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# PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

## Year End Review

### Bio Pharma Processing



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## India Accelerates Indigenous Biopharma Manufacturing Through DBT, BIRAC, NBM and PLI Push

The Government of India is rapidly strengthening entrepreneurship and indigenous manufacturing in the biopharma sector through a coordinated push involving DBT, BIRAC, National Biopharma Mission (NBM), BioE3 policy and the PLI scheme.

Department of Biotechnology (DBT) has set up Biotechnology Industry Research Assistance Council (BIRAC), a not-for-profit Section 8, Public Sector Enterprise, in 2012, as an interface agency to nurture and strengthen the startup ecosystem and encourage entrepreneurship with a focus on the healthcare sector that covers Pharma and Biopharma. BIRAC through funding grants has supported startups, SMEs, and innovators through flagship schemes such as BIG, SPARSH, SEED and LEAP.

Nearly 1,000 startups have benefited under BIG, while SPARSH has awarded 150+ fellowships, leading to 100+ startups and 65+ IPs. BIRAC has also built a nationwide innovation backbone with 94 incubators supporting over 3,000 incubates across 25 States and UTs.

Under DBT's National Biopharma Mission (NBM), over 100 biopharma projects have been supported, strengthening domestic capabilities in vaccines, biologics, diagnostics and medical devices. Key outcomes include the development and commercialization of COVID-19 vaccines ZyCoV-D and Corbevax, biosimilar Liraglutide, indigenous MRI scanners, bioreactors, diagnostic kits and ventilators. NBM has also enabled 18 shared R&D and GMP facilities, 7 Technology Transfer Offices, and 46 GCP-compliant clinical trial sites.

In a major structural reform, DBT has consolidated its 13 autonomous institutions into Biotechnology Research and Innovation Council (BRIC) to integrate research, training, innovation and commercialization. Complementing this, DBT rolled out the BioE3 Policy (2024) to promote high-performance biomanufacturing, including biofoundries and hubs focused on precision biotherapeutics such as mRNA, monoclonal antibodies, and cell and gene therapies. The PLI Scheme for Pharmaceuticals, with an outlay of ₹15,000 crore, has further boosted biopharma manufacturing. As of September 2025, 46 biopharmaceutical products are being manufactured, generating cumulative sales of ₹26,832 crore, including ₹16,290 crore in exports.

Parallel efforts by ICAR and CSIR laboratories are advancing indigenous vaccines, diagnostics, biosimilars and bioprocess technologies, reducing import dependence and enabling affordable commercialization. Together, these initiatives position India as a fast-emerging global hub for biopharma innovation, manufacturing and health security.

## CCRAS Launches SIDDHI 2.0 To Strengthen Research-Driven Innovation In Ayurveda Pharma Sector


The Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of Ayush, launched SIDDHI 2.0 (Scientific Innovation in Drug Development, Healthcare & Integration), its flagship industry–research interface, with a two-day national conclave in Vijayawada. The event was organized by the Regional Ayurveda Research Institute (RARI), Vijayawada, in collaboration with the Confederation of Indian Industry (CII). During the inaugural ceremony, CCRAS released its medico-historical publication, "Evolution of Ayurveda, Siddha & Unani Drug Regulations in India," and the Drug Inventory Management System portal.

SIDDHI 2.0 builds on PRAGATI-2024 and signifies a strategic shift toward research-led product development, indigenous technology advancement, accelerated translational pathways, and industry partnerships, aligning with India's Ayush innovation agenda. Prof. Vd. Rabinarayan Acharya, Director General of CCRAS, emphasized the growing relevance of Ayurveda's wellness-centric approach in addressing the rise of lifestyle-related diseases. Shri K. Dinesh Kumar, IAS, Director (Ayush), Government of Andhra Pradesh, proposed the establishment of a National Ayurveda Institute, noting the limited number of existing Ayurveda colleges and pharmaceutical units in the state.


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Dr. N. Srikanth, Deputy Director General of CCRAS, highlighted that the Council has validated over 150 Ayurvedic formulations. He encouraged the industry to utilize CCRAS's extensive data on quality, safety, and toxicity, pointing to the organization's industry-friendly research policy, including IPR-sharing.

CCRAS also supports Ayurveda-based, AI-driven, and innovative start-ups. Envisioned as a national translational accelerator, SIDDHI 2.0 ultimately aims to promote wider industry adoption of CCRAS technologies, strengthen institutional linkages, upgrade quality and regulatory frameworks, and support the development of globally competitive Ayurvedic pharmaceuticals, ensuring a modern, evidence-driven, and scalable future for Ayurveda.

## Piramal Pharma Solutions Achieves Regulatory Compliance for Nitrosamine Impurities

Piramal Pharma Solutions, a leading global Contract Development and Manufacturing Organization (CDMO) announced the successful completion of its journey to compliance with global requirements for nitrosamine impurities in pharmaceuticals.

Nitrosamines are unintended carcinogenic byproducts that can be found in certain medications. International guidelines on Nitrosamine Drug Substance-Related Impurities (NDSRIs) have evolved significantly over the last few years, requiring pharmaceutical companies to adapt their operations to maintain compliance. In response, Piramal Pharma Solutions has implemented a robust, multi-step action plan to ensure regulatory alignment with the latest NDSRI guidelines, and more importantly, patient safety.

The first step of this proactive approach involved the development of a cross-functional core team of subject matter experts from Regulatory Affairs, Central Quality, R&D, and Manufacturing. These experts offered specialized insights from their unique perspective, interpreted regulatory guidance as it was published, and ensured every operation across our organization remains compliant with international NDSRI guidelines.

This team played a pivotal role in the publication and continual update of the Position Paper, a centralized guidance document aligned with the latest regulatory expectations. By clearly defining roles and responsibilities, the Position Paper enabled site teams to adapt to the challenges and changes associated with the new requirements.

A critical component of the company's journey to nitrosamine compliance was prioritizing risk assessments for all relevant drug substances and drug products to analyze their level of safety and regulatory impact. All identified products received confirmatory testing, with control strategies and administrative controls implemented as needed. Currently, all existing Piramal Pharma Limited commercial products comply with global regulatory requirements. Some customer products are still pending approval, and new batches will only be executed following regulatory alignment.

The action plan also involved the development of in-house testing capabilities at key facilities, alongside the qualification of external laboratories to support additional testing needs. This included investments into new state-of-the-art equipment and capabilities at the Ahmedabad and Digwal pharmaceutical development sites to expedite testing and compliance processes and mitigate potential drug shortage issues. These enhancements also address industry-wide challenges posed by impurity standards and synthesis difficulties, enabling Piramal to synthesize and qualify impurities in-house, minimize impurity formation, and conduct additional screening studies to confirm product safety.

"At Piramal Pharma Solutions, patient well-being is our top priority. We are proud to have achieved regulatory compliance for nitrosamine impurities, which reflects our unwavering commitment to patient safety and operational excellence, while also solidifying our position as a trusted partner in the industry," said Rashida Najmi, Chief Quality Officer, Piramal Pharma Limited. "With our proactive approach and enhanced capabilities, we are well-equipped to adapt to evolving global NDSRI standards, ensuring the highest safety and quality standards for our products."

As international guidelines surrounding nitrosamines evolve, Piramal Pharma Solutions remains committed to patient safety, regulatory compliance, and operational

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excellence. The Company will continue to support partners as they navigate the complex landscape of nitrosamine control, prioritizing transparent communication and continuous improvement to maintain the highest standards of pharmaceutical quality and patient safety.

## Sun Pharma Introduces Ilumya® in India for Treatment of Moderate-To-Severe Plaque Psoriasis

Sun Pharma recently announced the launch of its global innovative drug, ILUMYA (Tildrakizumab) in India for moderate-to-severe plaque psoriasis. A novel biologic treatment, ILUMYA has been endorsed widely by dermatologists in the US and worldwide for several years as an effective and safe treatment of moderate to severe plaque psoriasis.

"ILUMYA offers a safe and effective treatment option for patients who are struggling to manage their moderate-to-severe plaque psoriasis," said Kirti Ganorkar, Managing Director, Sun Pharma.

"We are pleased to introduce this novel therapy in India from our global portfolio of innovative medicines. Already available in 35 countries, ILUMYA has consistently demonstrated significant and long-lasting skin clearance, beginning soon after initiation and sustained over years."

Sun Pharma's clinical study in India included 115 patients of moderate-to-severe plaque psoriasis. A 75 percent skin clearance (≥75% reduction in Psoriasis Area Severity Index Score) was seen in 62.3%, 83.3% and 93.9% patients, respectively at Weeks 12, 16, 28. A 90 percent skin clearance (≥90% reduction in Psoriasis Area Severity Index Score) was seen in 26.3%, 50%, & 78.1% patients, respectively at Week 12, 16 & 28. Patients received 3 subcutaneous injections of Tildrakizumab over a period of 16 Weeks (Day 1, Week 4 & Week 16) and were followed for a period of 28 weeks.

Significant improvements were also observed on additional efficacy endpoints such as, Dermatology Life Quality Index (DLQI) score. Tildrakizumab was well tolerated by Indian patients, with no immunogenicity concerns observed in this study.

"Having been involved in the clinical development of Tildrakizumab in India, I am pleased to see its potential as an effective, safe, and long-lasting treatment for psoriasis. In the Phase-3 trial, Tildrakizumab demonstrated significant improvements across all measures, with approximately 93.5% reduction in PASI score and pronounced skin clearance," said Dr. B. S. Chandrashekar, Chief Dermatologist and Managing Director at Cutis Academy of Cutaneous Sciences, Bengaluru, India, who was also an investigator in India Phase 3 trial.

"These results showcase its benefits in improving the quality of life for psoriasis patients." ILUMYA is the first IL-23 inhibitor to complete five years of study based on a pooled analysis of two Phase 3 efficacy and safety extension trials in moderate-to-severe plaque psoriasis. Patients living with moderate-to-severe plaque psoriasis need therapies they can use over long periods of time without loss of efficacy, and data shows that ILUMYA is a sustainable choice for patients over the long term.

## Lupin Receives EIR from US FDA for its Nagpur Injectable Facility

Lupin Ltd. has received the Establishment Inspection Report (EIR) from the United States Food and Drug Administration (US FDA) for its injectable facility in Nagpur, India, with a satisfactory Voluntary Action Indicated (VAI) classification.

The EIR was issued following an inspection of the facility from September 8 to September 16, 2025. Nilesh Gupta, Managing Director, Lupin, said, "We are pleased to have received the EIR from the U.S. FDA with a VAI classification for our Nagpur injectable facility. We are committed to upholding the highest standards of quality and compliance across our facilities, with continued focus on enhancements to our quality systems and operational excellence."

## Lupin Secures SBTi Validation for Emission Reduction Targets

**Mumbai**: Lupin Ltd. announced that its greenhouse gas (GHG) emission reduction targets have been officially validated by the Science Based Targets initiative (SBTi). These validations cover all three emission scopes – Scope 1, Scope 2, and Scope 3, aligning with the Paris Agreement to limit global temperature rise to 1.5°C. This milestone underscores Lupin's commitment to sustainability and decisive climate action, positioning the company among a select group that has achieved comprehensive SBTi validation within a year of setting its climate targets.

Key short-term targets: 1) Reduce absolute Scope 1 and 2 greenhouse gas emissions by 42.0% by FY 2030, with FY 2023 as the base year. 2) Reduce Scope 3

greenhouse gas emissions by 61.07% by FY 2033, across purchased goods and services, fuel- and energy-related activities, upstream and downstream transportation and distribution, business travel, employee commuting, processing and use of sold products, and franchises, using FY 2024 as the baseline.

These goals are aligned with the 1.5°C pathway and validated under SBTi's latest guidelines, thereby positioning Lupin as a key participant in the global effort to combat climate change.

Ramesh Swaminathan, Executive Director, Global CFO, and Head of IT and API Plus SBU, Lupin, said, "The validation from SBTi underscores Lupin's unwavering commitment to reducing greenhouse gas emissions through a rigorous, science-driven approach. By setting ambitious targets, we are embedding sustainability into both our financial and operational strategies. These goals guide investments in renewable energy, energy efficiency, and low-carbon technologies across our global operations. Proactive action on climate change is essential not only for mitigating risks and optimising costs but also for unlocking opportunities for innovation and long-term growth."

