VOL 24 | ISSUE 3 | OCTOBER 2025 | MUMBAI | TOTAL PAGES 48 | PRICE ₹ 150

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PHARMA BIO WORLD
R.N.I. No.: MAHENG/2002/08502

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Single Copy Price: ₹ 150/-
Annual Subscription: ₹ 1620/-, Foreign: USD 180

Registered Office: 26, Maker Chambers VI, 2nd Floor, Nariman Point, Mumbai 400 021, INDIA.
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PLACE OF PUBLICATION
JASUBHAI MEDIA PVT. LTD.
210, Taj Building, 3rd Floor, Dr. D. N. Road, Fort, Mumbai 400 001, Tel: +91-22-4037 3636

Printed and published by Mr Hemant K. Shetty
Address: 406-D, The Karachi Citizens Co-Op Hosg Soc Ltd., Juhu Varsova Link Road, Andheri West, Mumbai - 400053.

Printed at The Great Art Printers
25, Unique House, S A Brelvi Road, Fort, Mumbai 400 001.

Published from Jasubhai Media Pvt .Ltd. 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

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Future Outlook and Opportunities for CDMOs in India's Pharmaceutical Market

India's pharmaceutical industry has emerged as a global force, driven by innovation, scale, and cost-efficiency. At the heart of this growth are Contract Development and Manufacturing Organizations (CDMOs), which play a strategic role in enabling global market access, accelerating product development, and mitigating operational risks. With a projected market size of USD 130 billion by 2030 and a CAGR of over 10%, India's pharma sector is set for exponential growth. The country already contributes nearly 20% of the global generic medicine supply by volume and over 60% of the world's vaccine production, reflecting its manufacturing strength and regulatory compliance.

Arushi Jain, Director – Growth and Strategy, Akums Drugs and Pharmaceuticals Ltd emphasizes about the role of Contract Development and Manufacturing Organizations (CDMOs) in enabling global market access and future outlook for the CDMO sector.

CDMOs support pharmaceutical companies through end-to-end services—ranging from formulation development and technology transfer to large-scale commercial manufacturing, including models like loan licensing, contract development, and joint ventures.

This not only enables faster market entry but also reduces infrastructure investments and regulatory burdens. Backed by a robust talent pool and government initiatives, India continues to reinforce its position as the preferred global outsourcing hub. Among the key contributors to this success are large-scale CDMOs that have quietly powered domestic and international pharmaceutical growth through scale, trust, and quality.

Market Overview and Growth Dynamics

The Indian Contract Development and Manufacturing Organization (CDMO) market is undergoing a remarkable transformation, poised to reach USD 54.7 billion by 2031 with a compelling CAGR of 13.8%. This growth trajectory reflects India's rising prominence as a global hub for pharmaceutical innovation, cost-efficient manufacturing, and end-to-end development solutions.

Several factors are propelling this surge. India's vast scientific talent pool, regulatory expertise, and expanding infrastructure are aligning to create a conducive ecosystem for global pharmaceutical and biotech companies. Increasing demand for generics, biosimilars, and complex formulations, combined with a growing emphasis on specialty medicines, is driving clients to seek strategic CDMO partnerships in India. This dynamic expansion is exemplified by industry leaders who are scaling up capacities, diversifying dosage forms, and investing in R&D to stay ahead of the curve. Leading players are not only catering to domestic needs but are also serving regulated and semi-regulated markets like the EU, US , Canada. Australia , Brazil , meeting the highest quality and compliance standards.

Moreover, the shift towards integrated CDMO services—offering formulation development, analytical testing, manufacturing, and packaging under one roof—is reshaping client expectations. India's CDMOs are evolving into strategic allies, offering flexible models and accelerated timelines. With the government supporting, the momentum is only expected to grow. The next decade presents a golden opportunity for

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Indian CDMOs to become indispensable partners in global pharmaceutical supply chains, contributing not just to manufacturing volume, but also to innovation and value creation.

Quality Management and Regulatory Framework

The Indian pharmaceutical manufacturing landscape is further strengthened by stringent quality management systems and regulatory compliance requirements. CDMOs must adhere to regulations set by global authorities such as the US FDA, EMA, and India's CDSCO, maintaining comprehensive Quality Management Systems (QMS), Good Manufacturing Practices (GMP), and detailed documentation procedures. The manufacturing capabilities of Indian CDMOs are particularly impressive, with industry leaders like Akums operating multiple manufacturing plants capable of producing over 49 billion formulation units annually. This scale of operations is supported by advanced manufacturing technologies, robust quality control systems, and a skilled workforce, with some facilities employing over 16,000 personnel.

Technological Advancements and Innovation

The integration of advanced technologies such as artificial intelligence, machine learning, and advanced analytics is revolutionizing R&D processes in the Indian pharmaceutical sector. These technological advancements are enhancing drug discovery, clinical trials, and personalized medicine initiatives, making India an increasingly attractive destination for clinical trials and R&D investments. The focus on biologics and biosimilars has also intensified, with Indian life sciences companies expanding their global footprint not only as providers of generic drugs but also as innovators in these advanced therapeutic areas.

Cost Advantages and Manufacturing Efficiency

The cost advantage remains a significant factor in India's pharmaceutical manufacturing success. Manufacturing costs in India are approximately 33% lower than in the United States, with labor costs being 50–55% cheaper than in Western countries. This cost efficiency has established India as a preferred destination for pharmaceutical outsourcing. The sector's growth is further bolstered by loan licensing arrangements, which have emerged as a strategic mechanism allowing companies to utilize existing manufacturing facilities through licensing agreements, enabling rapid market entry, efficient capacity utilization, and cost-effective production scaling.

Strategic Collaborations and Joint Ventures

Technical collaborations and joint ventures have become increasingly important in the Indian pharmaceutical sector. Companies are forming strategic alliances with global counterparts to enhance their market position and expand service offerings. These partnerships focus on leveraging cutting-edge technologies, sharing resources and expertise, implementing innovative production processes, and expanding global market reach .

The industry is witnessing a shift towards non-asset based R&D partnerships, including consortia involving multiple stakeholders such as life sciences companies, academia, and government entities .Notable industry examples have demonstrated the successful execution of both in-licensing and out-licensing models. Indian firms are not only absorbing and localizing global technologies but also actively licensing out indigenous innovations to international partners. These models highlight India's growing role not just as a manufacturing powerhouse, but also as a contributor to global pharmaceutical innovation

Technology Transfer and Process Implementation

Technology transfer in India's pharmaceutical industry has become a strategic cornerstone, enabling efficient scale-up from R&D to commercial manufacturing. It involves the structured transfer of knowledge, data, and processes between organizations—often between a drug innovator and a manufacturing partner. Leading Contract Development and Manufacturing Organizations (CDMOs) in India have built strong frameworks for technology transfer, incorporating detailed documentation, cross-functional coordination, validation protocols, and regulatory alignment.

Process implementation goes hand-in-hand with technology transfer, focusing on adapting and optimizing transferred processes for full-scale production. This involves pilot trials, stability studies, equipment adaptation, and continuous quality monitoring. Indian CDMOs have also embraced digital tools and quality-by-design (QbD) approaches to make process implementation more data-driven and reproducible. As India strengthens its role in global pharma supply chains, robust technology transfer and efficient process

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implementation will continue to be differentiators—enabling faster market entry, cost competitiveness, and sustained product quality.

Government Support and Initiatives

Government support has played a crucial role in the sector's development through various initiatives and policies. The Production Linked Incentive (PLI) scheme, running from 2020 to 2028, aims to enhance the production of critical raw materials, including Active Pharmaceutical Ingredients (APIs) and drug intermediates, by offering financial incentives to encourage significant investments in the sector. The Bulk Drug Parks Initiative promotes local medicine production by providing government aid for infrastructure development, including testing centers, power plants, and waste management facilities.

Risk Mitigation Strategies

Risk mitigation strategies employed by CDMOs have become increasingly sophisticated, including backward integration for developing in-house processes for critical starting materials, comprehensive technology transfer procedures, and investment in advanced software solutions for quality management.

Future Outlook and Opportunities

The future outlook for India's CDMO sector remains highly promising, with global supply chain realignments creating a USD 10 billion opportunity for Indian CDMOs

Emerging trends include increasing demand for biologics and biosimilars, rising focus on specialty pharmaceuticals, growing adoption of advanced manufacturing technologies, and expansion into new therapeutic areas. The government's increased budget allocation for healthcare and initiatives further support the sector's growth trajectory .

India's CDMO Sector: Driving Global Pharma Growth with Resilience and Innovation

India's Contract Development and Manufacturing Organization (CDMO) sector continues to showcase exceptional growth and resilience, emerging as a critical pillar in the global pharmaceutical ecosystem. With its unique combination of robust manufacturing capabilities, cost efficiency, stringent quality compliance, and strategic alliances, the Indian CDMO landscape is redefining global pharma dynamics.

At the heart of this success lies a strong industrial foundation that enables high-volume production without compromising on quality. Indian CDMOs are known for their ability to meet regulatory requirements across diverse markets, including the US, EU, and Japan—making them reliable partners for multinational pharmaceutical companies.

Leading players like Akums exemplify the transformative role Indian CDMOs play. By integrating large-scale operations with world-class R&D, Akums demonstrates how Indian companies can deliver comprehensive, end-to-end pharmaceutical solutions that meet global standards. Their commitment to innovation, regulatory excellence, and customer-centricity reflects the broader strengths of the sector.

As the global pharmaceutical market becomes increasingly complex, Indian CDMOs are rising to the occasion—mitigating supply chain risks, reducing time-to-market, and providing agile manufacturing solutions. The continued focus on adopting advanced technologies, maintaining global quality benchmarks, and building long-term strategic partnerships will be critical in sustaining this momentum.

Government initiatives such as "Make in India" and the Production Linked Incentive (PLI) scheme are further accelerating growth, enhancing infrastructure, and attracting foreign investments.

Looking ahead, the Indian CDMO sector is well-positioned to play an even greater role in the global pharmaceutical value chain—not just as a manufacturing powerhouse, but as a strategic innovation partner. Its evolving capabilities and expanding global footprint signal a bright and impactful future for India in the world of pharmaceutical manufacturing. ■

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Innovation in Pharmaceutical Packaging

Innovation is often used but with contrastive meaning. Innovation is a process of transforming ideas into new products, services or improved products and services offered to customers. Innovation is crucial for organizations that offer products or services in a highly competitive marketplace to survive, sustain and be successful.

