technology as the Great Equalizer**

The convergence of artificial intelligence, machine learning, and mobile health technologies offers unprecedented opportunities to democratize sophisticated surveillance capabilities. Digital platforms can standardize data collection protocols, minimize human error, and enable real-time resistance trend analysis across geographically dispersed laboratories.

NITI Aayog's Vision 2035 for Public Health Surveillance explicitly emphasizes mobile health technologies and digital platforms as essential for connecting peripheral laboratories with central expertise. The vision calls for leveraging technology to create interoperable surveillance systems that can integrate diverse

data sources while maintaining quality assurance and enabling real-time decision-making across the surveillance network.

Artificial intelligence algorithms can analyze large datasets from decentralized laboratories to identify emerging resistance patterns and predict outbreak risks—capabilities particularly valuable for rural settings where limited microbiology expertise can be augmented by automated analysis and decision-support tools.

With the integration of new technologies, mobile health platforms can empower frontline healthcare workers to report resistance data in real time, improving the granularity and frequency of surveillance. Combined with geospatial mapping, this creates the foundation for dynamic, data-driven AMR dashboards—not just for researchers and policymakers, but also for hospitals, community health centers, and even pharmacies.

### Global Models, Local Adaptations

The European Antimicrobial Resistance Surveillance Network (EARS-Net) offers compelling precedent for decentralized surveillance success, operating since 1998 and collecting standardized resistance data from clinical laboratories across European countries, with descriptive data publicly accessible through the ECDC Surveillance Atlas.

However, Europe's relatively uniform healthcare infrastructure differs dramatically from India's disparate landscape. Unlike European networks with comprehensive coverage, India faces significant population disparities, with extensive surveillance networks in some regions while others rely on minimal hospital subsets. These variations demand flexible surveillance frameworks accommodating diverse local contexts while maintaining data quality and comparability.

### The Economic Imperative: Prevention as Investment

Decentralized AMR surveillance isn't merely a public health good—it's an economic necessity. Early resistance trend detection can prevent costly

outbreaks and reduce dependence on expensive last-resort therapies. Rural surveillance systems can identify emerging patterns before urban spread, potentially saving millions in healthcare costs and productivity losses.

The WHO emphasizes that AMR's economic impact transcends healthcare expenditure to encompass reduced productivity, increased treatment costs, and threats to food security. For India, where agriculture employs nearly half the workforce according to government data, and rural health affects economic growth, surveillance investment represents strategic foresight rather than charitable expenditure.

### Government Evolution: From Fragmentation to Integration

Recent government initiatives signal growing recognition of surveillance's strategic importance.

The National Centre for Disease Control's 2022 publication of antimicrobial consumption surveillance guidelines under NAC-NET represents significant progress toward comprehensive AMR monitoring that encompasses both resistance patterns and usage data.

The ICMR Annual Report 2023-2024 highlights ongoing efforts to strengthen surveillance through capacity building, protocol standardization, and data integration across healthcare levels. These initiatives provide foundations for scaling surveillance to rural and peripheral areas, but implementation requires sustained political commitment beyond electoral cycles.

The Kerala Antimicrobial Resistance Strategic Action Plan (KARSAP) launched in 2018 stands out as a leading state-led response to AMR in India, rooted firmly in the 'One Health' approach. What makes KARSAP a model worth emulating is its combination of strong political commitment, integrated strategy, and measurable outcomes. It effectively brings together surveillance, stewardship, and public engagement, backed by real-time data collection and strict regulatory enforcement to curb antibiotic misuse. The program's statewide impact has been significant—with a reported 30%

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reduction in overall antibiotic consumption, the suspension of over 450 pharmacy licenses for non-compliance, and a noticeable shift towards the use of WHO-recommended 'ACCESS' antibiotics, which are less prone to driving resistance.

Creating sustainable systems demands systemic changes: integrating AMR considerations into medical education curricula, establishing quality assurance programs for peripheral laboratories, and creating feedback mechanisms ensuring surveillance data informs clinical practice. The WHO's global research priorities emphasize implementation research addressing surveillance system deployment in resource-constrained settings—research agenda perfectly aligned with India's decentralization needs.

### **International Collaboration: Local Action, Global Impact**

Venus Remedies' Vivli AMR Register membership exemplifies how local surveillance efforts can contribute to global knowledge systems enabling worldwide researcher access to anonymized surveillance data, facilitating comparative studies and collaborative research informing global AMR strategies.

The WHO's TrACSS survey framework provides standardized tools for countries to assess surveillance capabilities and identify improvement areas. India's participation ensures international best practice alignment while addressing distinct local needs—a balance essential for effective global AMR response.