## Zydus, Myriad Genetics Partner to Launch Cancer-Risk Diagnostic Tests in India

Zydus Lifesciences, an innovation-led life-sciences company with an international presence, has entered into an agreement with Myriad Genetics, a leader in molecular diagnostic testing and precision medicine. Pursuant to the Agreement, Zydus will be introducing MyRisk® Hereditary Cancer Test, MyChoice® HRD Plus, Homologous Recombination Deficiency (HRD) Test and Prolaris® Prostate Cancer Prognostic Test to patients, clinicians, and healthcare systems across India.

With the increasing incidence of cancers globally, MyRisk® Test can help people safeguard their health and take precautionary steps and lifestyle changes that can minimise the risk of cancer. In patients suffering from prostate and ovarian cancers, the Prolaris® Test and MyChoice® HRD Plus Test, respectively, can help patients understand the disease progression and inform the right treatment path.

Commenting on this, Dr. Sharvil P. Patel, Managing Director, Zydus, said, "This agreement marks a major step in expanding access to precision diagnostic tests for cancer treatment in India. The prostate and ovarian cancer tests help doctors with actionable insights to develop personalised treatment plans, predict disease progression, arrive at treatment decisions and streamline clinical workflows. We are also bringing a test which will help identify hereditary risks in patients and their families. Enabling access to these critical diagnostic tests will benefit patients in getting better clinical outcomes and support their fight against cancer."

Dr. Patel further went on to say, "Reaffirming Zydus' deep commitment to patient centricity and precision oncology, this collaboration with Myriad Genetics will strengthen clinician education and diagnostic infrastructure so that patients will benefit from earlier, more accurate risk assessment and confident treatment planning. Together, we aspire to make personalised, evidence-based cancer care accessible to every patient who needs it, helping them navigate their journey with greater clarity and support."

"This collaboration with Zydus is an important step forward in expanding precision oncology across India," said Brian Donnelly, Chief Commercial Officer for Myriad Genetics. "Myriad tests aim to empower clinicians with actionable information to assess risk, understand tumour biology, and guide truly personalised care with greater clarity, confidence, and hope as they navigate critical health decisions."

As part of this agreement, Zydus will exclusively market, create awareness, access and engage clinicians on three of Myriad Genetics' broadly validated diagnostic platforms, MyRisk® Hereditary Cancer Test, MyChoice® HRD Plus Test for ovarian cancer, and Prolaris® a gene expression Prostate Cancer Prognostic Test. These tests have been widely adopted in North America, Europe, and major global cancer centres, and will now empower Indian oncologists with cutting-edge genomic decision-support tools.

MyRisk® Test is a germline multigene panel for individuals with personal or family history suggestive of hereditary cancer. It detects pathogenic variants in high, moderate and emerging-risk genes to estimate lifetime cancer risk and inform personalized prevention strategies. It is a comprehensive panel which analyses 63 clinically significant genes (BRCA1, BRCA2, PALB2, ATM, TP53, MLH1, MSH2, etc.) covering cancer types like, breast, ovarian, lung, pancreatic, colorectal, endometrial, prostate, gastric, and melanoma. It also includes RiskScore® which combines genetic and clinical data to predict 5-year and lifetime breast cancer risk, enabling individualised screening and prevention plans.

## Lupin Receives Positive CHMP Opinion for Biosimilar Ranibizumab

Global pharma major, Lupin announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization for its biosimilar ranibizumab, RanluspecTM, for both vial and pre-filled syringe presentations.

Ranibizumab is a recombinant humanized IgG1 monoclonal antibody fragment that binds to and inhibits vascular endothelial growth factor A (VEGF-A). Its indications encompass the treatment of patients with neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), proliferative diabetic retinopathy (PDR), and choroidal neovascularization (CNV).

The positive CHMP opinion is based on a demonstration of similarity to the reference product, including an analytical similarity assessment and a 600-patient global phase III clinical trial in patients with Neovascular AMD, conducted in the US, EU, Russia, and India.

Thierry Volle, President EMEA and Emerging Markets, Lupin, said, "We are very pleased with the CHMP's positive opinion for ranibizumab. This recognition underscores the quality of Lupin's Biologics development and manufacturing as well as our relentless pursuit of affordable solutions that transform patient care."

The CHMP positive opinion will now be considered by the European Commission (EC). Once approved, the EC will grant a centralized marketing authorization for EU member countries. As per the recently announced agreement, Lupin's biosimilar ranibizumab will be commercialized by Sandoz Group AG across the European Union (excluding Germany). In France, the product will be commercialized by two companies, Sandoz AG and Biogaran.

## Zydus Launches Biosimilar Denosumab to Support Bone Health in Cancer Patients

Zydus Lifesciences Ltd., an innovation-led healthcare company, with an international presence has launched 'Zyrifa', a Denosumab biosimilar. Denosumab is a monoclonal antibody with several indications related to bone health, primarily in the treatment of osteoporosis and the prevention of skeletal complications in cancer patients. This will provide access and treat patients with bone metastases due to breast, prostate, lung, myeloma, kidney, thyroid, head and neck, and other solid tumours.

Metastases, is when the cancer spreads to the bones and other organs in the body indicating an advanced stage of cancer. 'Zyrifa' is priced at MRP of Rs 12,49 5. Bone metastases are a serious complication across multiple cancers, significantly impacting patient quality of life. Patients experience pain, fractures, spinal cord compression, reduced mobility, and loss of independence, often impacting their dignity and increasing mortality risk.

The condition most commonly affects the axial skeleton (spine, pelvis, ribs), leading to severe complications. Speaking on this launch, Dr. Sharvil P. Patel, Managing Director, Zydus Lifesciences Ltd. said, "With Denosumab 120 mg SC, we aim to bring access, affordability of medication in cancer patients needing critical care. This will help patients to retain mobility, and support them in their fight against cancer."

Population scale analyses and registry studies consistently show high bone involvement rates in advanced disease; in advanced breast or prostate cancer, bone involvement affects 50 -70% of patients**,** whereas 15- 40% of lung, kidney, thyroid, and melanoma cases also develop skeletal metastases over time. Zydus Lifesciences has been launching a wide range of biosimilars to treat various cancers ranging from breast cancer to prostate cancer, various other solid tumours and blood cancer. The company has also partnered with diagnostic companies. ■

# High-Purity Niacinamide & Niacin: Innovations Strengthening Personal Care, Nutrition Pharmaceutical, and Industries

**Rishi Gangwar**
Head-Nutrition and Health Ingredients
Jubilant Ingrevia

Innovation today defines progress across sectors, and vitamin B3, whether as niacin or niacinamide, has emerged as a prime example of how a single molecule can influence multiple major industries simultaneously. Niacinamide now sits at the centre of a pivotal growth phase for the global vitamin B3 market. Rising consumer awareness, cleaner-label preferences, scientific validation, and tightening purity standards are accelerating its adoption across pharmaceuticals, nutrition, and personal care. The result is a convergence of opportunities that position niacinamide as one of the most versatile and scientifically established active ingredients in the world today.

Globally, the vitamin B3 market is valued around $386 million in 2025 and is projected to grow to approximately $489 million by 2030 at a steady CAGR of 4.27 per cent. This expansion is driven largely by the increasing use of Niacinamide in personal care applications. Niacinamide has become a prominent ingredient in skincare for its anti-aging, skin-brightening, and anti-inflammatory properties. The clean beauty trend, emphasizing natural and high-efficacy ingredients, further fuels this demand.

### Personal Care Imperative

No sector, however, reflects the molecule's versatility as clearly as the personal care industry. Niacinamide today is one of the most research-backed skincare actives globally, appreciated for its multi-functional benefits spanning anti-aging, brightening, barrier repair, collagen stimulation, ceramide synthesis and inflammation reduction. Its clinical efficacy in acne, hyperpigmentation and rosacea has made it a cornerstone of dermatology-aligned formulations. Last year witnessed a wave of new product introductions, including expansion of niacinamide-rich offerings across. Trends indicate steady consumer preference for higher-concentration serums in the 10-20 per cent range, as well as greater use of hybrid formulations combining niacinamide with retinoids, hyaluronic acid, AHAs and BHAs.

In recent years, high-purity niacinamide (vitamin B3) has gained renewed traction across pharmaceuticals, nutrition, and personal care, reflecting a convergence of applications previously treated as separate domains. In dermatology and personal care, niacinamide's multifunctional benefits such as anti-aging, skin brightening, barrier repair, pigmentation reduction and anti-inflammation are now supported by robust mechanistic and clinical evidence. Cosmetics-grade niacinamide is witnessing the fastest growth, advancing at a 6.78 per cent CAGR through 2030 as skincare brands embrace science-backed actives. One can note here, Jubilant Ingrevia is capitalizing on its cost-effective operations in India to delve into cosmetics-grade markets, recently debuting ultra-low-residual solvents niacinamide, tailored for K-beauty brands.

Manufacturing facility at Jubilant Ingrevia

At the cellular level, niacinamide supports synthesis of $NAD^+$, a critical co-enzyme for redox reactions, energy metabolism and DNA repair, mechanisms central to skin health, aging mitigation, and cellular resilience. Its topical application has been shown to stimulate ceramide and fatty-acid production within the stratum corneum, thereby improving barrier integrity, reducing transepidermal water loss, and enhancing hydration. On a structural level, niacinamide alters lipid-matrix organization and modulates keratin spacing under varying humidity, yielding increased water uptake and barrier flexibility, especially under humid conditions, supporting both skin hydration and resilience.

Clinical studies continue to validate these effects: niacinamide creams applied over weeks reduce hyperpigmentation, fade acne marks, and improve overall skin hydration and barrier function across skin types. Importantly, its safety profile and compatibility with other actives make it ideal for inclusion in complex, hybrid formulations, often combined with ingredients such as retinoids, hyaluronic acid, AHAs/BHAs, or ceramides to maximize outcome across skin aging, complexion, hydration and barrier repair.

On the technology front, polymeric nanoparticles derived from niacin can encapsulate bioactive molecules with high efficiency, enabling controlled delivery and improved cellular uptake, a promising platform for both therapeutic and cosmetic applications. Another recent development combines niacinamide into lipid nanocarrier systems and hybrid nano-gels, enhancing its permeation through the skin barrier and increasing photoprotection, thus enabling its use in UV-protection, anti-pollution and dermal health applications.

These advances are driving product innovation beyond traditional serums and moisturizers. The expanded tolerance and efficacy of niacinamide support its integration into multifunctional personal care, e.g., body-washes, hand creams, deodorants and even hybrid skincare targeting male grooming or broader demographic segments. The convergence between nutritional understanding, dermatological science and delivery technology reflects a modern paradigm: vitamin B3 is no longer merely a dietary supplement, but a foundational building block across health, wellness and cosmetic industries.

### Nutritional Transformation

The nutrition sector is undergoing its own transformation. In a landscape where 75 per cent of U.S. adults take dietary supplements, preventive health has become a mainstream behaviour, accelerating demand for vitamins such as B3. Government-backed fortification programmes, from Ireland's Food Safety Authority to Malaysia's Ministry of Health and Sweden's National Food Agency, reinforce its indispensable role in population-level nutrition. These regulations integrate niacin into categories such as flour, cereals and infant formulations to address deficiencies and improve foundational dietary quality.

In recent years, high-purity niacinamide (vitamin B3) and anti-inflammation are now supported by robust mechanistic and clinical evidence. Cosmetics-grade niacinamide is witnessing the fastest growth, advancing at a 6.78 per cent CAGR through 2030 as skincare brands embrace science-backed actives.

In response, the industry is rapidly adopting clean-label, sustainable and organic manufacturing philosophies. Functional foods fortified with niacin, ranging from pasta and cereals to baked goods, are expanding consumer choice, while the functional beverage category continues to grow. Pet-nutrition applications, particularly in markets such as Australia, highlight the

Manufacturing facility at Jubilant Ingrevia

molecule's applicability beyond traditional human-health boundaries.

### The Pharmaceutical Frontier

Vitamin B3 itself plays a foundational biochemical role. As an essential, water-soluble nutrient synthesised from tryptophan in plants and animals, niacin is present in multiple whole foods, especially poultry, meat, tuna, salmon and fortified packaged products. Its importance spans energy production, healthy digestion, cognitive function, inflammation control, and maintaining skin and nerve health. These fundamental physiological benefits explain the breadth of its applications, from human nutrition and personal care to pharmaceuticals, metal plating and agrochemical intermediates.