Chandi Prasad Ravipat, Head - Packaging Development, Aurobindo Pharma stated that innovation in Pharmaceutical Packaging is becoming paramount for Pharmaceutical Industry.

Chandi Prasad Ravipat
Head - Packaging Development
Aurobindo Pharma

Packaging emerged as a pivotal tool of attracting consumers where multiple brands of FMCG, Food, Beverages and electronic goods are flooded into the market for reasons such as Affordability, Awareness of IoT, E-Commerce and Millennials and dominating young population

Pharmaceutical Packaging is a different gamut that requires superior quality packaging for these reasons:

- Complexity of molecules
- Product characteristics such as dosage form and route of administration
- Longer shelf life compared to FMCG, Food and Beverages
- Highly Regulated industry
- Regulations by country where medicines are sold

Importance of Packaging in Indian Pharmaceutical Industry started two and half decades back due to advent of exports to regulated markets especially the USA and Europe. The technological advancement in pharmaceutical packaging during this period is phenomenal. From importing 100% of primary packaging materials required for drug products these markets for a decade (Year 2000 to 2010) to becoming

Made in India having Drug Master Files with best quality management systems for primary packaging materials catering to 90% demand of pharmaceutical industry. This is one of the best examples of partnership between pharmaceutical and packaging industry innovation ecosystem.

As per USFDA guidelines, all primary packaging materials should be sourced from Drug Master File (DMF) holders. From 2000 to 2005, almost 100% of primary packaging materials were imported from DMF sources. Today Indian Packaging Industry is capable of manufacture and supply 90% of demand having acquired DMF with best quality management systems. This is one of the best examples of partnership between pharmaceutical and packaging industry ecosystem.

The foremost importance of pharmaceutical packaging is given to establish and demonstrate conformance to suitability, protection, compatibility, safety and performance. The stringent requirements to comply are ever changing which is the most challenging aspect to the packaging technologists. This made pharmaceutical packaging a scientific branch and vital department in all pharmaceutical organizations doing inland, regulated and emerging markets business.

Innovation is key for today's self-sufficiency to manufacture resins and primary packaging materials inland by the packaging industry.

Factors driving innovation in pharmaceutical packaging

Generic Drug Products: While innovator or brand leader enjoys premium price for drug products in regulated markets, generic drug products are sold at 5 to 10% of innovator products. Innovation in packaging by design results in reduction of the cost and improvement in productivity and help organizations to sustain in business.

Trends in Formulation Development: It is vital to adapt to ever changing trends in new drug delivery systems, new complex drug products in many therapeutic segments and drug innovation are driving packaging novelty for new plastics and packaging components to switch over from traditional packs. Some of them are

- New dispensing/dosing devices for patient convenience and compliance
- Advantages of blow-fill-seal system compared to conventional filling, stoppering and sealing
- COC vials in place of glass vials
- Glass tube replaced by plastic tube for PFS
- Blow-Fill-Seal Technology in large volume parenterals in Medical grade PVC in place of glass bottles and polyolefins for small volume parenterals replacing glass ampoules/vials
- Conventional bottle and measuring devise replaced by closure with dose-metering
- Preference of unit dose for parenterals to multi-dose
- Biodegradable plastics

User Centric Packaging: The new aspect becoming more prominent and imminent to comply with is user compliance and safety i.e., patient and hospital administering staff. User compliance and safety features in packaging add cost. Innovative ideas help to optimise the cost and add high value to the users. Packaging technologists should focus on therapeutic category of drug products, general age of patients using a particular medicine, its dosage form, frequency of medication, requirements of hospital staff administering parenterals or disperse medicines to patients, expectations of patients. All the ideas are converged to bring a best possible solution of a safety device or communication that brings delight to user.

Smart Packaging & Digital Integration: With the advancements of information technology, using digitization which comes at very nominal cost, smart packaging enhances connectivity to the patients or medical professionals across the globe with the product. Usage of QR Codes on packages with critical information connect to user's electronic devices and can access the information including alarm for dosage regiment and when refill is required. This will largely help in adherence of dosage regiment and help patients to be healthier.

Inclusive Packaging: Packages should be designed particularly for differently abled and geriatric patients aged above 65 for ease of opening the packs, taking prescribed dose.

Sustainability Pharmaceutical Packaging: This is the new requirement, and many countries are bringing legislations tom follow sustainability in pharmaceutical packaging. Non-compliance will attract hefty penalties

and can even block those organizations exporting medicines. Packaging Industry and pharma industry are working together to bring biodegradable plastics in place of conventional plastics, eliminate unwanted packaging and downsizing packages.

Innovation of Packaging Machinery: Innovation is required in designing pharmaceutical packaging machinery. There is huge scope of automation in pharma industry to avoid manual intervention as minimum as possible. Automation brings more flexibility on packing lines, integration with Artificial Intelligence ensures compliance to avoid packing and labeling errors which result in 70% of market complaints and recalls.

Authenticity of Drug Products to Users: Spurious and counterfeit medicines are prevalent despite many anti-counterfeit overt and covert features implemented in packaging. Regulated markets in the USA and Europe have implemented serialization and aggregation for drug products to ensure security of genuine medicines in the entire supply chain from manufacturers to pharmacies. Major emerging markets also implemented Track & Trace regulations to provide authenticity of drug products to the patients.

To conclude, the growth factor for any economy is innovation with its multiple advantages of increasing output with the same resources, edge over competition with novel improvements in products and services. An innovation ecosystem is a network of relationships through which information and talent flow through systems of sustained value co-creation. ■

Why Chemistry Still Matters: The Heart of Successful CRDMO Execution

The development of small molecule drugs relies heavily on chemistry. As these compounds progress from discovery through preclinical studies, clinical trials to commercial manufacturing, chemistry enables the rational design, optimization, and control of every step in the development lifecycle.

Jayadeva Sajankila, Vice President - Operations, Aragen Lifesciences emphasizes about how chemistry plays an role in enabling Contract Research, Development and Manufacturing Organizations (CRDMOs) to transform molecular entities into effective therapeutics.

Despite advances in automation, regulatory sciences, and digital technologies, chemistry remains a core scientific discipline enabling Contract Research, Development and Manufacturing Organizations (CRDMOs) to transform molecular entities into effective therapeutics." The CRDMOs provide services from route design to final dosage form manufacture, with chemistry expertise informing every decision, from synthetic pathway selection to impurity clearance.

Reaction Mechanisms and Kinetics: Enabling Predictability and Control

Comprehending reaction mechanisms and kinetics is fundamental to successful API development. A reaction mechanism details the transformation of reactants into products, allowing chemists to anticipate side reactions, control stereochemistry, and select reagents and catalysts that ensure high product quality and regulatory compliance.

Concepts like transition state theory and intermediate mapping enables chemists to predict how factors like temperature, solvent polarity, and catalyst structure affect reaction outcomes. In asymmetric hydrogenations, for example, ligand–substrate interaction knowledge ensures high enantiomeric excess, vital in complex API synthesis.

Kinetic studies provide quantitative data on reaction rates and influencing factors. Techniques such as reaction calorimetry and real-time spectroscopy derive rate laws and activation energies, ensuring scalable and reproducible processes.

A noteworthy tool is the Kinetic Isotope Effect (KIE), where specific hydrogen atoms are replaced with deuterium to reveal the rate-determining steps of a reaction. This has improved Suzuki–Miyaura cross-coupling reactions by optimizing bases and ligands for better selectivity, yield, and efficiency. Advances in palladium-catalyzed coupling and metalla-aromatic reactions underscore the value of mechanistic understanding. Integrated with analytics, these insights ensure scalable processes that meet regulatory standards.

Thermodynamics and Solid-State Chemistry: Controlling Form and Function

Thermodynamics and solid-state chemistry are central to controlling the physicochemical behavior of APIs. Thermodynamic parameters like Gibbs free energy and entropy guides solubility, crystallization, and phase stability. Chemists use this to predict polymorph, solvate, and salt behavior, aiding purification and ensuring stability and bioavailability.

Solid-state chemistry focuses on molecular packing,

lattice energy, and intermolecular interactions in crystalline and amorphous forms. Polymorphism affects dissolution, mechanical properties, and shelf life. Crystallography and phase behavior are crucial for controlling solid forms. Tools like thermodynamic phase diagrams and computational models (e.g., COSMO-RS) help in solvent selection and process optimization.

Integrating thermodynamic modeling with solid-state characterization, CRDMOs to develop crystallization protocols ensuring polymorphic purity, particle size, and morphology—critical for product quality and intellectual property protection.

Formulation Chemistry: Intermolecular Interactions

Formulation chemistry optimizes the bioavailability and stability of drug products. Intermolecular interactions—such as hydrogen bonding, π–π stacking, van der Waals forces, dipole–dipole interactions, and ionic interactions—impact the solubility, stability, bioavailability, and overall performance of drug substances, particularly high-potency APIs (HPAPIs). Understanding these interactions is key to designing formulations that are both effective and manufacturable.

For example, hydrogen bonding affects crystallite size, polymorph stability, and API–excipient compatibility. π–π stacking and van der Waals interactions control aggregation and stability, while ionic interactions are key in salt formation and solubility. These forces are crucial in formulation strategies like solid dispersion development, salt screening, and co-crystal engineering.

Chemical modifications to APIs, such as altering logP, pKa, or hydrogen-bond profiles, strategically adjust intermolecular interactions. For instance, Dipyridamole was prodrugged for solubility, and Lopinavir was modified for better absorption. In developing amorphous solid dispersions, optimizing drug–excipient interactions is key. A favorable Δδp (difference in solubility parameters) indicates high miscibility. Techniques like differential scanning calorimetry (DSC), dynamic vapor sorption (DVS), and X-ray photoelectron spectroscopy provide insight interaction, guiding formulation.

Co-crystal engineering enhances the solubility and stability of poorly soluble drugs by forming co-crystals with a co-former through non-covalent interactions. This method allows the API to adopt new crystal lattices without altering its pharmacological activity. For example, the Theophylline–nicotinamide co-crystal significantly improves Theophylline's solubility, while the Losartan–saccharin enhances both solubility and bioavailability for antihypertensive treatments.