### **The Imperative Moment**

As 2025 unfolds, the surveillance transformation window remains open but won't last indefinitely. The WHO's projection that AMR could become a leading global death cause if current trends continue underscores building robust surveillance systems capturing resistance patterns across all populations—not just those conveniently located near medical colleges.

The Odisha study's and Kerala's KARSAP model demonstrates rural AMR surveillance feasibility when adequate resources and technical support are provided. Scaling these models requires sustained

political commitment, adequate funding, and ongoing technical assistance—investments that transform reactive healthcare into proactive health security.

Decentralized regional laboratories, supported by robust technology platforms and sustainable funding mechanisms, represent more than public health intervention—they embody our commitment to health equity and evidence-based medicine. The convergence of technological innovation, policy commitment, and multi-stakeholder collaboration creates unprecedented opportunity to transform India's AMR surveillance landscape.

The choice before us is stark: continue monitoring resistance where it's convenient to measure, or build surveillance systems that serve all Indians regardless of postal code. Our collective future—and our credibility as a global health leader—depends on choosing wisely, and choosing now. ■

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## 32<sup>nd</sup> International Exhibition and Conferences

**3-6 February 2026**

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### Concurrent Events



#### Scope for ChemTECH World Expo 2026

- Plant Machinery & Industrial Consumables
- Engineering Consultants
- OEMs for Chemicals & Pharmaceutical Processing Equipment
- Metals & Metallurgy
- Bioprocessing Equipment
- Construction Services Providers
- Plant Maintenance Services Providers
- Logistics & Supply Chain Solutions Providers
- Instrumentation & Process Control
- Industry Automation (Process & Factory)
- Systems Integration & ERP Solutions Providers
- Water & Waste Water Treatment Consultants
- Environment Solutions Providers
- Waste Management Consultants
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- Material Handling Solutions
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- Welding Solutions
- Quality Health & Environment Solutions
- Analytical & Laboratory
- Packaging Materials, Machinery & Systems
- Business Consultants

#### Scope for Specialty Chemicals World Expo 2026

- Agrochemicals Intermediates
- Adhesives & Sealants
- Agrochemicals & Crop Protection
- Bulk Drugs & Intermediates
- Enzymes
- Colorants, Dyes & Pigments
- Cosmetics & Personal Care Ingredients
- Hygiene & Cleaning Chemicals
- Laboratory Chemicals
- Surfactants
- Water Treatment Chemicals
- Catalysts
- Electronic Chemicals
- Flavours & Fragrances
- Contract Manufacturers

#### Scope for Biopharma World Expo 2026

- Materials Processing
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**HIGHLIGHTS OF BIO-PHARMA WORLD EXPO 2024**



**NAVIGATING THE PATH TO LEADERSHIP IN BIOPHARMA EXCELLENCE**



(L to R) Guest of Honour Dr Krishna Ella , Executive Chairman, Bharat Biotech International Ltd, Prof (Dr) Samir Kulkarni , Head, Department of Biological Sciences & Biotechnology, Coordinator, DBT – ICT Centre, Dr Rajesh Gokhale, Secretary , DBT, Ministry of Science & Technology, Govt. of India & Chief Guest, Mr Suresh Prabhu Former Union Minister, Govt. of India & Chief Patron & Brand Ambassador, ChemTECH World Expo 2024



Biotech is one of the fastest-growing industries in the world right now, especially in India. The Indian bioeconomy registered a remarkable 28% growth in 2022. The past three years have been enormously successful, especially considering the challenges posed by the COVID-19 pandemic. The Indian

bioeconomy is forecasted to reach USD 300 billion by 2030, a significant increase from its current valuation of USD 140 billion, which constitutes 4% of the total GDP of our country's growth. The BioPharma industry contributes approximately 43% to the economy and extends beyond pills; it encompasses aspects of healthcare, wellbeing, and cognitive enhancement. To capitalize on green growth and the bio economy, we are establishing Bio enablers in the form of Bio manufacturing hubs through Public-Private Partnerships.

**Dr Rajesh Gokhale**  
 Secretary, DBT, Ministry of Science & Technology, Govt. of India

**FACTS & FIGURE 2024**

<b>750 EXHIBITORS</b> FROM 15+ COUNTRIES	<b>25871 VISITORS</b> FROM 63 COUNTRIES	<b>1500+ BUSINESS DELEGATES</b>	<b>60+ GLOBAL CLIMATE TECH STARTUPS</b> FROM 20 COUNTRIES <b>40 TECHNICAL PRESENTATIONS</b>
<b>8 TECHNICAL CONFERENCES</b>	<b>250+ GLOBAL SPEAKERS</b>	<b>2500+ STUDENT OUTREACH PROGRAM</b> FROM 28 STATES & UNION TERRITORIES	<b>BRICS WORKING GROUP BRAIN STORMING SESSION</b>

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