Inositol hexaniacinate is a compound that combines niacin (vitamin B3) and inositol for flush free application & widely used in Nutraceutical applications especially in USA market.

### Clinical Applications

The pharmaceutical domain, in particular, is entering a frontier phase where high-purity niacinamide is enabling advancements in metabolic, cardiovascular, renal and cellular-energy research. Its use in lipid management, impacting HDL, LDL and triglycerides, continues to guide therapeutic development. Research is expanding into areas such as Type 1 diabetes progression management, hyperphosphatemia treatment for hemodialysis patients and NAD+ precursor therapy for improving cellular energy, healthy aging and chronic-care support.

These innovations are strengthened by improvements in analytical and purity standards, including the adoption of ultra-high-performance liquid chromatography protocols in South Korea and 2024 updates by the U.S. Pharmacopeia that introduced spectroscopic fingerprinting technologies. With pharmaceutical-grade material now routinely exceeding 99 per cent purity and accompanied by stricter identity verification procedures, the category is transitioning toward unprecedented quality benchmarks.

Delivery technologies are evolving in parallel. Extended-release capsules and tablets are now complemented by injectable formats used in severe deficiency states, while consumer-friendly options such as gummies, effervescent tablets and liquid solutions enhance accessibility without compromising efficacy. This progress reflects a broader transition toward improved tolerability and patient adherence, both of which remain central to chronic therapy outcomes. AI-enabled formulation design and precision dosage optimisation further support efficacy, safety and quality control, helping manufacturers better predict performance, stability and consumer response.

### World-Class Products and Services

In this landscape, Jubilant Ingrevia has positioned itself as a global leader and is the world's second-largest manufacturer of Vitamin B3 (which includes Niacinamide and Niacin). Jubilant Ingrevia's complete backward integration for basic feedstock allows unrivalled advantages vis-à-vis consistent quality and availability for niacin and niacinamide. The company leverages its global scale of pyridine and beta picoline (basic organic chemicals used in producing vitamin B3) manufacturing operations. Thanks to the high quality and reliability of its products, the company enjoys tremendous trust among customers across the globe and for various applications including human and animal nutrition, personal care, pharmaceuticals, and agrochemicals.

Jubilant's production facilities are fully certified and compliant with world-class standards necessary for the manufacturing of food ingredients under FSSAI, FSSC-22000, US FFR, RC 14001:2015, Halal, Kosher, ISO, WHO-GMP, OHSAS and FAMI-QS regulations.

### Sustainable Manufacturing Operations

With Jubilant using bioethanol as the primary feedstock and not naphtha or petroleum-based feedstock, the

company ensures a significant reduction in the level of its GHG (greenhouse gas) emissions. This process also helps customers establish a greener supply chain by using niacin and niacinamide produced by Jubilant. In this way, the company saves approximately 4.1 to 4.3 tonnes of $CO_2$ per tonne of niacin and niacinamide produced, respectively.

### Ensuring Quality Standards - An Absolute Necessity

Underlying these advancements is a strong foundation of quality, manufacturing excellence and regulatory alignment. The industry's rapid shift toward high-purity, high-stability formats is supported by more than 750 patent filings related to encapsulation technologies in 2024 alone. Continuous-flow manufacturing across 14 facilities worldwide has improved consistency and efficiency, while shelf stability of up to 60 months and stringent trace-impurity detection protocols ensure reliable performance.

Regulatory harmonisation across the FDA, EMA and Asian authorities, and growing emphasis on GMP, USP, EP and BP compliance, demonstrate the global commitment to safety and standardization. The focus on sustainability reinforces this trajectory: green chemistry adoption, reduced packaging waste, lower carbon footprints and transparent supply chains are increasingly embedded into production models. Our Vitamin B3 process uses bio based ethanol as a primary feedstock enabling savings of 4.1 to 4.3 tonnes of $CO_2$ per tonne of niacin or niacinamide produced with respect to Petro based sources and allowing customers to strengthen their own sustainability commitments.

As the world moves deeper into an era defined by preventive health, scientific innovation and personalised wellness, niacinamide stands out as a molecule with commercial versatility. Its role across pharmaceuticals, nutritional fortification and personal care continues to expand, powered by consistent research and strong market demand. With quality investments differentiating premium products and emerging derma cosmetics uses on the horizon, vitamin B3 is poised to deliver broader global health impact, enhanced accessibility and next-generation formulations that meet the needs of a rapidly evolving world.■

# Vaccine Development: An Overview

Public health plays a vital role in enhancing the productivity of a nation's workforce and its overall economic growth. Access to clean water is one of the most cost-effective means of controlling many debilitating infectious diseases within populations. Widespread vaccination is the next most crucial intervention, second only to clean water, in strengthening public health.

**Dr. Rajan Sriraman, Research Director - Vaccines Reliance Life Sciences** provides the overview of the vaccine development process and highlight the strategies employed by the industry to overcome challenges. Although the focus is on human vaccines, the development process for veterinary vaccines follows a very similar pathway.

**Dr. Rajan Sriraman**
Research Director- Vaccines
Reliance Life Sciences

Governments and donor agencies worldwide recognize the importance of vaccinating entire populations. As a result, they allocate significant funds to immunize children, thereby ensuring a healthier future workforce.

Given the significance of vaccines in public health programs, several substantial challenges must be addressed.

These challenges include cost of goods associated with vaccine manufacturing; scale of production required to meet the demand for hundreds of millions of doses annually; Ensuring vaccines are transported and stored under strictly monitored cold-chain conditions to reach the remotest areas; the speed of vaccine development and deployment to respond to emerging infectious diseases and Combating misinformation spread by vested interest groups, which discourages people from getting vaccinated.

### Identifying the Causative Agent

Before a vaccine can be developed, the causative agent of the disease must be identified. This initial step is critical in creating an effective vaccine to prevent the onset of an infectious disease. Academic institutions and government health agencies play an essential role in this phase of vaccine development.

Nature of the disease-causing agent, ease of handling and operator safety determines the type of vaccine that can be developed. For instance, most of the vaccines developed for COVID-19 were recombinant sub-unit vaccine as the virus was highly infectious and against which no effective clinical management protocols were available.

### Prophylactic Nature of Vaccines

Vaccines are predominantly prophylactic, meaning they are administered to healthy individuals before the onset of the disease. Unlike therapeutic agents, which are given after a person falls ill, vaccines are preventive in nature and do not generally require administration under professional supervision. This creates a higher regulatory expectation for their safety and efficacy. As a result, every vaccine, regardless of the manufacturer, is considered a "new drug" by regulatory authorities and must be rigorously tested to demonstrate both safety and efficacy. This testing involves a comprehensive clinical development program that includes non-clinical toxicology studies in laboratory animals, as well as Phase I, II, and III clinical trials in human subjects.

### Regulatory Expectations and Development Timeline

Due to the stringent regulatory requirements, vaccine development and commercialization are often lengthy and resource-intensive processes. Typically, it takes between 5 to 7 years to develop a vaccine and bring it to market, depending on the number of doses required and the spacing between them. This timeline can only be shortened when the regulatory risk appetite is higher, as was the case during the COVID-19 pandemic. In such scenarios, when no existing disease management tools are available, and large populations are at risk, regulatory agencies may accelerate approval processes.

### Vaccine Composition and Immune Response

Vaccines are sterile, injectable formulations designed to stimulate the immune system of an individual to recognize and combat a future invasion by a pathogen. The active ingredients in vaccines are derived from the same or similar organisms that cause the disease. The primary goal is to trigger the immune system to produce specific proteins (antibodies) or primed cells (T-cells) capable of responding to any future exposure to the pathogen. The body's ability to retain pathogen-specific information and recall it years later, when re-exposed to the infectious agent, is known as the memory response. This response is a key indicator of an effective vaccine.

Vaccines can contain a wide range of biological agents, including Live bacteria or viruses, Attenuated (weakened) bacteria or viruses, Bacterial fractions, such as toxins, toxoids, or polysaccharides, Recombinant immunogenic proteins from bacteria or viruses (subunit or virus-like particles), Bacterial polysaccharides chemically conjugated (linked) to a protein (conjugate vaccines), Nucleic acids, such as DNA or mRNA and Immunogenic proteins delivered using another virus or bacteria that are non-infectious (vectored vaccines)

### The Vaccine Development Process

The development of vaccines follows a process similar to that of bio-therapeutic products. The first major step is to identify the pathogen causing the infection, which then leads to the identification and selection of a suitable antigen or immunogen. This is the foundation for developing an effective vaccine. Lead identification often takes several years, involving research conducted in academic settings or within industry. The process is highly knowledge-intensive and requires expertise in areas such as disease biology, molecular biology, immunology, bioanalytical techniques, biochemical engineering, and protein or polysaccharide chemistry.

Once a promising vaccine lead is identified, it is validated using a disease model or surrogate animal model. Following validation, a consistent manufacturing process is developed to translate the lead into an effective vaccine, which then undergoes full clinical development. Preclinical (or non-clinical) studies in animals help establish the vaccine's safety profile, and this is followed by three phases of clinical trials involving healthy human volunteers. These trials evaluate the vaccine's safety (Phase I), efficacy (Phase II), and further confirmatory efficacy (Phase III). During this process, all components of the vaccine, in-process materials, final product specifications, and the manufacturing process are established. Regulatory considerations are factored into the development process, including the manufacturing scale, which is chosen to ensure sufficient material for clinical trials and stability testing.

Vaccines required for human trials are produced in cGMP (current Good Manufacturing Practices) facilities. Three or more consistent production lots are needed for Phase III trials, which are conducted at full production scale.

### Regulatory Oversight and Global Distribution

Many countries rely on the World Health Organization's (WHO) guidelines for vaccine product quality, published in its Technical Report Series (WHO TRS). Vaccine manufacturers that meet these regulatory expectations can export their products to economically disadvantaged countries through UNICEF or the Global Alliance for Vaccines and Immunization (GAVI), which support childhood immunization programs.

Vaccines undergo comprehensive analytical and bio-analytical (immunological) testing to demonstrate that both the vaccine and its key intermediates meet the specified requirements outlined in pharmacopoeias. Every vaccine must meet rigorous standards for safety, efficacy, and potency before it can be released for public use. In India, as well as other countries, national pharmacopoeias provide monographs outlining standardized requirements for each approved vaccine. Both the manufacturer and central testing laboratories must test formulated vaccines for safety and efficacy before each batch is released for use in humans.

### Formulation and Technological Advancements

Multicomponent vaccines, which protect against several infectious agents, have increased compliance and reduced the number of clinic visits and needle pricks. Formulating vaccines with multiple components, each with different physicochemical properties, is a complex task that requires both scientific and practical expertise. Most vaccines, except for seasonal flu vaccines, have a shelf life of two years or more. Flu vaccines are unique because the WHO revises the list of strains to be incorporated into the vaccine annually.

Adopting new process technologies, such as single-use reactors, process automation, needle-free delivery systems, and thermostable formulations, can significantly reduce production costs and improve vaccine performance. For example, single-use reactors can lower utility consumption, reducing overhead costs, while automated processes can decrease input costs and minimize batch failures. These advancements contribute to reducing the overall cost of vaccine production, making them more accessible worldwide. Greater vaccine coverage helps prevent the emergence of infectious diseases, benefiting both public health and the global economy.

### Future Trends in Vaccination

While childhood vaccination is currently the primary focus in many developing countries, there is a growing demand for vaccines for adults and the elderly, driven by increasing life expectancy worldwide. As populations age, the need for vaccines that protect against diseases prevalent in adulthood and old age will rise.

Currently most available vaccines are directed to prevent the onset of the disease – Prophylactic. Development of an effective therapeutic vaccine is also being attempted.

### Conclusion

Vaccine development is an interdisciplinary and resource-intensive process, requiring a deep understanding of various scientific fields. As human activity continues to encroach on natural habitats, due to deforestation and urbanization, the risk of new infectious diseases, such as COVID-19, emerging from wildlife remains high. Ongoing disease surveillance and epidemiological research will be critical in preparing for and combating future infectious disease outbreaks. The need for developing and improving vaccines will always be relevant. ■

# Pharmacovigilance and Drug Safety: Evolution, Challenges and Future

The word 'Pharmakon' in Greek means 'Drug' & 'Vigilare' in Latin means "To keep watch awake or alert'. Pharmacovigilance is noble and important clinical science with an end objective of rational and safe use of medicines. It intends to educate and share information with patients for informed decisions and take appropriate actions when required.