Scale-Up and Technology Transfer: Chemistry in Action

Scale-up in chemical processes is the transition from lab-scale experiments to full-scale manufacturing, ensuring that reactions can be efficiently and safely performed on a larger scale while maintaining product quality and stability. Key chemistry-driven factors include:

- **Thermodynamic Optimization:** Efficient heat transfer and mixing prevent thermal runaways. Reaction calorimetry, guided by enthalpy data, ensures safe thermal profiles.
- **Solvent Selection for Crystallization:** Polarity and temperature affect solubility. Van't Hoff plots help select solvents and optimize crystallization conditions.
- **Managing Reaction Kinetics and Intermediates:** Reactive intermediates can degrade products. Real-time spectroscopy and modelling help manage them effectively.
- **pH and Reflux Time Control:** pH influences ionization; reflux time affects conversion. Mechanistic insight helps optimize both for purity and yield.
- **Continuous Manufacturing:** Offers precise control over process variables, improving reproducibility—especially for sensitive or high-volume APIs.
- **Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs):** These are important for successful technology transfer requires. Defining and controlling CPPs like temperature, pH, and solvent choice, supported by mechanistic studies and stability testing, ensures regulatory compliance and consistent product quality during commercialization.

Flow Chemistry: Advancing Process Efficiency

Flow chemistry offers precise control of kinetics and thermodynamics in continuous systems, where reactants move through microreactors or tubular reactors under tightly regulated temperature, pressure, and residence time. Residence time-the duration

reactants spend in the reactor-is a key parameter, directly impacting reaction rate, conversion, selectivity, and product quality by dictating molecular interactions.

Flow systems finely tune residence time to match kinetics, outperforming traditional batch methods. For example, in the Simmons-Smith reaction, precise residence time control prevents intermediate decomposition and ensures efficient ring formation. In nitrations, critical for nitroaromatic compounds in antibiotics and cardiovascular drugs, short residence times reduce over-nitration and thermal risks. Optimized residence times in Grignard additions and transition-metal-catalyzed couplings enhance reactivity and minimize side products, crucial for building complex APIs.

Flow reactors maintain steady-state conditions, stabilizing challenging short-lived intermediates like carbenes and diazonium salts. Integrated in-line analytical tools (FTIR, UV-Vis, HPLC) enable real-time monitoring and dynamic adjustment of residence time and stoichiometry, supporting multistep reactions.

For CRDMOs, flow chemistry offers faster process development, improved safety, and scalable, energy-efficient production.

Biocatalysis: Enabling Selective and Efficient Chemical Transformations

Biocatalysis uses enzymes as natural catalysts to accelerate reactions under mild, aqueous conditions, making it highly valuable for CRDMOs. Its high stereoselectivity and substrate specificity are ideal for enantiomerically pure APIs, ensuring drug efficacy and safety. Enzyme-catalyzed reactions occur at specific active sites, offering precise control over chemo-, regio-, and stereoselectivity.

Advances in enzyme engineering and immobilization allow tailored properties and expanded reaction scope via techniques like directed evolution. In continuous flow systems, biocatalysis enhances scalability and sustainability. For CRDMOs, this enables cost-effective, selective, and eco-friendly manufacturing.

Bioconjugation: Bridging Chemistry and Biology

Bioconjugation enables covalent attachment of drugs or probes to biomolecules like proteins or nucleic acids, foundational for diagnostics, delivery, and imaging.

One of the most impactful applications of bioconjugation is in Antibody-Drug Conjugates (ADCs), targeted cancer therapies that combine monoclonal antibodies with potent cytotoxins via a chemical linker. This system relies on precise chemical engineering for effective, safe, and targeted drug delivery.

Linker Chemistry in ADC Design

The linker is critical to ADC performance, affecting pharmacokinetics and drug release. It must be stable in circulation but cleavable at the target site. Linkers fall into two main categories:

- **Cleavable linkers** respond to stimuli such as acidic pH, enzymatic cleavage (e.g., cathepsin B-sensitive peptides), or reducing conditions (e.g., disulfide bonds).
- **Non-cleavable linkers,** such as thioethers, rely on the complete antibody degradation to release the drug.

For example, trastuzumab emtansine (T-DM1) uses a non-cleavable thioether linker (SMCC) to attach the cytotoxic payload DM1, ensuring high plasma stability and controlled release upon internalization.

Advances in Conjugation Chemistry

The chemical method used to attach the drug to the antibody significantly affects ADC homogeneity, stability, and therapeutic index. Traditional approaches like lysine or cysteine conjugation often result in heterogeneous drug-to-antibody ratios (DARs). Modern ADCs employ site-specific conjugation techniques such as:

- **Engineered cysteines or unnatural amino acids** (e.g., p-acetylphenylalanine) that enable selective reactions like click chemistry or oxime ligation.
- **Enzyme-mediated strategies,** using transglutaminase, sortase A, or glycosyltransferases, allow precise modification at defined peptide or glycan sites, enhancing reproducibility and pharmacological predictability.

Bioorthogonal and Responsive Chemistries

Click reactions—particularly strain-promoted azide-alkyne cycloaddition (SPAAC)—offer high selectivity and are increasingly used to create ADCs that release drugs only after reaching the tumor microenvironment. These strategies provide spatiotemporal control and reduce systemic toxicity.

Hydrophilicity and Payload Optimization

Many potent cytotoxic drugs are highly hydrophobic, risking aggregation and rapid clearance. Chemical solutions to this challenge include:

- **PEGylated linkers,** which enhance solubility, reduce aggregation, and shield labile functional groups.
- **Hydrophilic-hydrophobic balance tuning** within the linker architecture, which improves delivery and release kinetics, especially in high-DAR constructs.

Conclusion

Chemistry remains central to drug development and manufacturing. CRDMOs apply chemical expertise—understanding mechanisms, solid-state behaviour, and formulation science—to efficiently scale discoveries into therapies. Advances in flow chemistry, biocatalysis, and conjugation support selective and sustainable manufacturing. Through predictive modelling and process control, chemistry enables high-quality, compliant therapeutics. As technologies evolve, chemistry remains the engine driving innovation and patient impact. ■

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The Evolving Landscape of Diagnostic Innovations

Diagnostics has always been the first step in saving lives. Whether it's detecting infections, monitoring chronic diseases, or guiding treatment decisions, the ability to diagnose quickly and accurately can mean the difference between life and death particularly in critical conditions like sepsis, cancer, and antimicrobial resistance (AMR). The diagnostic industry has undergone significant transformative evolution over the past decade owing to rapid technological advancements and now shaping the way diseases are being detected, monitored, treated and making tests faster, more accurate, and accessible to a wider population.

From traditional laboratory-based methods to AI-driven diagnostics and point-of-care (PoC) testing, innovations in this space are bridging the gap between early disease detection and effective treatment ensuring that more lives are saved through timely intervention. However, as the burden of infectious diseases, AMR, and chronic illnesses continues to rise, the demand for better diagnostic solutions has never been greater.

As the burden of infectious diseases, antimicrobial resistance (AMR), and chronic illnesses continue to rise, the demand for better diagnostic solutions has never been greater.

Dr. Preeti Nigam Joshi, Founder Director and CEO FastSense Innovations Pvt. Ltd explores the key trends, breakthroughs, challenges, and prospects in diagnostic innovations, shedding light on how they are transforming healthcare and bringing us closer to a world where early detection becomes the norm rather than the exception.

From Waiting Days to Instant Answers

Not too long ago, getting test results even for routine tests, often meant waiting for days, if not weeks of anxious waiting. Blood samples were collected, sent to centralized labs, and processed using bulky equipment. While this system was effective, this system had limitations—delays in diagnosis could cost lives, especially in cases like sepsis, antimicrobial resistance (AMR), or rapidly spreading infections where early intervention is needed. Even today, culture tests take more than 24-72 h and 5 days in some cases.

Today, innovation is rewriting these rules. Point-of-care (PoC) diagnostics allow doctors to get real-time answers right at the patient's bedside. Whether it's a rapid test for infections, a portable device for chronic disease monitoring, or AI-driven analysis that detects patterns invisible to the human eye, the new era of diagnostics prioritizes speed, accuracy, and accessibility.

The impact of faster diagnostics is particularly evident in critical care settings. For instance, in infection management, every hour of delay in initiating the right treatment increases mortality risk. Similarly, in cancer care, early detection can significantly improve survival rates, but drug-resistant infections pose a severe challenge to patients undergoing chemotherapy. Rapid diagnostics that detect infections and AMR early can prevent complications and save lives.

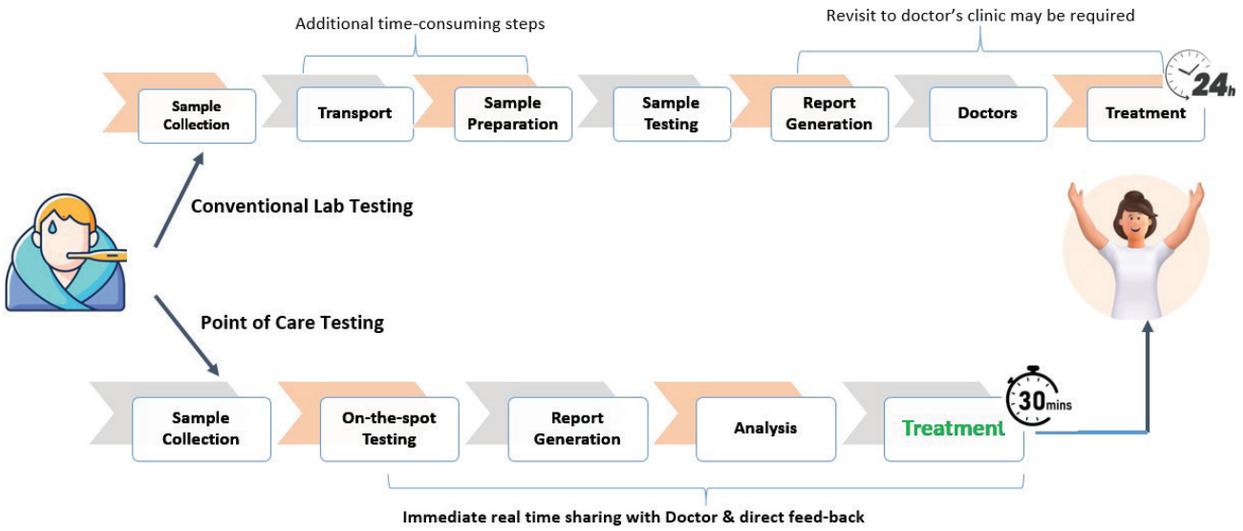

Figure-1: Reducing Diagnostic Delays: A Comparative Workflow of Conventional Lab vs. Point-of-Care Testing

What's Driving the Change? The Bigger Picture

In January 2025, Pune witnessed a significant outbreak of Guillain-Barré Syndrome (GBS), a rare neurological disorder where the body's immune system attacks the peripheral nerves. Few lives were lost and many are still dealing with the after-effects post hospital discharge. Health authorities quickly traced the outbreak to Campylobacter jejuni, a bacterium often linked to contaminated food and water and keep the situation under-control. Although measures are being taken to prevent such situations in future, this outbreak highlighted how rapid diagnostic advancements are transforming public health responses. Unlike traditional methods that could take weeks, modern molecular diagnostics, particularly PCR-based tests, helped quickly detect Campylobacter jejuni, enabling authorities to act swiftly. This early detection was crucial in controlling the outbreak before it escalated further.