**Dr. Prabhu Kasture (MD, DPH), Director Medical Services & Pharmacovigilance, Blue Cross Laboratories Pvt Ltd** shares insights about the evolution of Pharmacovigilance and its challenges. He also spoke about the future of pharmacovigilance in India.

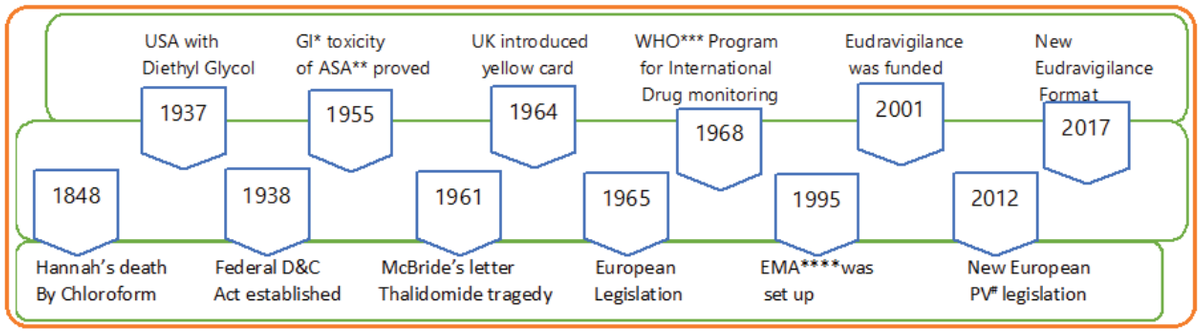
**Dr. Prabhu Kasture (MD, DPH)**
Director Medical Services & Pharmacovigilance,
Blue Cross Laboratories Pvt Ltd

Adverse drug reaction (ADR) is one of the known leading cause of death, thus highlighting the need to monitor safety aspect of a drug available for use throughout its life cycle & thus making it necessary to protect the public health by promoting safer drug therapy.

Pharmacovigilance is defined by the World Health Organization (WHO) as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem' & it's of paramount importance for doctors and patients to have enough information to make an informed decision while choosing medicine for treatment.

The history of pharmacovigilance is more than 170 years, although it wasn't termed until 1961. Post the Thalidomide disaster the WHO in 1968 took cognizance on the safety issues related to the consumption of drugs and there by established the program of pharmacovigilance for international drug monitoring.

In India, this program is still at the dawning stage and require concerted efforts from all the stakeholders. Pharmacovigilance in India was initiated in 1986 with a formal adverse drug reaction (ADR) monitoring system, under the supervision of the Drug Controller of India. In 1998, India had joined the World Health Organization (WHO) for drug monitoring. The National Programme of Pharmacovigilance was launched in 2005 and later




Historical evolution of Pharmacovigilance.* GI: Gastrointestinal **ASA: acetylsalicylic acid; ***WHO: World Health Organization; ****EMA: European Medicines Agency #PV: Pharmacovigilance

renamed to Pharmacovigilance Program of India (PvPI) in 2010. Currently, the PvPI is implemented through the National Coordination Centre at Ghaziabad under the aegis of Indian Pharmacopoeia Commission (IPC). Materiovigilance for medical devices has been initiated since 2015.

Numerous challenges have prevented the successful implementation of PV program in India. Lack of awareness, regarding the occurrence of adverse reactions with the medicines amongst the general population and lesser participation from the healthcare professionals have led to underreporting.

The knowledge, attitude and practice of PV is lacking even amongst the health care professionals. Half of the HCPs are not aware of PvPI and out of those aware, two-thirds of HCPs are not aware from where to obtain an ADR reporting form contributing to lesser reporting of spontaneous adverse cases.

The unprecedented pandemic that the world witnessed in 2020 highlighted the importance of robust pharmacovigilance systems during the mass vaccination campaigns and numerous repurposed drugs for covid treatment which left many adverse events go unreported. Thus, the Central Drugs Standard Control Organization (CDSCO) continued to enhance the PvPI by integrating more advanced technologies and expanding its network of institutions and stakeholders in pharmacovigilance.

The emphasis has been on strengthening the data management systems, improving transparency, and fostering collaborations with professional & international bodies for better global harmonization. A strong public private partnership for providing quality training to all the stakeholders and regular monitoring of program by the regulatory authority can help improve the implementation of PV program in India.

## Challenges

- **Scant Resources:** Limited resources of finances and human resources pose a significant challenge. We have often struggled to allocate sufficient funding and trained personnel to pharmacovigilance activities, hindering their ability to establish comprehensive monitoring systems.

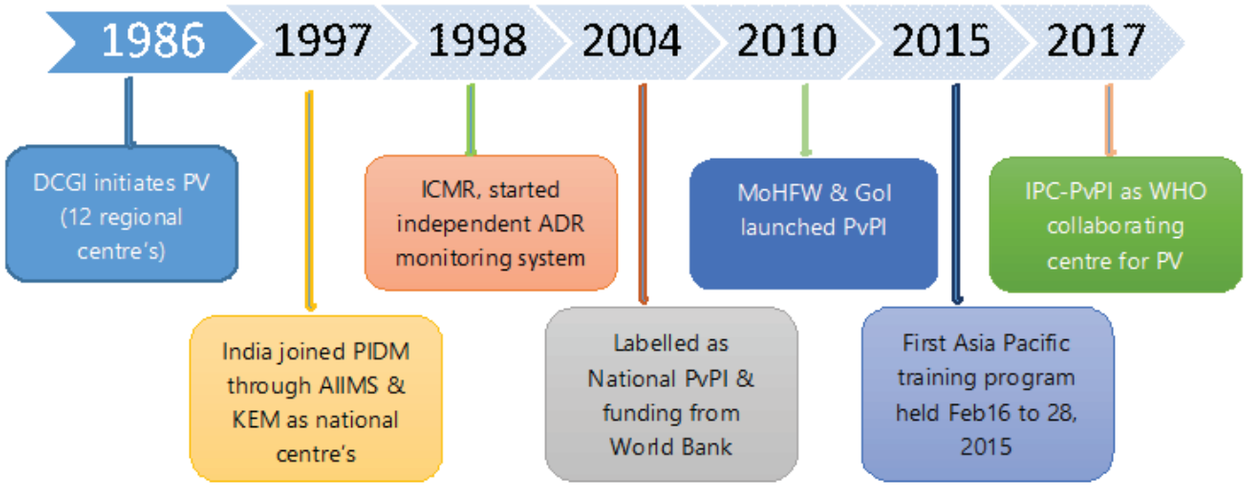
- **Poor Infrastructure:** Inadequate healthcare infrastructure, especially in rural areas, restricts the seamless flow of information.

- **Data Quality and Reporting Culture:** Inaccurate or incomplete reporting, coupled with a lack of reporting culture, affects the reliability of the collected data, making it challenging to derive meaningful insights.

- **Integration of Traditional Medicine:** India's rich tradition of alternative medicine, including Ayurveda, Unani, and Siddha, adds a layer of complexity to pharmacovigilance. Integrating these traditional practices with conventional pharmacovigilance systems is challenging but essential for comprehensive safety monitoring.

## Drivers to overcome these challenges

- Raising awareness and education: There is a need to raise awareness and education about pharmacovigilance among healthcare




DCGI: Drugs Controller General of India; ICMR: Indian council of medical research; PIDM: Program for international drug monitoring; MoHFW: Ministry of health & family welfare;IPC: Indian pharmacopoeia commission; PvPI: Pharmacovigilance program of India; WHO: World Health Organization

professionals and the general public in India. Training programs through partnerships, information education communication (IEC) campaigns, wiser dissemination of pertinent information through social media and influencers.

- **Promoting collaboration and partnerships:** Collaboration between the various stakeholders like governments, international organizations, the pharmaceutical industry, academia and professional bodies is essential & can facilitate better pharmacovigilance practices

- **Advancements in Technology:** The digital revolution shall help streamline the collection and analysis of adverse event through electronic health records (EHRs) thus enhancing the efficiency of pharmacovigilance practices, making all the stakeholders more accessible and responsive. Further AI/ML shall augment the quality of data ingestion and enhance the reporting.

- **Regulatory Reforms**: strengthening regulations and enforcing compliance standards ensure that pharmacovigilance becomes an integral part of the healthcare system.

**The future of pharmacovigilance in India looks promising and dynamic, with several key trends and developments shaping its evolution:-**

- **Regulatory Advancements**: The Indian regulatory landscape for pharmacovigilance is becoming increasingly sophisticated. The Central Drugs Standard Control Organization (CDSCO) is working towards aligning with international standards and enhancing regulatory frameworks to improve drug safety monitoring.

- **Integration of Technology**: The use of technology, including artificial intelligence and machine learning, is expected to play a significant role in pharmacovigilance. These technologies can help in analyzing large datasets, predicting adverse drug reactions, and improving signal detection.

- **Strengthening Data Collection and Reporting:** Efforts are being made to improve the quality and consistency of data collection and reporting mechanisms. This includes the adoption of electronic reporting systems and better training for healthcare professionals and patients on reporting adverse drug reactions.

- **Public Awareness and Education**: Increasing awareness among healthcare professionals and the public about the importance of pharmacovigilance is crucial. Educational initiatives and training programs are likely to expand, fostering a culture of safety and vigilance.

- **Collaborations and Global Integration:** India is expected to further integrate its pharmacovigilance practices with global standards. Collaborations with international organizations and participation in global pharmacovigilance networks will enhance the country's ability to monitor and respond to drug safety issues effectively.

- **Patient-Centric Approaches:** There will likely be a greater focus on patient-centric approaches, involving patients more directly in the reporting and monitoring of adverse drug reactions. Patient engagement can improve the quality of data and the overall effectiveness of pharmacovigilance efforts.

- **Improved Risk Management:** Enhanced risk management strategies, including more sophisticated risk assessment and mitigation plans, will become more prevalent. This will help in better managing the risks associated with new and existing medications.

## Current and Future Directions

Overall, the future of pharmacovigilance in India is geared towards greater efficiency, accuracy, and global integration, aiming to ensure the safety and well-being of patients through robust and innovative monitoring systems. The ongoing development of digital tools and databases, along with increased awareness and training among healthcare professionals, is likely to drive further improvements in pharmacovigilance practices in India. ■

# Leveraging CDMOs for Nutraceutical Research and Development

India's rich heritage in the nutritional value chain, rooted in ancient healing practices using herbs and natural resources, has positioned it as a global leader in this domain. Students and medical experts from around the world flock to India to study its extensive medicinal techniques derived from nature, which have been honed over thousands of years. The philosophical, practical, and spiritual significance of herb-based cures underscores their efficacy and acceptance, especially in addressing chronic diseases where modern medicines often fall short.

**Yuvraj Datta, Director of Manufacturing & Process Excellence, Zeon Lifesciences Ltd** emphasizes about the increasing trend of outsourcing services in the nutraceutical industry opened significant growth opportunities for contract development and manufacturing organization (CDMOs).

### The Rise of India's CDMO Sector

A contract development and manufacturing organization, or CDMO, offers end-to-end, fully cohesive drug development and manufacturing solutions and services that caters to biotechnology and pharmaceutical companies. This market is projected to reach USD278.98 billion by 2026. This implies that CDMOs play a crucial role in nutraceutical research and development.

India's Contract Development and Manufacturing Organization (CDMO) sector has rapidly emerged as a pivotal player in the global healthcare landscape. With its nutraceutical manufacturing facilities earning global accreditations, India has demonstrated a strong commitment to delivering high-quality products and services. Indian CDMOs are now interfacing with regulatory authorities, addressing challenges, and expanding their scope beyond mere manufacturing to become integral partners in the research and development (R&D) ecosystem.

The increasing trend of outsourcing services in the nutraceutical industry has opened significant growth opportunities for CDMOs. National and international players are increasingly relying on external service providers for their R&D and manufacturing needs. India has long been a preferred location for global companies to outsource these services, thanks to its robust technical expertise and regulatory-compliant facilities. Indian CDMOs, with their comprehensive capabilities ranging from clinical trials to commercial production, have proven to be capable partners for the global industry.