The Pune GBS outbreak serves as a reminder of why continuous innovation in diagnostics is essential. Faster, more accurate testing not only helps identify the cause of disease outbreaks but also ensures timely public health interventions, preventing widespread impact. As diagnostic technology evolves, the ability to predict, detect, and contain such health crises improves aligning it with global health goals for better disease surveillance and prevention.

The COVID-19 pandemic completely transformed the way we approach diagnostics. Before 2020, routine lab testing was the norm, and Point-of-Care (PoC) diagnostics were mostly limited to specific diseases like glucose monitoring or pregnancy tests. Post-COVID, we are witnessing an accelerated shift towards rapid, decentralized, and technology-driven diagnostic solutions.

Here's what's driving this change:

Shift Towards Decentralized & PoC Diagnostics

The pandemic highlighted the inefficiencies of centralized lab testing, especially when mass-scale testing was needed. PoC devices are being developed for a wider range of diseases (e.g., infectious diseases, AMR, STIs like chlamydia etc.) that results in faster diagnosis, reduced hospital burden, and early disease containment. Although a long way to fully transform the healthcare landscape but progress so far is good. Fig. 1 is demonstrating how PoC diagnostics is shaping the future of healthcare.

Technological Innovations:

AI, IoT & 3D Printing

Accelerated research in AI-powered diagnostics, smart biosensors, and 3D-printed medical devices.

Smart algorithms can now analyze test results, predict disease progression, and even identify patterns that help in early detection. AI-driven diagnostics are particularly effective in detecting cancers, infectious diseases, and even rare genetic disorders.

For instance, AI-powered imaging tools can detect tumors at an early stage with remarkable accuracy, helping oncologists make informed decisions about treatment. AI-assisted PoC tools improve accuracy & speed, while 3D printing enables on-demand, low-cost diagnostic production (useful for outbreaks like GBS in Pune). It improves personalized diagnostics, reduces dependency on global supply chains, and sustainability. 3D printing and open-source diagnostic platforms are lowering production costs, ensuring affordable testing solutions in low-resource settings. As governments and global health organizations invest in decentralized healthcare, PoC devices will continue to play a transformative role in ensuring equitable access to early detection and better patient outcomes worldwide; well aligned with WHO sustainability goals of universal health coverage (SDG 3) and reducing inequalities (SDG 10).

Advances in Molecular Diagnostics Tools

Polymerase Chain Reaction (PCR) and Loop-Mediated Isothermal Amplification (LAMP) are game-changers in diagnostic science. These molecular methods allow for rapid and highly sensitive detection of pathogens, even from tiny biological samples. Unlike traditional culture methods that can take days, PCR and LAMP deliver results in under an hour, enabling faster treatment decisions. During the COVID-19 pandemic, PCR became the gold standard for detecting the virus,demonstrating its value in infectious disease management. Now, similar molecular approaches are being adopted for detecting tuberculosis, and sexually transmitted infections (STIs) with unprecedented speed and accuracy.

Wearable & Home-Based Diagnostics: Diagnostics are no longer confined to hospitals and labs. The rise of wearable health devices and home-based diagnostic tools has empowered individuals to monitor their own health. Devices like continuous glucose monitors for diabetes management, smartwatches with ECG capabilities, and at-home pregnancy or ovulation tests are reshaping how people engage with their health.

The Push for Personalized Medicine: Diagnostics are essential in the era of personalized medicine, where treatments are customized based on a patient's genetic makeup, disease profile, and lifestyle. Companion diagnostics help doctors figure out which treatments will work best for each patient, reducing guesswork and improving outcomes. For cancer patients, genetic testing can identify the most effective chemotherapy drugs, cutting down on side effects and improving survival rates. In infectious diseases, molecular diagnostics can pinpoint the exact bacterial strain causing an infection, helping doctors choose the right antibiotic and fight antimicrobial resistance (AMR).

Global Investment & Policy Shifts: The world of diagnostics is changing faster than ever, driven by major global investments and shifts in healthcare policies. The COVID-19 pandemic exposed critical gaps in disease detection and response, leading governments, health organizations, and private investors to prioritize faster, more accessible diagnostic solutions. Today, we see a strong push toward decentralization, affordability, and innovation, ensuring that even remote and underserved areas have access to life-saving tests.

One of the biggest changes is the rise in funding for next-generation diagnostics. Government funding organizations are investing heavily in point-of-care (PoC) technologies, AI-driven diagnostics, and antimicrobial resistance (AMR) surveillance. At the same time, venture capital and private investors are pouring resources into startups working on smart, portable testing devices that can deliver results in minutes rather than days. This shift is not just about convenience—it's about saving lives through early detection.

Alongside these investments, policy changes are making it easier for innovative diagnostic tools to reach the market. Regulatory bodies are trying to streamline approval processes for emergency-use tests and AI-integrated diagnostic platforms. Governments are also encouraging self-testing and home-based diagnostics, recognizing that people need faster, more accessible healthcare solutions. Another critical development is the adoption of 3D printing and open-source platforms, which reduce production costs and make diagnostics more affordable in lower-income regions.

Beyond Innovation: The Challenges Ahead

Despite the progress, there are hurdles to overcome. The road ahead in diagnostics evaluation presents several significant challenges. Major challenges faced by diagnostics innovations are:

Cost Barriers: Many advanced diagnostic technologies remain expensive, restricting access, particularly in low-resource settings.

Regulatory Challenges: The lengthy and complicated regulatory approval processes often delay the launch of life-saving diagnostic innovations. To speed things up, more effort is needed, and raising awareness is crucial. Regulatory bodies must focus on educating stakeholders about the regulatory framework. An out of box approach is needed to fill the gaps w.r.t. regulatory pathways for new era diagnostics tool and conventional techniques.

Limited Access in Low-Resource Settings: High costs and lack of infrastructure prevent widespread adoption of state-of-the-art diagnostic tools in underfunded healthcare environments.

Rise of Antimicrobial Resistance (AMR): The increasing prevalence of AMR necessitates not just rapid detection but also the development of smart, decision-support tools to guide appropriate treatment choices.

Need for Smart Diagnostic Tools: The focus is shifting from just rapid diagnostics to tools that can help clinicians make informed, context-specific treatment decisions, particularly in critical situations.

Integration into Healthcare Systems: While new diagnostic tools are being developed rapidly, integrating and their adaption into existing healthcare infrastructures still remains a huge challenge. Training healthcare workers, ensuring interoperability with electronic health records, and addressing logistical constraints are essential for seamless implementation.

A Future Where Diagnostics Save More Lives

The diagnostic industry is no longer just about testing; it's about transforming healthcare. The shift toward faster, more personalized, and AI-powered solutions is already making a tangible difference in patient care. The question is no longer whether we can innovate but how quickly can we make these technologies available to everyone who needs them.

Investments in research, policy support, and global collaboration are crucial to ensuring that diagnostic breakthroughs translate into real-world impact. Initiatives promoting decentralized testing, AI-driven disease surveillance, and affordable PoC devices will play a key role in bridging gaps in healthcare access in coming years.

After all, a diagnosis is not just a test result—it's a turning point in a patient's life. The faster and more accurately we diagnose, the better we can treat, save, and heal. With continuous advancements in diagnostic science, we are moving closer to a future where early detection becomes the standard, not a privilege.

Because the first step in saving lives starts with knowing what we're fighting!! ■

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Ensuring Quality and Innovation - A Key to Success

The global pharmaceutical Industry is known for its high degree of innovation, research & development and following stringent regulatory standards to deliver safe and efficacious medicines of highest quality. India has established globally as Pharmacy of the World.

Kaushik Desai, Executive Committee Member, Industrial Pharmacy Section FIP and Dr. Satish Desai, Quality Consultant emphasizes that the pharmaceutical industry is rapidly transforming due to technological advancements and encompasses revolutionary innovations that reshape the fundamental aspects of healthcare.

Quality and Innovation are vital components of any successful organisation. By integrating it in pharma environment, the innovation processes are expected to -

- enhance customer satisfaction and trust,
- drive operational efficiency,
- foster a culture of continuous improvement,
- stimulate growth and expansion,
- create a competitive advantage.

Quality plays a critical role in ensuring patient safety, product efficacy, and regulatory compliance in meeting the patient needs.

QUALITY is the backbone of INNOVATION

Ensuring both quality and innovation in the pharmaceutical industry requires a multifaceted approach, including fostering a culture of continuous improvement, leveraging technology, embracing agility, and nurturing a culture that values robust quality management systems, rigorous quality control specifications, stringent quality assurance checks, adherence to regulatory guidelines and continuous improvement in manufacturing processes and technologies, all while developing a culture of innovation and actively seeking and evaluating new ideas while balancing risk and reward.

10 Key Enablers Ensuring Quality and Innovation are :

Fostering a Culture of Quality and Innovation

- Embrace Continuous Improvement
- Encourage Creativity and Idea Generation
- Promote Collaboration by encouraging cross-functional teams to work together
- Emphasise Customer Focus

Implementing Robust Quality Management Systems

- Define Clear Quality Standards like measurable quality metrics
- Implement Quality Control Measures
- Conduct Regular Audits and Inspections
- Establish Feedback Loops

Quality Control and Assurance

- Good Manufacturing Practices (GMP)
- Quality Management Systems (QMS)
- Rigorous Testing and Analysis

- Documentation and Traceability
- Audits and Regulatory Compliance
- Validation and Qualification
- Focus on errors and defects Prevention
- Continuous Improvement through data analysis

Driving Innovation

- Identify Opportunities for Improvement
- Evaluate Innovation Ideas
- Embrace Experimentation and Prototyping
- Learn from failures to improve future innovation efforts
- Consider Design Thinking

Fostering Innovation

- Investing in Research and Development through Collaboration and Partnerships
- Digital Transformation through Embracing technologies
- Continuous Manufacturing
- Intellectual Property (IP) Protection
- Data Integrity and Compliance
- Innovation in Manufacturing Processes

Continuous Improvement & Process Innovation

- Lean Manufacturing principles
- Six Sigma methodology
- Kanban System
- Vendor Managed Inventory (VMI)

Technology & Analytics

- AI-powered Quality Control
- Data Analytics for Quality
- IoT for Real-time Monitoring

Agile Methodologies & Rapid Innovation

- Agile Development
- Rapid Prototyping
- Iterative Development

Fostering a Culture of Innovation

- Cross-functional Teams
- Open Communication & Idea Sharing
- Recognising and Rewarding Innovation
- Embracing Customer-Centricity
- Innovation Culture fosters a culture of continuous learning and remains at the forefront of technological advancements.

Quality Practices in Innovation

- Understanding the Importance of Quality
- Adopt a Customer-Centric Approach in Quality practices
- Implementing Rigorous Testing Procedures for product's quality, reliability and
- Encouraging Employee Training and Development
- Leveraging Cutting-Edge Technology
- Ensuring Compliance with Industry Standards
- Incorporating Continuous Improvement Strategies
- Promoting a Culture of Innovation
- Utilising Predictive Analytics for QUALITY
- Establishing a Robust Feedback Mechanism

PHARMACEUTICAL INNOVATIONS AND TRENDS

- **Precision Medicine and Personalised Therapies**

Precision medicine introduces a novel paradigm in healthcare. Instead of applying uniform treatments universally, medical practitioners utilise a person's genetic information, lifestyle, and medical background to create a personalised treatment strategy. This approach involves scrutinising genetic variations associated with disease, employing sophisticated technology to decode genes, and identifying telltale indicators within the body. The researchers are focusing more on oncology and biologics where demand is highly specific and patient centric.

The 3D printing is one such technology that offers a novel approach to drug delivery, enabling the creation of personalised and complex dosage forms with precise control over drug release and shape. 3D-printed pharmaceuticals have largely been relegated to niche markets and prototyping due to limited scalability and reliance on technicality of manufacturing processes. This innovation permits the creation of tablets that

can regulate the release of medication, ensuring the most effective therapeutic outcomes. To date, one 3D printed drug Levetiracetam, a rapidly dissolving tablet product has been approved by the US Food and Drug Administration (FDA) for human use. In February 2021, Triastek have received US FDA approval for a clinical study using a 3D printed drug for patients with rheumatoid arthritis. 3D printing has great potential to advance personalized medicine with patient centricity that enables customized doses for a specific patient population.

Sustainability and Green Initiatives

The pharmaceutical industry is embracing sustainability and green initiatives to minimise its environmental impact. This involves reducing carbon emissions through energy-efficient manufacturing and renewable energy sources, implementing waste reduction strategies, adopting eco-friendly packaging materials, developing greener chemical synthesis methods, and conserving water in manufacturing processes. Globally these initiatives are taking momentum to reduce carbon footprint. The newer manufacturing facilities are now adopting green lighthouse principles.

mRNA Vaccines Development : The success of mRNA vaccines against COVID-19 has proved that mRNA technology is a versatile platform for developing vaccines against a wide range of diseases, including cancer, Zika, autoimmune diseases etc.

Immunotherapy Advancements: Immunotherapy represents a unique approach to treating illnesses by leveraging the body's natural defenses. CAR-T cell therapy, a method that involves modifying a person's immune cells to target cancer cells effectively. These modified cells are reintroduced into the body, resulting in a direct and potent attack on cancer cells. CAR-T treatments have demonstrated remarkable efficacy in blood cancers. Scientists are exploring its potential applications. The research areas also include gene therapy.

Digital Therapeutics: Digital therapeutics are healthcare programs that Patient may utilise on personal phone or computer. They provide sound scientific guidance on how to deal with various health issues. Patient can use them in addition to their normal therapies. These technical applications can encourage patients to follow prescribed treatment regimens, diets, and exercise routines. The digital wearable devices are much in demand and ensures patient compliance to dose regime.

Continuous Manufacturing: Continuous manufacturing changes how medicines are made, making them faster and smoother. Usually, medicines are made step by step, in a batch process which takes a long time. But with evolvement of continuous manufacturing, everything happens continuous by negligible process contamination and real time monitoring of quality parameters are done during the entire integrated process ensuring higher with less product recalls and lower risk of contamination. quality of finished drug in much lesser time. This supports in smooth uninterrupted supply of medicines. Pharmaceutical companies are making a conscious effort to reduce their carbon footprint by initiating continuous manufacturing in their development plan.

Automation and Digitisation : Automation and robotics are being used to streamline manufacturing processes, enhance efficiency, improve product quality & safety, minimise human errors, minimise contamination, reduce costs, decrease waste, and ensure regulatory compliance. The pharma 4.0 concept which is a combination of digitization and automation is the new game changer.

The goal of a digital transformation, as outlined in the new McKinsey book 'Rewired: A McKinsey Guide to Outcompeting in the Age of Digital and AI (Wiley, June 20, 2023)', is be to build a competitive advantage by continuously deploying technology at scale to improve patient experience and lower costs. It is a journey of continuous improvement. Robotics although in nascent stage today, it is going to be the future of technological advances for pharma processing and packaging operations. The application of digitization tools like AI, Machine Learning, Internet of Things (IoT) coupled with automation will support innovative companies to grow and be a market leader globally.

Nanotechnology in Drug Delivery: Nanotechnology is revolutionising medication delivery by using nanoparticles and nanomaterials to deliver medicinal compounds to particular parts of the body with extreme accuracy. Nanotechnology is considered a new and rapidly emerging area in the pharmaceutical and medicinal field. Nanoparticles, as drug delivery systems, impart several advantages concerning improved efficacy as well as reduced adverse drug reactions. These microscopic particles can be precisely

manufactured to release drugs in a regulated manner, ensuring optimal drug concentration at specific targeted sites while minimising impact on healthy tissues.

Portable Diagnostic Devices: Portable medical diagnostic devices have transformed the way healthcare is delivered, making it possible for professionals to perform tests anywhere—from a patient's home to remote villages. These devices are compact, lightweight, and user-friendly instruments that allow healthcare professionals to perform diagnostic tests outside traditional clinical settings. It helps in saving time, reduce the burden on hospitals, and provide real-time data, all of which contribute to better patient outcomes.

Shipping Containers for thermolabile medicines: Specialised shipping containers are being developed to ensure the safe and efficient transport of temperature-sensitive medicines and biologics. Technological advancements are revolutionizing cold chain management, enabling real-time monitoring, enhanced traceability, and improved efficiency through tools like IoT, blockchain, AI, and smart packaging. Cold chain management in supply chain is very critical for biologics and vaccines storage and distribution.

CHALLENGES INVOLVED IN INNOVATION

Despite life-saving Innovations to improve quality of life, pharmaceutical industry faces various challenges that require careful consideration and mitigation.

- High Risk and Cost pressure
- Ethical Considerations
- Collaboration, Partnerships, and innovation confidentiality
- Patents and Licensing for cost of innovation
- Ensuring the costs of developing biotechnology innovations are covered through patents and licensing deals.
- Stringent regulatory compliance
- Ensuring consistent supply chain through Quality Maturity
- Counterfeit drugs
- Trust and open environment
- Skilling, upskilling and reskilling

KEY INNOVATIONS ON THE HORIZON

Few quality innovations to modernise the manufacture of drug substances and drug products are as under –

- **Drug Discovery and Development –** Artificial Intelligence (AI) is accelerating drug discovery by analysing vast datasets, identifying potential drug candidates, and predicting their efficacy, leading to faster and more efficient drug development. The various regulatory bodies have developed guidelines on the use of AI to protect the interest of patients.

- **New routes to drug substances -** Innovations in manufacturing technology to synthesise active pharmaceutical ingredients (APIs) or drug substances include photochemical and electrochemical approaches, biocatalysis, cell-free protein synthesis, and cell-based biosynthesis that uses alternative hosts.

- **Co-processed APIs -** An innovation in the manufacture of APIs is the addition of a non-active excipient or carrier to improve efficacy of drug or to manipulate attributes of a process stream to achieve a desired outcome. Co-processed APIs might be advantageous in particle formation, crystallisation, or drying operations to improve the stability of a desired solid state or to tailor Physico-chemical properties of the drug substance.

- **Process intensification -** Technological advancements that foster more efficient and higher-yielding processes, while also allowing for smaller manufacturing spaces and lowering both capital and operating expenses, are referred to as process intensification.

- **Advanced process control and automation -** The advances are being made in sensor technology, data analytics, and system modeling, and manufacturers will increasingly rely on these innovations to design, understand, and control complex processes.

- **Modular systems -** Modular systems are composed of interconnected unit-operation "modules" that can be arranged and adapted to enable a single facility to manufacture a large array of drug products.

- **Data analytics -** This has brought new opportunities in Biotechnology Innovation. With Data analytics

increasing, the speed of development process can be considerably expedited and researchers are able to accessing more biological, social, and environmental insights, improved and more sustainable products which could be on the horizon in future.

- **Predictive Analytics for QUALITY -** Predictive analytics implementation in quality is about leveraging data to forecast potential issues, thus enabling preemptive action. This strategic approach not only helps in identifying problems before they surface but also in understanding patterns that could give rise to them. When data is abundant, predictive analytics effectively turns data into actionable insights and drives decisions that enhances the product quality and customer satisfaction.

- **Regulatory Evolution -** Regulatory authorities are developing adaptive approval processes for novel medicines. There are innovative approaches like hybrid inspection and digitization which were positive outcome of COVID pandemic. The regulatory bodies encourage paper less submissions of documents for faster decisions. The number of guidance documents are developed supporting innovations in technology and processes.