### Benefits of Outsourcing to CDMOs

Outsourcing to CDMOs offers several advantages. Companies can optimize their fixed costs by leveraging the cost-effective business models of CDMOs. This flexibility allows firms to scale their operations efficiently, reducing the financial burden associated with maintaining in-house R&D and manufacturing capabilities. Moreover, outsourcing enables companies to focus on their core competencies, such as marketing and distribution, while entrusting specialized tasks to experts in the field.

### Innovation Through Collaboration

Collaboration between nutraceutical companies and CDMOs is a driving force behind innovation in

the industry. By combining their strengths, these partnerships can accelerate the development of new products and technologies. CDMOs bring a wealth of expertise in process development, regulatory compliance, and quality assurance, ensuring that products meet the highest standards of safety and efficacy.

For instance, the development of a new dietary supplement might involve several complex steps, from initial formulation to large-scale production. A CDMO can provide end-to-end support, including raw material sourcing, formulation development, clinical trial management, and regulatory submissions. This comprehensive approach not only streamlines the development process but also enhances the overall quality of the final product.

### Addressing Regulatory Challenges

Navigating the complex regulatory landscape is a major challenge in the nutraceutical industry. CDMOs play a vital role in helping companies address these challenges by providing guidance on regulatory requirements and ensuring compliance with relevant standards. This is particularly important in the context of nutraceuticals, where regulatory frameworks can vary significantly between regions.

Indian CDMOs have developed strong relationships with regulatory authorities and possess a deep understanding of the regulatory environment. This expertise enables them to provide valuable support to their clients, from initial product development to market authorization. By partnering with CDMOs, nutraceutical companies can mitigate regulatory risks and accelerate their time to market.

Furthermore, Indian CDMOs have been proactive in adopting international best practices and certifications, such as Good Manufacturing Practices (GMP) and ISO standards. These certifications not only enhance the credibility of the CDMOs but also provide assurance to international clients about the quality and safety of the products developed and manufactured in India.

For example, the Indian CDMO industry has made significant strides in achieving compliance with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) regulations. This compliance ensures that the nutraceutical products manufactured in India can be readily exported to and marketed in these regions, thereby expanding the global reach of Indian-made nutraceuticals.

### The Future of CDMO-Nutraceutical Partnerships

The future of the nutraceutical industry lies in fostering even closer collaborations between companies and CDMOs. As consumer demand for natural and health-enhancing products continues to grow, the need for innovative solutions will become increasingly important. By leveraging the capabilities of CDMOs, nutraceutical companies can stay ahead of the curve and deliver cutting-edge products to the market.

One area of potential growth is the development of personalized nutraceuticals, which are tailored to meet the specific needs of individual consumers. This approach requires a deep understanding of both traditional medicine and modern science, making CDMOs ideal partners for such initiatives. By working together, nutraceutical companies and CDMOs can create personalized solutions that offer significant health benefits and cater to the unique preferences of consumers.

Another promising area is the integration of advanced technologies, such as artificial intelligence (AI) and machine learning, into R&D processes. These technologies can help in identifying new bioactive compounds, optimizing formulations, and predicting consumer responses to new products. CDMOs equipped with these advanced capabilities can offer a competitive edge to nutraceutical companies by accelerating the innovation cycle and enhancing product efficacy.

Additionally, sustainability is becoming a critical consideration in the nutraceutical industry. Consumers

are increasingly seeking products that are not only beneficial for their health but also environmentally friendly. CDMOs that adopt sustainable practices, such as sourcing raw materials responsibly, reducing waste, and minimizing their carbon footprint, will be in a strong position to meet this growing demand. By prioritizing sustainability, CDMOs can contribute to the overall well-being of the planet while delivering high-quality nutraceutical products.

### Conclusion

Innovation through collaboration is the key to unlocking the full potential of the nutraceutical industry. India's CDMO sector, with its rich heritage in traditional medicine and strong technical expertise, is well-positioned to lead the way in this dynamic field. By partnering with CDMOs, nutraceutical companies can accelerate their research and development efforts, navigate regulatory challenges, and bring high-quality products to market more efficiently.

The growing trend of outsourcing in the nutraceutical industry underscores the importance of strategic partnerships. As companies continue to seek cost-effective and flexible solutions, the role of CDMOs will become increasingly crucial. Together, through collaboration and innovation, we can achieve mastery in the nutraceutical value chain, reaching new heights in health and wellness. ■

## Author

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# Advancing Biopharma: Cutting-Edge Technologies That Are Transforming the Scope of Biopharmaceutical Manufacturing

Biopharmaceuticals represent some of the most promising therapeutic approaches in modern medicine, providing targeted and effective treatments for conditions once deemed untreatable, as well as for emerging infectious diseases.

**Alex Del Priore, Senior Vice President, Manufacturing Services, Syngene International.** emphasizes about the technologies that is transforming Biopharma industry. He also spoke about how contract research organisations (CROs) can benefit from Artificial intelligence (AI).

As the demand for these therapies increases in the post-pandemic era, the biopharmaceutical contract manufacturing market plays a crucial role in ensuring their availability and accessibility. The market is expected to grow at a CAGR of 7.38% from 2024 to 2030, reflecting the industry's rapid evolution driven by new technologies and methodologies. However, biopharma development remains complex, lengthy, and costly. Traditional methods can span over a decade in the journey from discovery to market, with low success rates and high financial investment.

Recent advancements, particularly in artificial intelligence (AI), machine learning (ML), and data-driven innovation, are transforming the biopharma ecosystem, making processes faster, more efficient, and scalable. In this article, we will explore how these technological advancements are streamlining drug discovery, enhancing process efficiency, and creating new possibilities in biopharmaceutical manufacturing.

## AI-driven innovations in drug discovery

Artificial intelligence (AI) has significantly changed how researchers approach drug discovery. Early on, AI primarily aided in data processing, but recent advances have introduced machine learning models capable of analyzing massive datasets, identifying patterns, and providing actionable insights. These improvements in data processing power and algorithmic sophistication have accelerated every phase of drug discovery, from target identification to clinical trial optimization.

### Let us look at each of these in detail

### Target identification

Identifying a disease-associated molecular target is the first step in drug discovery. This process has traditionally relied on lengthy research, where candidates often fail in clinical trials due to issues with efficacy or safety. AI-driven systems, however, allow scientists to analyze large biological data repositories, identifying high-potential therapeutic targets by assessing multiple parameters simultaneously. By examining genetic data, patient records, and even medical literature, AI algorithms can prioritize disease targets more effectively and with greater accuracy, ensuring that resources are spent on the most viable candidates.

### Lead optimization

Once a target is identified, researchers focus on finding lead compounds that could influence it therapeutically. Here, AI algorithms streamline the process through virtual screening and predictive modelling. AI optimizes the design-make-test-analyze (DMTA) cycles by

predicting how different molecules might behave in the body, how they could be optimized for efficacy, and their likely safety profile. This allows for faster iteration and refinement of promising leads, reducing the overall time spent in this critical phase.

### Preclinical testing

Preclinical testing assesses a compound's safety and efficacy before it reaches human trials. AI's predictive capabilities in pharmacology enable researchers to anticipate potential side effects or toxicities. By modelling interactions in silico, AI provides a safer pathway toward clinical trials by screening out compounds with higher risks and focusing on candidates with robust safety profiles. The accuracy of AI in predicting these outcomes has already demonstrated a higher success rate for compounds advancing to human trials, reducing the likelihood of costly failures later in development.

### Clinical trial optimization

Clinical trials often represent the most time-consuming and expensive stages of drug development. AI is now being used to streamline trial design, patient recruitment, and data analysis. Predictive analytics can identify the ideal patient populations, reduce trial times, and help researchers make data-driven adjustments in real-time. Adaptive trial designs powered by AI enable trials to be more flexible, with protocols that adjust as data accumulates, improving efficiency and increasing the chances of regulatory approval.

### How CROS can benefit from making AI a part of their daily workstreams

AI largely mirrors traditional drug discovery processes—identifying a target from scientific data, screening compounds for selectivity, and refining efficacy and safety. The difference lies in the computational power of AI, which accelerates these steps and even enables some to run concurrently.

To maximize AI's potential, it's essential to focus on targeted scientific and operational challenges and embed AI fully into research workflows rather than using it as a standalone tool.

Although AI poses challenges for traditional contract research organisations (CROs), they must adopt a proactive stance by implementing AI-driven methods and strategies to thrive in an industry increasingly focused on data-centric drug discovery. The pressure to enhance efficiencies in R&D processes and the DMTA cycle is mounting. By integrating AI into operational workflows, CROs can improve efficiency, accelerate decision-making, and optimize experiment design, ultimately boosting customer satisfaction.

Historically, CROs have adhered to protocols dictated by their clients, but this strategy may not guarantee sustainable success as AI becomes more integral to the drug development lifecycle. To maintain their competitive advantage, CROs must focus on innovation and delivering the highest quality products and services.

### Addressing challenges in AI implementation

Despite the potential benefits, the integration of AI into biopharmaceutical processes is not without challenges. Companies and research institutions often face issues related to data availability, regulatory requirements, and the high costs associated with adopting AI technologies.

AI models rely on high-quality, comprehensive data to function effectively. However, biopharmaceutical data is often fragmented across platforms, lacking standardization. Organisations are now focusing on data harmonization and establishing data-sharing frameworks and consortiums like the Syngene Data Consortium to address these issues. Syngene's SynSight is an opt-in consortium of clients who consent to anonymized usage of their data towards predictive models with higher reliability and broader applicability, leading to better decision-making, timelines, and outcomes on their projects. This collaboration among stakeholders is key to unlocking the full potential of AI.

Secondly, implementing AI systems in biopharma requires significant investments in computing infrastructure, data management systems, and skilled personnel. Some organisations, especially smaller firms, find these costs prohibitive, limiting widespread AI adoption.

Integrating AI into biopharmaceutical R&D also demands specialized knowledge and skill sets that many companies are still developing. Beyond technical expertise, there's also a need for cultural adaptation to encourage a data-driven approach across all levels of an organisations.

Finally, the use of AI in healthcare involves significant ethical considerations, especially in patient data privacy and transparency. Additionally, stringent

regulatory requirements add complexity, as AI-driven drug discovery and manufacturing solutions must meet rigorous safety and efficacy standards before approval.

### Transforming biopharma through advanced technologies

The biopharma industry is undergoing a transformation through advanced technologies, with AI-driven approaches now playing a significant role in drug discovery and development. For instance, companies have developed AI-based pipelines that facilitate target identification and lead discovery. These AI systems help in identifying novel disease associations and prioritizing them through multiparameter risk-benefit analyses, with applications extending into fields like drug repurposing and animal health. The lead discovery process includes virtual screening and molecule generation, optimized for small molecules, peptides, and antibodies, allowing for precise and efficient lead optimization.

In AI-integrated drug research and development, three critical aspects stand out. First, AI brings context and clarity to data, enabling researchers to synthesize and analyze vast datasets to guide decision-making. Second, predictive models allow scientists to forecast drug properties, outcomes, and potential liabilities, reducing the need for exhaustive lab testing. Lastly, AI shows promise in prescriptive roles, suggesting actions and even guiding design at every stage. Generative AI, for example, is advancing the ability to explore novel chemical and biological spaces, ultimately aiding experts in identifying unique targets, designing innovative molecules, and formulating hypotheses.

An AI-native R&D ecosystem, such as Syngene's Syn. AI, exemplifies how companies integrate AI to enhance project data integration, optimize target prioritization, predict molecular properties, and improve molecule screening and design processes. This system ties into broader capabilities, making organisations more robust in drug discovery. Future plans include expanding into new modalities and adding translational tools for clinical applications, with enhancements in biologics design using generative models, animal health analysis, and clinical trial optimization.

Furthermore, as ethical and regulatory shifts push for reduced animal testing, AI-driven in vitro and in silico models are increasingly significant. Platforms like HepTox exemplify efforts to develop non-animal toxicity testing, aiming for regulatory acceptance and accurate replication of biological systems without animal subjects. These initiatives reflect a growing commitment to ethical science and a future-focused approach to drug discovery and development.

### The path forward

The future of biopharmaceutical manufacturing lies in the successful harnessing of cutting-edge technologies to overcome existing challenges and drive innovation. As AI, machine learning, and advanced data analytics become increasingly integrated into biopharma processes, they will not only enhance efficiency and precision but also unlock new possibilities for therapeutic development. The ability to rapidly analyze complex biological data, streamline drug discovery, and optimize production processes promises to transform how medicines are developed and delivered.