Considering the importance of innovation and to have upper edge globally, the Indian government has undertaken several industry friendly initiatives to encourage innovation in research. The Government has launched Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) Scheme which aims to transform India into a global R&D hub, with a focus on strengthening research infrastructure and promoting industry – academia collaboration. This is expected to nurture quality research and enable research and innovation for future health challenges. There will be establishment of Centers of excellence at seven National Institutes of Pharmaceutical Education & Research (NIPERs) and there will be significant investment in the R&D ecosystem within the pharma sector. The need is felt to inculcate creative and innovative mind set during early days of teaching. The day is not very far to see positive outcome from such collaborative approach between Government, Industry and Academia. The beginning has been made but we have a long way to go to catch up with developed countries in Innovation front.

India aims to become global hub not only for supplier of affordable quality medicines but also a key growth driver in path breaking technological advances by the year 2047 with active involvement of all stakeholders. ■

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Pharma Packaging: Trends and Opportunities

The pharmaceutical industry has witnessed remarkable transformations across every facet of its business over the past three decades. Few changes have been as profound and multifaceted as those occurring in pharmaceutical packaging. What was previously considered to be nothing more than a container is now a vital factor that determines drug efficacy, patient compliance, brand security, and now, environmental responsibility. **Sheetal Arora, Promoter and CEO, Mankind Pharma** emphasizes about the challenges landscape, future trends and opportunities for Pharma Packaging.

As we navigate through 2025, the pharmaceutical packaging world finds itself at an interesting crossroads. The global market, valued at over USD 300 billion at present, is maintaining its robust growth trajectory with projections reaching USD 342.16 billion by 2034. This whopping CAGR of 8.88% is a reflection not only of expanding markets but also of the increasingly complex demands being placed on packaging solutions.

The Changing Landscape of Pharmaceutical Packaging

The pharma packaging industry has evolved by leaps and bounds from modest beginnings. The initial goal was to simply house and shield the drugs; however, the present packaging performs multiple functions beyond containment. Modern pharmaceutical packaging is a culmination of the convergence of scientific principles, technological innovation, regulatory compliance, and understanding of consumer behaviors.

The recent years have seen increased focus on patient-centered design, green packaging materials, anti-counterfeiting technology, and supply chain transparency. These have all collectively shifted the priorities and strategies of the industry towards packaging development.

The biopharma industry, by itself, produces a staggering 300 million tonnes of plastic waste annually, much of which is in the form of single-use packaging materials. This ecological cost has put the question of sustainability at the forefront of industry minds, compelling the manufacturers and the packaging partners to re-examine traditional methodologies.

Simultaneously, the increase in counterfeit medicines poses serious threats to public health and the integrity of the pharmaceutical sector. As estimated by the World Health Organization, the value of counterfeit drugs sold annually is close to $83 billion, with internet pharmacies being particularly vulnerable to this. A report by AstraZeneca indicates that over 50% of medicines bought online from illicit sources are counterfeit. These alarming statistics underscore the critical importance of robust anti-counterfeiting measures in modern pharmaceutical packaging.

Key Challenges in Pharmaceutical Packaging

Sustainability with Safety: Squaring the Circle

Perhaps the most pressing challenge facing pharmaceutical packaging today is product integrity as well as environmental stewardship. While consumer packages have no such requirements, pharma packages must continue to have superior barrier properties, stability, and safety aspects. These were historically served by materials such as plastic, glass, and aluminum foil.

The industry faces intense pressure to reduce environmental impact without compromising drug safety or regulatory compliance. As the Association of the British Pharmaceutical Industry notes, any changes to improve sustainability must ensure no increased risk to patient safety or product contamination.

The multi-component nature of drug packaging compounds the problems of sustainability. Blister packs consisting of plastic and foil, for example, are notorious for being difficult to recycle, which means millions of them end up in landfills each year.

Despite these obstacles, new solutions are starting to appear. One such solution is the mono-packaging of a single recyclable polymer. Other innovative companies have also worked together to create the first medicine container made from wood-based bio-PET, offering the same functionality one would find in conventional PET bottles but with a significantly reduced carbon footprint.

Industry collaboration is also accelerating progress in this domain. In Japan, four major pharmaceutical companies have formed a coalition to share knowledge and promote environmentally friendly packaging solutions. Such collaborative efforts across the industry are essential to achieving meaningful progress in sustainable packaging.

Anti-Counterfeiting and Supply Chain Security: Protecting Patient Trust

Counterfeit and substandard drugs are a threat to patient safety and the integrity of the pharma industry itself. Even with regulatory mechanisms like the EU Falsified Medicines Directive and the US Drug Supply Chain Security Act (DSCSA), which mandate the use of serial numbers on every package that is sold, the counterfeiters continue to adapt and change their strategies.

Instituting total anti-counterfeiting solutions is now a top priority program for R&D and operations staff throughout the pharmaceutical value chain. Serialization has become the industry's lead response. This provides an electronic pedigree to each pack and makes it more difficult to distribute counterfeits.

Beyond serialisation, advanced anti-counterfeiting features include:

- Tamper-evident seals and packaging designs that reveal if products have been opened or altered
- Sophisticated holograms and color-shifting inks that resist replication
- Embedded RFID or NFC tags enabling authentication via scanning
- Forensic markers such as microscopic taggants or chemical identifiers in packaging materials

While these technologies offer powerful tools against counterfeiting, implementation challenges remain significant. Cost considerations often restrict the most advanced solutions to high-value medications, and global harmonisation remains elusive, with varying levels of security infrastructure across markets.

Patient Usability and Compliance: Designing for the Human Element

The third major challenge confronting pharmaceutical packaging is enhancing patient-centricity through designs that are accessible, intuitive, and supportive of medication adherence. Traditionally, pharmaceutical packaging prioritised safety and compliance, sometimes at the expense of user-friendliness.

The consequences of poor packaging design extend beyond inconvenience; non-adherence to medication regimens costs healthcare systems billions annually and contributes to thousands of preventable hospitalisations. This recognition has catalysed a shift toward viewing packaging as an integral part of the product's user interface.

Several subscription-based medication services are at the forefront of this patient-centric revolution, delivering medications in personalised, perforated pouches labeled by date and time of dose. This represents a significant improvement over managing multiple traditional pill bottles for patients with complex medication schedules.

Digital enhancement of physical packaging represents another promising frontier. QR codes linking to instructional videos or medication reminders have gained traction, while regulatory bodies in the EU are exploring electronic product information (ePI) to complement traditional paper leaflets with digital, interactive content.

Implementation challenges include navigating regulatory requirements, such as child-resistant packaging mandates, while maintaining accessibility.

Serialisation: Meeting Global Regulatory Requirements

Serialisation requirements have become a defining feature of pharmaceutical packaging worldwide. These mandates aim to enhance supply chain security by enabling end-to-end product tracking, but implementation has proven complex and resource-intensive. Companies must navigate a patchwork of regional regulations while ensuring serialisation capabilities across their global manufacturing and distribution networks.

Rising Costs and Efficiency Demands

Economic pressures represent another significant challenge for pharmaceutical packaging. Raw material cost fluctuations, coupled with the growing complexity of packaging components and manufacturing processes, have strained budgets across the industry.

Contract packaging organisations (CPOs) have emerged as valuable partners in addressing these challenges. As industry experts note, experienced and flexible CPOs can efficiently handle small-batch projects that might be impractical for larger, less agile operations. This adaptability helps bridge the gap between cost efficiency and production flexibility.

Future Trends and Opportunities

As the industry navigates these challenges, several promising trends are emerging that will shape the future of pharmaceutical packaging:

Smart Packaging Technologies

Intelligent packaging features like electronic dose monitoring, environmental condition sensors, and connected communication capabilities represent a promising frontier. These technologies can enhance patient compliance, provide real-time quality monitoring, and enable deeper insights into medication usage patterns.

For instance, some prescription blister packs now incorporate concealed electronic trackers that record when a dose is removed, providing valuable adherence data for clinical trials and real-world usage monitoring. As these technologies mature and costs decrease, their potential applications will likely expand dramatically.

Precision Dosing and Combination Packaging

Innovation in dosage forms is driving corresponding evolution in packaging design. The growing adoption of flexible sachets for combination formulations, such as granulated powders and pharmaceutical pellets with different release profiles, is an excellent example of this trend.

This shift toward more sophisticated dosage combinations requires equally sophisticated packaging solutions. Modern Horizontal Form-Fill-Seal technology illustrates the industry's response, offering precision multi-dosing capabilities for complex formulations. Their systems can accurately measure granulated powder doses as small as 100mg and pellet doses as low as 10mg, enabling precise delivery of combination therapies in convenient single-dose formats.

Packaging for Novel Therapies

The emergence of advanced therapeutic modalities, particularly biologics, cell therapies, and mRNA-based treatments, is creating unique packaging challenges that demand novel solutions. The COVID-19 vaccine development effort highlighted these challenges, with Pfizer developing specialized thermal shippers equipped with GPS-enabled temperature sensors to distribute vaccines at -70°C.

Environmental, Social, and Governance (ESG) Priorities

ESG considerations have moved from peripheral concerns to core strategic priorities across the pharmaceutical value chain. As industry leaders have observed, pharmaceutical organisations are establishing specific ESG policies and targets and expecting the same commitments from their supply chain partners.

This shift extends beyond environmental concerns to encompass broader societal responsibilities, including ethical sourcing, community engagement, and governance practices. Companies throughout the

pharmaceutical ecosystem are responding by investing in sustainability certifications, implementing waste reduction initiatives, and enhancing transparency around ESG performance.

The Road Ahead: Strategic Priorities for Pharmaceutical Companies

As the pharmaceutical packaging landscape continues to evolve, several strategic priorities emerge for forward-thinking organizations:

Integrate Sustainability Throughout the Product Lifecycle

Rather than treating sustainability as a discrete packaging consideration, pharmaceutical companies should incorporate environmental responsibility throughout the product lifecycle, from initial formulation through delivery system design to end-of-life considerations. This holistic approach can identify opportunities for meaningful environmental impact reduction while maintaining or enhancing therapeutic efficacy and patient experience.

Embrace Technology as a Packaging Enabler

Digital technologies, from authentication systems to patient engagement tools, represent powerful opportunities to enhance packaging functionality while potentially reducing material requirements. By leveraging technologies like blockchain for supply chain transparency, augmented reality for patient education, and IoT-enabled monitoring for condition verification, companies can create packaging solutions that deliver value beyond physical protection.