Moreover, the shift toward a more data-driven approach in biopharmaceutical manufacturing will encourage greater collaboration among industry stakeholders, fostering an environment where knowledge is shared and innovations are rapidly adopted. As regulatory frameworks adapt to these technological advancements, the biopharma industry is poised to deliver a new era of healthcare solutions that are more personalized, effective, and accessible to patients worldwide.

In an era where precision, speed, and adaptability are essential, the biopharmaceutical sector is positioned to deliver transformative healthcare solutions more efficiently than ever. Through continued investment in technology and collaborative efforts to address challenges, the industry stands to make significant strides in tackling some of the most pressing health issues of our time. ■

## Author

**Alex Del Priore**
Senior Vice President, Manufacturing Services, Syngene International

# The Future of Capsule Manufacturing: Trends and Innovations Shaping the Industry

India has solidified its position as a global leader in capsule manufacturing, ranking second only to China. As demand for medicines grows, technological advancements evolve, and healthcare trends shift, the industry is transforming rapidly.

**Sunil Mundra, CEO & Managing Director, Natural Capsules Ltd** emphasizes about the trends and innovations driving the future of capsule manufacturing.

## India's Dominance in Capsule Manufacturing

India has become a powerhouse in the global capsule manufacturing market. Hard capsule production is concentrated in a few key regions, with India and China at the forefront. The country exports approximately 40% of its total capsule production to nearly every continent, further establishing its role in the global pharmaceutical supply chain.

Countries with large populations, such as China, India, the USA, Brazil, Indonesia, and Nigeria, contribute significantly to global capsule consumption. India's production capacity, paired with its skilled workforce, ensures that the country is well-equipped to meet the growing global demand for capsules.

## Advantages of Hard Capsules in Healthcare

Hard capsules, which are the second-most widely used dosage form after tablets, offer several advantages that make them an essential component in modern healthcare:

**Masking Properties:** Capsules can effectively mask the taste, odor, and color of encapsulated substances, making them more patient-friendly.

**Ease of Use:** Their smooth surface ensures they are easy to swallow, improving patient compliance.

**Versatility:** Capsules can be filled with powders, pellets, liquids, or even tablets, making them adaptable for a wide range of therapeutic applications.

Controlled Drug Release: Capsules can be engineered for fast or slow drug release, allowing for precise therapeutic management.

These benefits make hard capsules indispensable not only in modern medicine but also in traditional and herbal remedies, further expanding their usage.

## India's Domestic Market Potential

Despite India's dominance in pharmaceutical manufacturing, its per capita drug consumption remains among the lowest globally. India's domestic pharmaceutical market is valued at approximately ₹2.3 lakh crore, with per capita spending on medicines at only ₹1,500—significantly lower than in developed economies.

As India's economy grows and per capita income rises, we expect to see an increase in medicine consumption. The government has set an ambitious target to reach a ₹22 lakh crore pharmaceutical industry by 2030, which will inevitably drive growth in the production of all dosage forms, including hard capsules.

## India: The Pharmacy of the World

India's reputation as the "Pharmacy of the World" is well-earned. We supply affordable, high-quality medicines to nearly every country. With the global demand for medicines on the rise, especially due to aging populations and increased income levels, India's pharmaceutical exports are poised to grow even further.

Government initiatives aimed at expanding health insurance coverage will also contribute to higher domestic medicine consumption. As insurance penetration increases, the demand for affordable and effective dosage forms like hard capsules is expected to rise substantially.

## Technological Advancements in Capsule Manufacturing

Capsule manufacturing has evolved significantly, with modern, high-speed automated machinery enabling manufacturers to produce at greater volumes. In India, the adoption of such technologies ensures that

manufacturers can remain competitive in the global marketplace.

Automation also helps address challenges related to the need for skilled labor. While the capsule manufacturing process requires technical expertise, India's large pool of trained professionals offers a distinct advantage over countries facing labor shortages.

### Cost Efficiency and Competitive Edge

India's hard capsule industry benefits from competitive production costs, which can be attributed to efficient manufacturing processes, skilled labor, and robust infrastructure. Although freight costs associated with temperature-controlled containers pose a challenge, India's overall cost advantage keeps the country competitive on the global stage.

To maintain this edge, Indian manufacturers must focus on continuous innovation—developing better-quality capsules with diverse applications to meet the needs of untapped market segments.

### Innovations Driving the Future of Capsules

The future of capsule manufacturing will be shaped by innovation and adaptability. Key areas of focus include:

**Quality Enhancement:** Ensuring capsules meet stringent global standards for quality and durability.

**Product Diversification:** Developing specialized capsules to cater to unique therapeutic needs and new user segments.

**Sustainability:** Focusing on eco-friendly capsule materials and sustainable production practices.

**Faster Delivery:** Meeting market expectations for quicker delivery while strengthening client relationships.

### Emerging Trends in Capsule Applications

The versatility of hard capsules enables their use across a wide variety of applications:

- **Herbal and Traditional Medicine:** With rising consumer interest in natural remedies, the demand for capsules in this segment is growing rapidly.
- **Custom Drug Delivery:** Capsules designed for targeted or delayed release are gaining traction, particularly in the personalized medicine space.
- **Nutraceuticals:** The booming health and wellness industry presents significant opportunities for capsules in dietary supplements and functional foods.

### Impact of Policy Changes on Capsule Demand

Policy reforms in healthcare, particularly those aimed at expanding insurance coverage, will drive higher medicine consumption in India. As financial burdens are eased for patients, more people will gain access to affordable treatments, which will naturally boost demand for cost-effective dosage forms like hard capsules.

### Challenges to Overcome

Despite its advantages, the hard capsule industry faces several challenges:

- **Regulatory Compliance:** Manufacturers must adhere to rigorous international standards to maintain competitiveness in global markets.
- **Skilled Labor Shortage:** While India enjoys an edge in terms of manpower availability, continuous training and skill development are essential to sustain growth.
- **Freight Costs:** The reliance on temperature-controlled shipping containers adds to logistics costs, affecting profitability.

### A Promising Future

The Indian hard capsule industry is poised for significant growth. The key to continued success will be to maintain high-quality standards, ensure timely delivery, and embrace innovation.

With its competitive cost structure, skilled workforce, and leadership in capsule manufacturing, India is well-positioned to remain a critical player in the global pharmaceutical landscape. By addressing challenges and capitalizing on emerging opportunities, Indian manufacturers will continue to shape the future of capsule manufacturing and solidify their leadership in the industry for years to come. ■

## Author

**Sunil Mundra**
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# Trends in Pharma 4.0: Addressing the Unspoken Challenges of Business Growth

The Indian pharmaceutical industry has long been a global healthcare powerhouse, renowned for producing affordable, high-quality medicines. Yet, this success has not come without challenges. Issues of quality and intellectual property disputes have occasionally jeopardized its reputation.

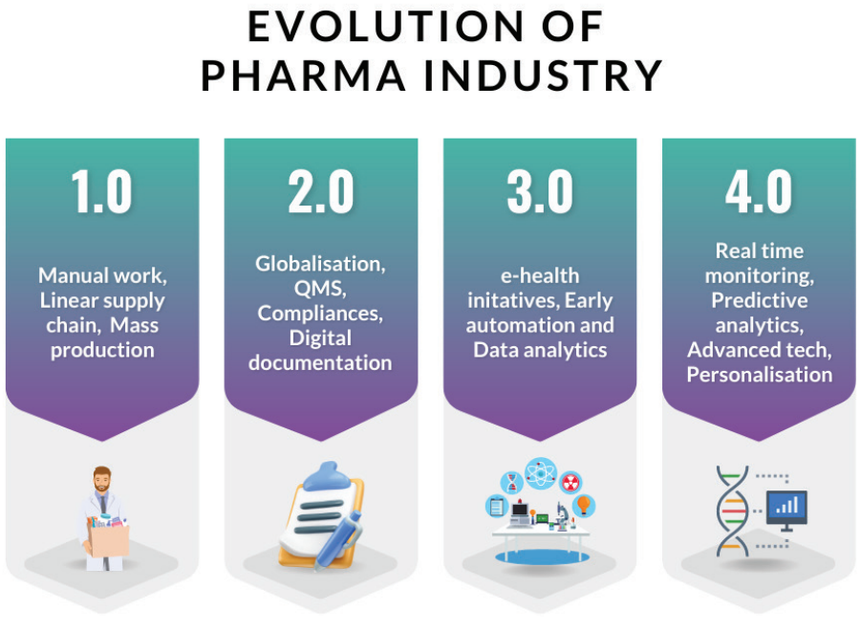
**Ashutosh Parasnis- Founder, NewBox Consulting** emphasizes the latest trends in Pharma 4.0, and shares an actionable methodology to navigate this new era of data-driven manufacturing and benefit from digital transformation.

The healthcare landscape is witnessing a significant and rapid shift toward personalization, with a laser-like focus on outcomes and value. Pharma companies cannot afford to ignore these market forces.

They must reassess how these forces impact their core pillars: cost, speed, quality, compliance, and competitiveness which ultimately determine the financial performance.

Meanwhile, the emergence of Industry 4.0 around the mid-2010s, heralded a new era of smart, automated, and data-driven manufacturing. This seismic shift laid the groundwork for what we now call Pharma 4.0. These shifts have been significant enough for the government to focus on ensuring the adherence of companies to global quality norms and allocating budgets for skilling people in Industry 4.0.

The industry stands at a pivotal juncture, where the need for adaptation is not just important—it's imperative. The old adage, "What got you here won't get you there," has never been more relevant.



### The Essence of Pharma 4.0

Pharma 4.0 isn't just a technological leap; it's the culmination of centuries of evolution within the pharmaceutical industry, transitioning from manual, smallscale production to a highly automated, data-driven, and patient-centric model. It represents how technology can help discover and develop targeted drugs faster, reduce manufacturing costs while maintaining flexibility, assure unwavering quality, optimize supply chains, and ensure the industry remains responsive to a rapidly changing world.

Yet, most companies are still grappling with the earlier stages of this evolution, not even achieving Pharma 3.0 maturity. The key takeaway for growth-oriented businesses is to not get lost in nomenclature but to ensure they stay ahead.

### Emerging Trends Shaping Pharma 4.0

When discussing Pharma 4.0 trends, the focus often gravitates toward technology. While some understand it, many find it complex and overwhelming, particularly smaller businesses that may not even be aware of the term. Here's a look at two dimensions of these trends.

### The Research World Technological Trend

Technology is often the star of the show.

Basic technologies such as Sensors, Automation, Connectivity and Basic Data Analysis have delivered reduced costs, increased revenue and waste reduction.

Common applications in manufacturing include managing records like EMRs, Batch Records, Compliance Reports, Optimizing Machine Productivity, Quality Management, and Supply Chain Traceability. Other applications include lab automation, clinical trials, distribution etc.

On the horizon are advanced technologies such as Artificial Intelligence (AI), Machine Learning (ML), Robotics, Cloud Computing, 3D Printing, and Digital Twins.