Forge Strategic Partnerships Across the Value Chain

The complexity of modern pharmaceutical packaging necessitates collaboration across traditionally separate domains between drug developers and packaging engineers, material scientists and regulatory experts, sustainability specialists and security professionals. By fostering these cross-functional relationships both internally and with external partners, organizations can unlock innovative packaging approaches that address multiple challenges simultaneously.

Balance Quality, Innovation, and Affordability

As packaging experts thoughtfully observe, the industry must resist the temptation of a race to the bottom on price at the expense of quality. The pharmaceutical industry's fundamental mission, improving and saving lives, demands unwavering commitment to quality and safety. The challenge lies in identifying approaches that balance this commitment with accessibility and affordability, ensuring that innovative packaging solutions contribute to rather than hinder broader access to medications.

Conclusion: An Integrated Vision for Pharmaceutical Packaging

The pharmaceutical packaging landscape of 2025 presents both formidable challenges and tremendous opportunities. By approaching these challenges with creativity, collaboration, and unwavering commitment to patient welfare, the industry can develop packaging solutions that simultaneously enhance therapeutic outcomes, strengthen supply chain security, reduce environmental impact, and improve the patient experience.

Packaging represents not merely a container for products but an integral component of healthcare solutions. The ongoing journey of innovation and growth requires commitment to advancing packaging approaches that protect both patients and the planet, ensuring that medicines that reach patients are not only effective and authentic but delivered in packaging that reflects values and responsibilities as healthcare providers. ■

Author

Sheetal Arora
Promoter and CEO,
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Indian Clinical Trials Market

There is a continual quest by mankind for the advancement in medical knowledge as well as patient care, and clinical research plays a pivotal role in this pursuit. This has resulted in incremental increase in the number of clinical trials conducted across the globe and the Indian scenario is no different.

The Indian clinical trials market has been growing significantly over the past few years, driven by several factors such as a large patient pool, cost-effective operations, and a well-established pharmaceutical industry.

Sujay S. Salvi, Head – Clinical Trial Supplies Management, Siro Clintech Pvt Ltd emphasizes about the Indian Clinical Trials Market and how it fares compared to the global clinical trials market.

Global Clinical Trials Market

Market size and growth: The global clinical trials market was valued at approximately USD 50 billion in 2023 and is projected to grow at a CAGR of around 6% through 2032 at approximately USD 85 billion as per Straits Research.

North America (particularly the U.S.) dominates the global market, followed by Europe and Asia-Pacific.

Dominated by large pharmaceutical companies (e.g., Pfizer, Novartis, Roche etc.) and CROs (e.g., IQVIA, Parexel, Syneos Health etc.).

Global Market Drivers:

- High R&D spending by pharmaceutical and biotech companies.
- Focus on decentralized trials and personalized medicines.
- Increasing prevalence of chronic diseases (e.g., cancer, diabetes).
- Adoption of advanced technologies (e.g., AI, blockchain, and wearable devices).
- Growth in biologics and gene therapies.

Global Market Challenges:

- High costs of conducting trials in developed countries.
- Stringent regulatory requirements leading to longer approval timelines.
- Difficulty in patient recruitment and retention, especially for rare diseases.

Global Market Opportunities:

- Growth in decentralized and virtual clinical trials.

- Expansion of trials in emerging markets (e.g., Asia-Pacific, Latin America).
- Increasing focus on rare diseases and orphan drugs.

Global Trends:

- Adoption of decentralized clinical trials (DCTs) using digital tools.
- Increased use of real-world evidence (RWE) and artificial intelligence (AI).
- Focus on patient-centric trials and personalized medicine.

Indian Clinical Trials Market*:

Market size and growth:

India accounts for a smaller but rapidly growing share of the global market, valued at around USD 2 billion in 2024 and is projected to grow at a CAGR of around 8% through 2030 at approximately USD 3 billion as per Techsci Research.

India holds 8% of the global clinical trial market and represents about 10-15% of global clinical trial recruitment.

Presence of both international and domestic experienced CROs (e.g., IQVIA, SIRO etc.).

**Pharma/Devices/Biologics*

Presence of majority of global pharma giants (e.g. Pfizer, Novartis, Abbott, Novo Nordisk, Roche etc.)

Growing participation of Indian pharmaceutical companies (e.g., Wockhardt, Biocon, Cipla, Dr. Reddy's, Sun Pharma etc.) in clinical research.

Indian Market Drivers:

Cost Efficiency: Conducting clinical trials in India is generally more cost-effective compared to Western countries. This includes lower costs for patient recruitment, clinical site management, and labour.

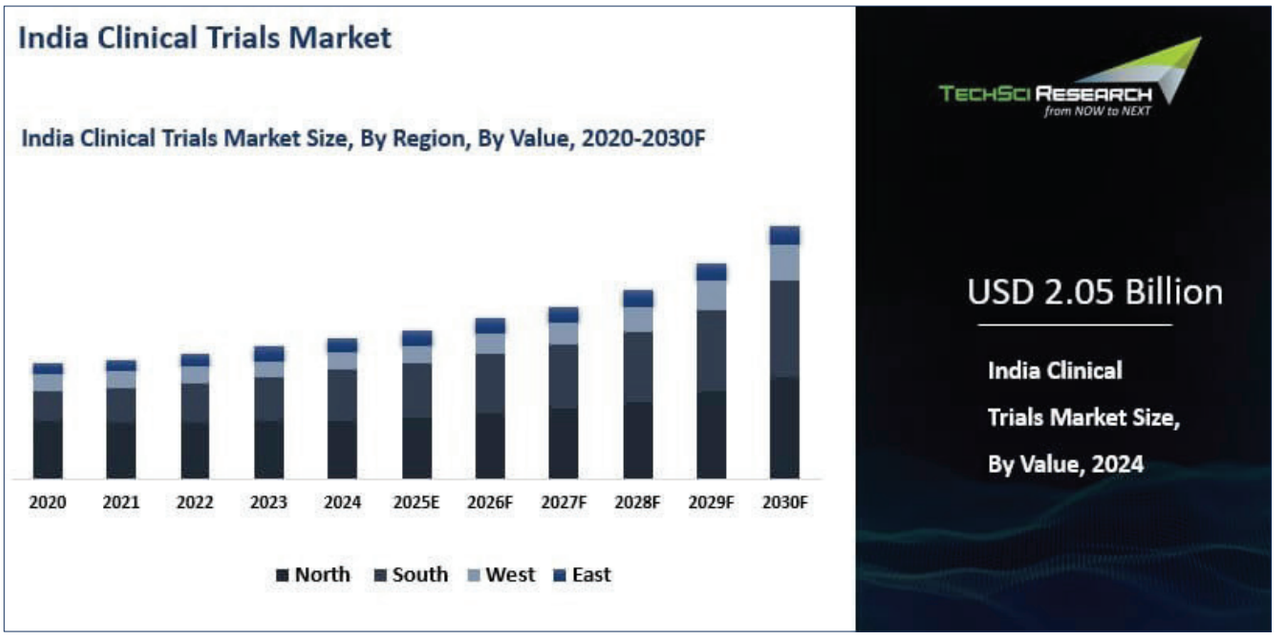
Large and Diverse Patient Pool: India's population of over 1.4 billion provides access to a wide range of disease conditions and faster recruitment.

Regulatory Reforms: The Indian government has implemented several regulatory reforms to streamline the clinical trial process, making it more attractive for global pharmaceutical companies. The "New Drugs and Clinical Trials Rules, 2019" streamlined approvals and improved transparency.

Skilled Workforce: India has a large pool of highly skilled medical professionals and researchers, which is crucial for conducting high-quality clinical trials.

Indian Market Challenges:

Regulatory Delays: Despite reforms, delays in approvals and queries persist.



Ethical Concerns: Ensuring informed consent and protecting vulnerable populations.

Compliance: Concerns over data integrity & GCP adherence.

Infrastructure Gaps: Limited clinical trial infrastructure in rural areas.

Patient retention and awareness: Dropout rates due to lack of awareness in rural areas.

Compensation Disputes: Ambiguities in compensation for trial-related injuries or deaths.

Indian Market Opportunities:

Cost Advantage: Lower operational costs attract global sponsors.

Diverse Population: Enables trials for a wide range of ethnicities and genetic profiles.

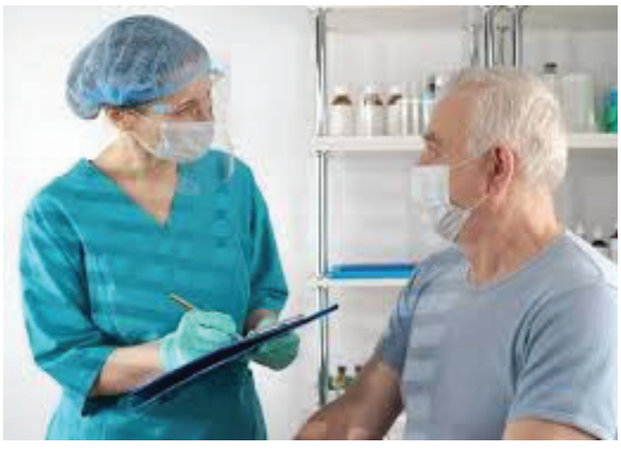
Government Initiatives: Policies to promote India as a global hub for clinical research.

Emerging Sectors: Growth in Biosimilars, Vaccines, Medical Devices and Ayurvedic drug trials.

Indian Trends:

Rising number of multicentric trials involving global sponsors. Growth in contract research organizations (CROs) and clinical trial sites. Increasing focus on biosimilars, generics, and vaccines.

The global clinical trial market is larger and more mature, with advanced technologies and stringent regulations driving innovation. The Indian clinical trial market, while smaller, is growing rapidly due to cost advantages, a large patient pool, and regulatory reforms. India is increasingly becoming a preferred destination for global clinical trials, particularly for generics, biosimilars, and vaccine research. Both markets face challenges, but opportunities for growth and collaboration are significant, especially with the rise of digital technologies and patient-centric approaches.



Experts anticipate significant growth in India's clinical trials market, driven by various strategic initiatives and inherent advantages.