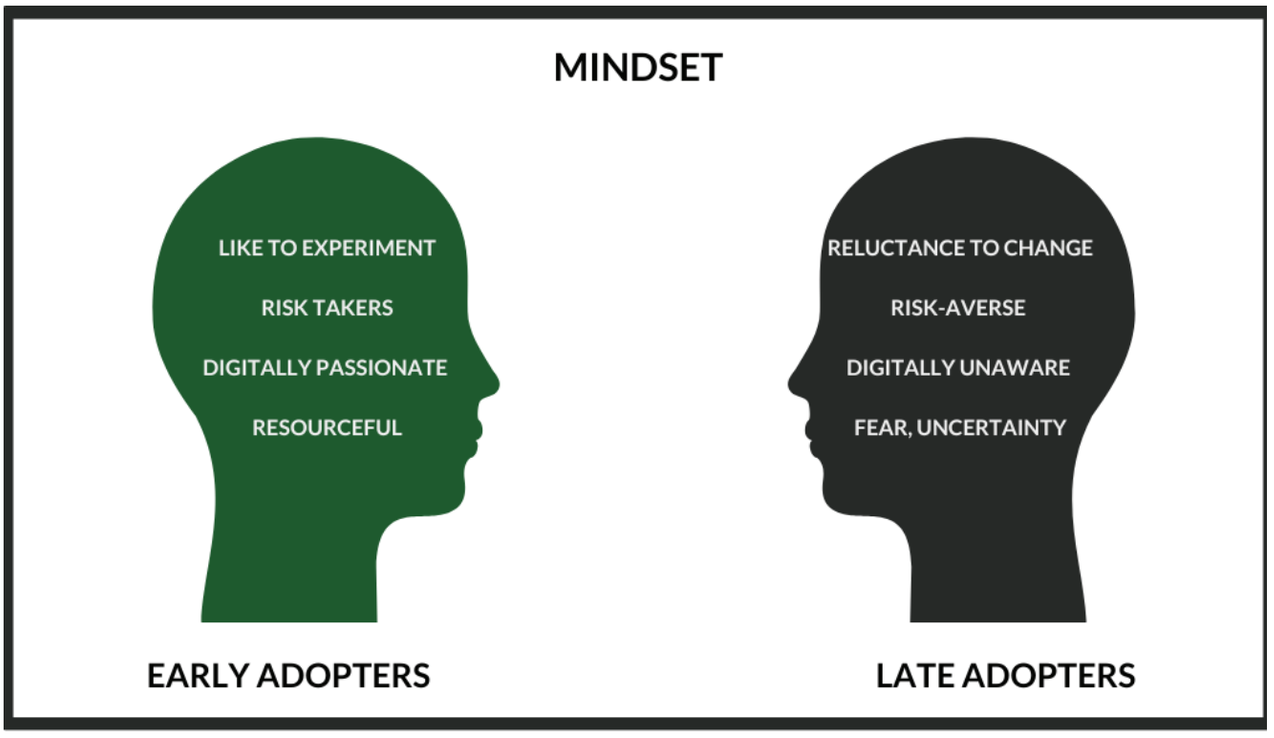
Together, these technologies not just help in understanding what is happening but in anticipating what may happen opening doors to more opportunities.

However, access to an appropriate technology, its cost-effectiveness and people's capability to use it effectively matters a lot in business.

Unless everything comes together in a meaningful manner, businesses will not adopt them.

### The Real World Business Trend

The industry thus faces several hurdles: understanding



the technology, developing industry-specific use cases, and overcoming issues like the lack of established policies, digital infrastructure, financial and talent constraints, and data security concerns. Transitioning from traditional processes to digital ones demands a significant mindset shift, which is neither quick nor easy.

**Mindset is the biggest challenge that organisations face:**

For Pharma 4.0 to be widely adopted, businesses need a clear vision to overcome these obstacles. The journey toward digital business transformation is largely a function of mindset. Innovators and early adopters, driven by growth and a thirst for innovation, spearhead this change. These trailblazers are often a small group, but they create differentiation and value that fuel their growth. On the other hand, late adopters, who prioritize risk avoidance and do not prepare themselves for upcoming change, find themselves in a constant game of catch-up. By the time they adopt, the growth opportunity is lost as early adopters capture the market.

### How Companies are Fast-Tracking Pharma 4.0 for Early Gains with Minimal Risk.

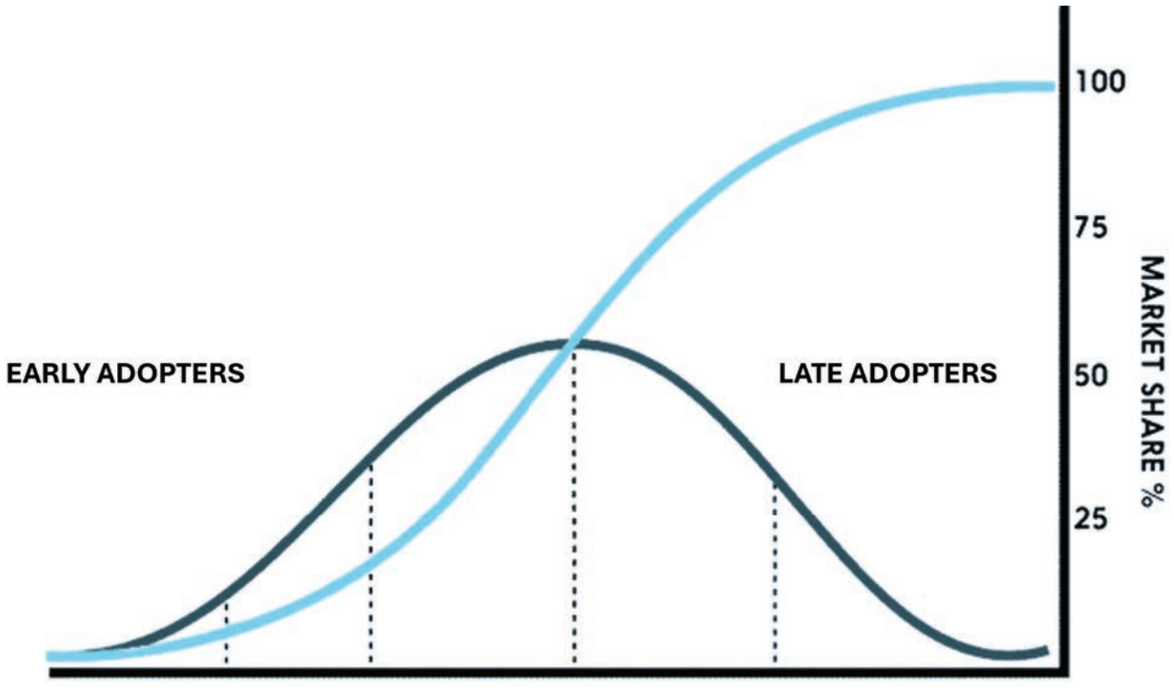
Here's the trend we see among companies successfully growing with Pharma 4.0.

- Workforce development, including leadership on business, tech and regulations.
- Collaborating with technology partners, consulting firms and startups as needed. (to identify and implement meaningful innovation)
- Phased implementation with small projects and small wins. (generating real business benefits)

This trend is most relevant to Pharma companies. It allows them to move quickly while protecting their interests and mitigating risks.

Achieving the needed organisational mindset becomes easier. The focus is more on business leveraging technology and not technology driving your business. Successful adopters are thus well-placed to dominate the market as compared to those who prefer the wait-and-watch game.

For example, a company might start with an immediate project to improve quality through technology, reducing costs and enhancing brand recognition. These short-term wins help the organization pace its transformation confidently. At the same time, it can define long-term objectives like accelerating drug discovery through AI/ML or digital twins or positioning itself as a dominant player in the export market.



### Recommendations for the Indian Pharma Industry

While large Indian pharmaceutical companies like Cipla, Dr. Reddy's, Sun Pharma, and Emcure have begun embracing Pharma 4.0, the overall adoption remains in its infancy. Globally, only 15-20% of companies have made significant progress, with North America and Europe leading the charge, driven by regulatory pressures, a focus on innovation, and access to advanced technology infrastructure. China and India, both aspiring global players, are adopting these practices more slowly while emerging markets lag even further behind.

According to our research, successful implementers of technology follow a series of steps that require time but yield a healthy compound annual growth rate (CAGR) year after year. In contrast, those who rush through or skip these steps create an illusion of speed but rarely achieve satisfying results.

5 steps to adopt Pharma 4.0 without breaking the bank or losing momentum in their current business:

### Pause and Reflect

Business leaders should dedicate quality time to understanding the changes impacting their business. This reflection is critical to developing a clear, actionable vision for the future.

### Prioritize People

Invest in skilling your entire team to navigate new business and technological dynamics. Communicate the need for change clearly and effectively. This approach preserves existing talent and helps address the industry's talent shortage.

### Focus on Meaningful Improvement

Learn and deploy problem-solving and innovation techniques to identify which initiatives will make sense for your specific business. This ensures allocation of resources where they can have the most significant impact.

### Adopt Practical Technology

Don't get bogged down by complex tech jargon. Seek assistance to understand and implement simple, cost-effective solutions. You need to begin with an understanding of smart sensors, basic automation, and data analysis methods that can drive immediate benefits in the initiatives identified above.

### Develop a Strategic Roadmap

As you gather suggestions and ideas, put a process in place to evaluate, prioritize, and align them with your business needs. It's unrealistic to execute everything in one year, but a well-defined roadmap will help you stay on track and monitor progress effectively.

### In Conclusion

This straightforward approach offers a twofold advantage. It provides an agile, cost-effective pathway to kickstart your Pharma 4.0 journey while simultaneously driving both business and workforce growth. By cultivating a forward-thinking team adept at leveraging technology, your business will not only navigate the anxiety of digitization but also carve out a position as a global leader in the Pharma 4.0 revolution. ■

## Author

**Ashutosh Parasnis**
Founder
NewBox Consulting

# How do Logistics Providers and Pharma Companies Collaborate to Build More Resilient & Future-Ready Facilities?

Over the past few years, the pharmaceutical supply chain has undergone a dramatic transformation. Global disruptions from the COVID-19 pandemic to climate events and geopolitical shifts have tested the resilience of even the most advanced distribution systems. In response, the industry is moving away from reactive strategies and instead focusing on proactively building agile, future-proof infrastructure that can withstand ongoing uncertainty. **Yash Sharma, Executive Director, CCI Group** emphasizes about how India has become a powerhouse for pharmaceutical logistics and pharma companies and logistic providers come together for future expansion.

Today, resilience is no longer defined solely by the ability to recover. It's about developing systems that can anticipate, adapt, and advance ensuring continuous availability of life-saving drugs and therapies. For pharmaceutical companies, this means collaborating with logistics partners who don't just move goods but understand the complexity of the industry and deliver integrated, compliant, and tech-driven solutions.

### India, as a Strategic Manufacturing Partner

India's Contract Research, Development, and Manufacturing Organization (CRDMO) industry is projected to grow from USD 7 billion to USD 14 billion by 2028, driven by pharmaceutical outsourcing and regulatory support. The industry's growth could reach a high-teens CAGR due to factors like the US Biosecure Act, potentially pushing it to USD 22 billion by 2030.

As global pharmaceutical companies look for cost-effective and reliable manufacturing partners, India is emerging as a preferred destination for drug research development and production. India is increasingly becoming the preferred choice for pharmaceutical outsourcing due to multiple factors such as a favourable regulatory environment, competitive cost structures, and rising global demand for outsourced pharmaceutical manufacturing. These advantages collectively position India's CRDMO sector for sustained and accelerated growth in the years to come.

Today, resilience is not just about bouncing back but building systems that can anticipate, adapt, and advance. For pharma, that means aligning with logistics partners who understand the nuanced demands of the industry and can deliver not just services, but solutions.

### The Evolution of Logistics: From Vendors to Value Partners

Traditionally, logistics partners were viewed as extensions of a transportation network focused on moving goods from point A to point B efficiently. But in today's landscape, logistics firms are becoming critical co-creators of value. Collaborations are now starting at the infrastructure planning stage, with both parties jointly designing facilities that are compliant, tech-enabled, and capable of scaling to future demand.

These facilities are no longer generic warehouses. They are specialized pharma-grade environments designed with GDP compliance, multiple temperature zones, air filtration systems, real-time monitoring capabilities, and contingency protocols built in. The emphasis is on flexibility and modularity, ensuring that facilities can accommodate fluctuating inventory, new product lines, or emergency needs without compromising product integrity.

### Adoption of Technology for Visibility and Control

Digital transformation is central to these collaborations. With real-time visibility becoming non-negotiable in

pharma logistics, modern facilities are now embedded with smart technology from the ground up. Advanced Warehouse Management Systems (WMS), Transport Management Systems (TMS), and IoT-enabled cold chain tracking are no longer add-ons — they are foundational.

This level of integration empowers pharma companies with control and foresight. It allows for continuous temperature and humidity monitoring, predictive alerts for potential excursions, and automated compliance documentation all of which significantly reduce risk and improve decision-making speed.

Moreover, the adoption of AI and data analytics tools is allowing for better demand forecasting and inventory optimization. In many cases, these tools are co-developed or customized through collaboration, ensuring alignment with the specific operational and regulatory frameworks of each partner.

### Prioritizing Sustainability and Compliance

As environmental accountability takes center stage, pharma-logistics partnerships are also becoming vehicles for shared ESG goals. Companies are jointly investing in green infrastructure such as solar-powered warehouses, electric/LNG fleets, energy-efficient HVAC systems, Rain water harvesting pits, Sewage treatment plants to reduce water waste and sustainable packaging solutions.

Sustainability is also being integrated into operations through reverse logistics programs that ensure safe and compliant returns, recycling, and disposal. These initiatives reduce environmental impact while maintaining the highest standards of product handling and traceability.

Compliance, naturally, remains paramount. Leading logistics providers are actively aligning with global regulatory bodies and engaging in continuous training and audits. When infrastructure is built in partnership with pharma stakeholders, it ensures that every element right from racking systems to documentation protocols, meets the highest standards of regulatory readiness.

### India: An Emerging Powerhouse in Pharma Logistics

India's prominence in global pharmaceutical production makes it a compelling case study. The country is seeing a wave of investment in pharma-focused logistics hubs particularly in regions like Pune, Bhiwandi, and Hyderabad. These hubs are not only strategically located but are also designed specifically for pharma distribution, with multi-temperature storage, tech-enabled dock management, and rapid fulfillment capabilities.

We've seen firsthand how such collaborative models work in practice. In one instance, a leading pharma brand partnered with our team to co-develop a smart, compliant distribution center that enabled 30% faster delivery to healthcare providers during peak demand periods. The success of that initiative was rooted not in technology alone, but in a shared understanding of the mission: safeguarding human health through reliable, transparent logistics.

### A Glimpse Into the Future

Looking ahead, the future of pharma logistics will likely include greater automation, integration of digital twins, and enhanced collaboration through shared data platforms. The convergence of robotics, AI, and cloud-based control towers will enable unprecedented levels of precision and responsiveness.

But beyond the technology, what truly defines a future-ready facility is the strength of its partnerships. It's about building trust, aligning on long-term goals, and embracing co-innovation as the default mode of operation.

As the pharmaceutical industry continues to evolve, one thing remains clear: its ability to deliver critical therapies and vaccines to the world will depend not just on scientific breakthroughs, but on the strength and sophistication of the logistics networks that support them. Together, pharma companies and logistics providers are building the future of - one resilient facility at a time. ■

## Author

**Yash Sharma**
Executive Director
CCI Group

# Internet of Things in Pharma

The Internet of Things (IoT) refers to the interconnected web of devices around us. These devices gather and exchange data with each other to process and present a myriad of information to users, enabling the "smart" in technologies that touch all facets of our lives.

**Akshay Ray, Senior Manager, Technology Research & Advisory, Aranca** emphasizes how IoT brings value to healthcare in improving patient health through remote monitoring, personalized treatment and enhanced diagnostics.

Over the past century, advancements in medical science have more than doubled human life expectancy from 32 years in 1900 to 71 years in 2021. Even though rapid industrialization and urbanization have created a new set of health challenges, access to better drugs and healthcare regimens has contributed significantly to the longevity. Adhering to a prescribed regimen of drugs and diet is the cornerstone of modern medicine, and it is ably supported by advances in non-invasive and rapid diagnostics and patient monitoring.

IoT has the potential to address several challenges in healthcare, including patient monitoring, patient compliance, decision making, engaging patients and infrastructure costs. The IoT ecosystem consists of data collection devices (such as smart watches, fitness trackers, ingestible sensors, implants), connectivity technology (such as Bluetooth, Wi-Fi, 5G network), and computing systems to analyze the data and provide decision-making insights and data points.

IoT brings value to healthcare by improving patient health through remote monitoring, personalized treatment and enhanced diagnostics, improving healthcare professionals' productivity and healthcare facility workflow by accessing, analyzing, and making available electronic health records on a real-time basis.

**The use cases of IoT are as follows:**
**Remote monitoring & personalized treatment**

Using IoT devices facilitates continuous monitoring of patients suffering from chronic diseases such as cardiac disease, hypertension, and diabetes. Smart devices track vitals and report them back to health professionals in real-time, enabling timely life-saving interventions as and when required. Continuous glucose monitoring systems, such as Dexcom G6, help track diabetic patients' blood sugar levels and relay the data to healthcare providers in real-time. Remote monitoring reduces the cost burden of hospital facilities while ensuring that the caregivers receive current vital stats for the patients.

Specialized wearable devices, such as ECG monitors (AliveCor and KardiaMobile), pulse oximeters (Masimo Rad-5v), smart blood pressure monitors (Omron), and neurological monitors (NeuroSky), widen the data points that can be monitored remotely to facilitate timely actions by the healthcare providers.

### Healthcare professional productivity

IoT helps streamline administrative processes, reducing wait times and improving patient flow within healthcare facilities. Telehealth came into sharp focus during COVID-19, where the communicable nature

of the pandemic necessitated remote consultations. Underpinned by advances in communications technology, IoT helped increase healthcare professionals' reach and efficiency to attend to a substantial portion of patients remotely, particularly in rural and underserved regions.

Amwell is an example of a telehealth platform that facilitates virtual visits and has integrated devices like TytoCare, which augment virtual consultation with the ability to perform remote physical exams such as measuring temperature and heart rates, and performing non-invasive examinations of the skin, lungs, and heart. Another example is XRHealth that helps healthcare professionals remotely administer physical and mental health therapy through immersive virtual reality platforms individualized for physical, occupational, and mental health therapies.

### Healthcare facility workflows

IoT helps optimize healthcare facility workflows and day-to-day operations by aiding workflow automation, medication management, asset tracking, patient and environmental monitoring and enhanced communications.

Hospitals use RFID and IoT based systems, such as GE Healthcare's AssetPlus, to track medical equipment and supplies, ensuring availability and proper maintenance of critical equipment, and reducing the time spent by hospital staff searching for the equipment. On the other side, remote patient monitoring systems, such as Medtronic's Vital Sync™, help hospitals manage patient data more efficiently, reducing wait times and improving care coordination.

Hill-Rom, a leader in hospital bed systems, developed a smart bed – Centrella Smart+ bed, which monitors patient movement and adjusts to prevent bed sores and alerts the nursing staff of patient attempts to get up to significantly reduce fall risks.

Vocera communications developed wearable badges that allow instantaneous communication between hospital staff to improve response time and coordination. Several hospitals now use IoT sensors and systems to automate day-to-day activities such as administrative tasks, predictive maintenance for equipment, and patient care.

### Artificial intelligence (AI) and machine learning (ML) integration

The rapid increase in computing power made available in the small forms enables powerful AI and ML tools to be developed and applied to healthcare, where health data collected by IoT devices is analyzed to predict health issues and provide personalized recommendations. Computer-assisted diagnostics or CAD is an emerging field that relies on automated visual analysis of tissue samples for early detection of diseases and generating prognoses. Aidoc is one such platform used to analyze medical images to detect abnormalities. The output helps prioritize urgent cases for radiologists, improving diagnostic efficiency.

Other examples of AI use for analyzing large volumes of medical data are IBM's Watson Health which analyzes patient health data to improve diagnosis and Google's DeepMind Health that analyzes data gathered by IoT devices to predict patient deterioration. Babylon Health provides personalized health assessments, triage, and consultations based on AI through its app.

### Outlook

With technology advancing rapidly, several different platforms are used to create IoT-based healthcare solutions, which brings new challenges in terms of interoperability of various platforms, infrastructure costs associated with advanced communications systems, and data protection.

The landscape of IoT in healthcare is very fragmented, with several different corporates and academia developing solutions tailored to specific challenges that they are tackling. This opens an opportunity to work on enhancing the interoperability between diverse systems, and Fast Healthcare Interoperability Resources (FHIR) standard by HL7 is a step in the right direction.

Fast communication is an important pillar of IoT and the wide roll out of 5G infrastructure will prove significantly advantageous for healthcare. Rush University Medical Center partnered with AT&T to become the first hospital to deploy 5G connectivity throughout their facilities, aiding use of IoT devices for patient care and telemedicine. On the other side of the world, Huawei and Guangdong Provincial People's

Hospital partnered to make the world's first remote robotic brain surgery over a 5G network possible.

Another significant challenge that IoT-enabled healthcare faces, in the medium- to long-term future, is that of data security. To enable analysis and quick decision-making, large amounts of personal health data are captured by the IoT devices and transferred over communications networks, which is vulnerable to hackers. Cybersecurity developers, such as MedCrypt and Irdeto, offer data security solutions for medical devices and patient data.

### Conclusion

IoT-enabled healthcare paints a rosy future for improving patient care, enabling personalized treatment, enhancing operational efficiency and resource utilization, aiding healthcare professionals' productivity, and enabling new forms of patient engagement.

Rapid developments in AI, IT, communications technology, and cybersecurity and their wide adoption promises upliftment of the global healthcare standards and improve accessibility to effective healthcare worldwide. However, as is the case with any new technology, it is rife with several different solutions, and governments worldwide will have to adapt quickly to formulate appropriate regulatory frameworks to prevent misuse of a wonderful boon to humanity that has the potential to be a bane of equal, if not larger, proportion. ■

## Author

**Akshay Ray**
Senior Manager, Technology Research & Advisory, Aranca

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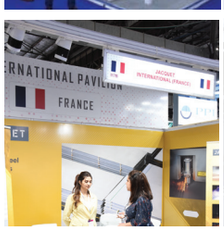

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| EPC 2026 Engineering Procurement Construction<br>Conference on 3rd February 2026 | SPECIALTY CHEMICAL WORLD EXPO 2026<br>Conference on 3rd February 2026 | Health Safety & Environment World Expo 2026<br>Conference on 3rd February 2026 | BIO-India World Expo & Conferences 2026<br>Conference on 4th February 2026 | Refining & Petro CHEMICALS 2026<br>Conference on 4th February 2026 |
| Industry AUTOMATION & Control 2026 PVF Pumps, Valves & Fittings WORLD EXPO 2026<br>Conference on 4th February 2026 | Global Meet AGROCHEMICALS & Fertilizers Innovations and R&D World Expo & Conferences 2026<br>Conference on 5th February 2026 | WaterEX WORLD EXPO 2026<br>Conference on 5th February 2026 | Surface Engineering Coating & Corrosion World Expo 2026<br>Conference on 5th February 2026 | SCALE@CHEMTECH World Expo 2026 3-5 February 2026<br>2026 Student Outreach Program Develop Future Leaders 3-5 February 2026 |

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## Reimagining the Future of Biotech in India

# BIO-X India
World Expo & Conferences 2026

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Association of Biotechnology Led Enterprises

## International Exhibition & Conferences

**3-6 February 2026**
**Venue:** Bombay Exhibition Center, Goregaon (East), Mumbai, India

## Bio-X India World Conferences 2026

### Theme - Reimagining the Future of Biotech in India

### Wednesday - 4th February 2026 - 9:30am to 5:30pm

- Inaugural Session
- Session 1: Frontier Tech in Healthcare: Gene Editing, mRNA and Precision Medicine
- Session 2: Synthetic Biology in Food: Precision Fermentation and Cellular Agriculture
- Session 3: Next-Gen Bioplastics and Green Chemicals: India's Edge in Sustainable Manufacturing
- Session 4: AI-Driven Drug Discovery and Diagnostics: National Pathways
- Session 5: India as Global Biomanufacturing Hub: Opportunities for FDI and Scale
- Session 6: Beyond Cost Advantage: India's Value Proposition in Global Clinical and Manufacturing Services in the BioE3 Era

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## HIGHLIGHTS OF CHEMTECH WORLD EXPO 2026

- 800+ EXHIBITORS FROM 15+ COUNTRIES
- 26000+ VISITORS FROM 50+ COUNTRIES
- 9 TECHNICAL CONFERENCES
- 1500+ BUSINESS DELEGATES
- 250+ GLOBAL SPEAKERS
- 1200+ STUDENT OUTREACH PROGRAM
- SCALE@CHEMTECH World Expo: 60+ GLOBAL CLIMATE TECH STARTUPS

Concurrent Events

EPC | Specialty Chemicals | Refining & Petro Chemicals 2026 | Health Safety & Environment World Expo 2026 | Agrochemicals & Fertilizers Innovations and R&D World Expo & Conferences 2026 | Industry Automation & Control 2026 | PVF World Expo 2026 | WaterEX World Expo 2026 | Surface Engineering Coating & Corrosion World Expo 2026 | SCALE@CHEMTECH World Expo 2026 | Student Outreach Program 2026 Develop Future Leaders

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