Here are some key points about the Indian clinical trials market:

Market Segmentation:

By Phase: Clinical trials are typically segmented into Phase I (FIH, BA/BE), Phase II, Phase III, and Phase IV (PMS/RWE).

By Therapeutic Area: Key therapeutic areas include oncology, cardiovascular diseases, diabetes, infectious diseases, and central nervous system disorders.

By Sponsor: The market is segmented into MNC and domestic pharmaceutical companies, contract research organizations (CROs) and academic and government institutes.

By Study Design: Randomized controlled trials, Observational & real-world evidence studies, Decentralized trials etc.

By Services: Clinical Operations, Data Management, Medical Writing, Biostats, Pharmacovigilance, Clinical Trial Supply and logistics, Laboratory Services etc.

Regulatory Environment:

India's clinical trial regulatory framework has evolved significantly, with a focus on patient safety, ethical conduct, and streamlined approvals.

Key Regulatory Bodies:

Central Drugs Standard Control Organization (CDSCO), operates under the Ministry of Health and Family Welfare):

The national regulatory authority responsible for approving clinical trials, new drugs, and medical devices.

Headed by the Drugs Controller General of India (DCGI).

Ethics Committees (ECs):

Institutional or independent committees that ensure the protection of participants' rights, safety, and well-being.

Must be registered with the CDSCO.

Indian Council of Medical Research (ICMR):

Provides ethical guidelines for biomedical research, including clinical trials.

Manages the Clinical Trials Registry – India (CTRI), ensuring transparency and public accessibility of trial information.

In addition, Ministry of AYUSH is the primary governing body overseeing Ayurvedic research and trials. They have published GCP-ASU (Good Clinical Practice for Ayurveda, Siddha, Unani) guidelines, which provide a framework for conducting trials involving these products.

Medical Devices Trials need to follow the Medical Devices Rules, 2017 (amended in 2020 & 2024) under the CDSCO.

Recent Developments:

Recent reforms include the introduction of the New Drugs and Clinical Trials Rules, 2019 & 2023 amendments, which aim to streamline the clinical trials approval process and ensure patient safety.

Mandated compensation for trial-related injuries or deaths.

Fast-track approvals for trials involving drugs for unmet medical needs or life- threatening conditions.

Online submission of applications through the SUGAM portal. Increased transparency and efficiency in the approval process. All trials must be registered in the Clinical Trials Registry - India (CTRI) before enrolment begins. All Clinical Research Organizations to be registered with the CDSCO.

Future Outlook:

In addition, the below latest and upcoming government initiatives are expected to boost growth in this sector.

National Digital Health Mission (NDHM): Improving Patient Data Accessibility.

Draft Pharma Policy: Encouraging innovation and R&D investments.

PLI (Production Linked Incentive) Scheme for Pharma: Promoting domestic manufacturing and clinical research.

Experts have urged India to revise its clinical trial regulations to capture a larger share of the global market, where it currently holds 8% compared to China's 29%.

Recommendations include expediting regulatory processes to attract more sponsors.

The market is expected to continue growing, driven by increasing R&D investments, rising prevalence of chronic diseases, and ongoing regulatory improvements.

The adoption of advanced technologies such as artificial intelligence and big data analytics in clinical trials is also expected to boost market growth.

Decentralized Clinical Trials (DCTs): Post COVID there is a growing trend towards decentralized clinical trials, which leverage digital technologies to conduct trials remotely.

Increased Focus on Rare Diseases: There is an increasing focus on clinical trials for rare and orphan diseases, driven by both regulatory incentives and unmet medical needs.

Collaborations and Partnerships: Strategic collaborations between pharmaceutical companies, CROs, and academic/government institutions are becoming more common to leverage complementary strengths. For example, India's first indigenously developed COVID -19 vaccine (Covaxin by Bharat Biotech) involved collaboration between ICMR/NIV and industry.

AI is playing a crucial role in modernizing India's clinical trial sector by enhancing data analysis, operational efficiency, and personalized patient care. These advancements are positioning India as a major hub for innovative clinical research.

In summary, the Indian clinical trials market is poised for a substantial growth, supported by a favourable regulatory environment, cost advantages, digital initiatives and a large patient pool. However, challenges related to ethical concerns, GCP compliance and regulatory complexities need to be addressed to fully realize the market's potential. ■

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New Frontiers of Growth in the Life Sciences Industry

The life sciences industry is on the cusp of change. While this change does give rise to some challenges, it throws open doors for new opportunities and possibilities. In order to capitalize on these opportunities, an organization must be on a dual mission of 'renew - new' – one that simultaneously focuses on renewing existing systems and processes for greater efficiency and adopting new advancements in technologies to gain value. In this paper, we discuss these opportunities and the way forward for the life sciences industry.

Recent scientific and technological advances coupled with an aging population, expansion in the emerging markets, and an exponential increase in mainstream adoption of digital technologies have set the ball rolling for the life sciences industry, providing it with a renewed platform to revive its fortunes.

With an explosion of digital data availability – electronic health records, social, genomics, clinical, insurance, and more digitally engaged consumers, the stage is set to derive benefits from an integrated drug development and manufacturing environment. Such an environment not only provides the best care for patients but also generates significant revenue growth. Furthermore, there is significant focus on personalized healthcare from both the Life Sciences industry and policy maker perspective. A case in point is President Barack Obama's precision medicine initiative. Personalized healthcare, however, would require a complete shift in how the industry evaluates the market (focus on an individual instead of a population), analyzes higher volumes of data, and puts in place newer processes and methods to complete their studies. The spate of recent investments in the immuno-oncology therapies is pointing towards a significant growth in the coming decade.

Technology is playing a massive role in enabling the industry to achieve these objectives, be it analytics in personalized medicine, cloud computing in collaboration, or wearable devices in remote and self-health monitoring. As the world becomes increasingly connected, information and communication technologies will fundamentally reshape both the consumption and delivery of services in life sciences. The industry must prepare for the future by embracing next-generation technologies and systems throughout the life sciences value chain.

We believe life sciences companies must adopt a more proactive strategy, one that allows them to maximize value from prior investments by renewing existing solutions and processes and generate new value by embracing new technologies, systems, and best practices.

Opportunities for 'renew' in Life Sciences

The Life Sciences industry is undergoing a major transformation. A large part of this is fueled by the integration of digital that has driven a powerful re-imagination of the Life Sciences industry landscape.

This transition has opened up new opportunities for development, but also comes with its own challenges.

- Innovate through cloud: Cloud's greatest impact is in facilitating innovation through increasing accessibility of both internal and external data. While initially the reasons for cloud adoption were centered on reducing the cost and the time for infrastructure provisioning, it is now providing many more strategic benefits such as enhancing collaboration and providing much greater computing power across the entire value chain from R&D, sales & marketing to enabling functions such as HR and finance.

In pharmaceutical research where large volumes of data (notably next- generation DNA sequencing systems and genomic tools) needs to be mined and the cost of obtaining this sequence is rapidly decreasing, data has further increased the number of both, instruments being used and labs using them. Through cloud's agility of provisioning and pricing (pay-per- use), setting up massive infrastructure resources for data crunching, analysis, or simulation is no longer an impediment.

Similar cases are happening in clinical research. A large pharma company is setting up a cloud-based solution to integrate clinical data across all its global trials and provide it to its global operations team for analysis. These big data solutions that receive clinical data instantly from all the current trails will reduce the time taken to analyze and predict the path of the trials, while decreasing the operating expenses substantially. On a broader application, the scope of collaboration is expanding to include R&D processes outsourcing, exemplified in virtual laboratories where thousands of researchers from contract research organizations can seek and provide help. Overall, by opening the doors of collaboration, exploding analytical power, and making information more accessible and manageable, the cloud is encouraging new practices such as open innovation in life sciences.

The industry must leverage these to the fullest.

- Smarter and transparent supply chains: Due to globalization and the ever increasing size of organizations, the need to integrate supply chains and gain visibility into them has become critical. Wide diversity of the product mix (biologics versus small molecule) will further compound the need for supply chains that can handle this mix. Furthermore, regulatory policies on transparency are evolving and several states in the U.S. have passed product pedigree laws, and many others are contemplating such legislations. In summary, supply chains will need to transport an increasingly diverse range of products in a challenging environment with resources that are much more geographically scattered while simultaneously optimizing costs.

As technology erases the distinctions between the virtual and the physical, it sets up the opportunity to create intelligent, analytics-driven, next-generation supply chains that provide real-time, end-to-end visibility and control. A smart supply chain, integrated across all business processes and systems, can also leverage real-time data and analytics to enable more accurate forecasting, shorter response times, optimized supply chain processes, and faster decisions.

To enable transparency, pharma organizations are not only implementing global track and trace solutions but are also experimenting with cloud-based, leaner supply chain management solutions. While more prevalent in the CPG Industry, discussions in the pharma community on these lean solutions that can provide visibility on their products after they leave their warehouses have taken place. These solutions are being used in the developing nations that have a more complex network of distributors and wholesalers. Such solutions will promote growth by preventing stock-outs and allowing further optimization of inventory and support recalls.

- Renew through automation and modernization: Most large pharmaceutical organizations are born out of numerous mergers and acquisitions and have inherited portfolios of IT applications in various stages of modernization. In our experience, a substantial part of the legacy portfolio is either outdated or manual, creating high cost burden

of managing them while ensuring they meet the complex and evolving regulatory compliance standards. While legacy systems are integral to the continued operational maintenance, they hinder the adoption of newer digital solutions.

Best-in-class companies are standardizing business processes, measuring manufacturing, focusing on visibility, and using the right tools. They are using automation to manage the processes and drive increased business value. Automation is being welcomed in the industry as an alternative to manual steps, especially across processes that have repetitive steps. Automation not only reduces the time taken to execute a task but also frees up time for valuable resources to focus on productive tasks. In manufacturing, Process Analytical Technologies (PAT) are being integrated across the assembly line to automatically capture unit operations data and integrate it with the plant quality equipment. This automation allows instant feedback on the batch quality based on the analysis of data while preventing waste and reducing costs. In R&D, numerous research labs are going paperless by integrating their critical solutions such as ELNs and LIMS with their high throughput chromatographs.

This has not only reduced the time taken, but also minimized errors and allowed scientists to collaborate more effectively leveraging digital data. Additionally, in core IT services, a novel use of automation is in enabling testing of large and complex enterprise solutions. Panaya, which was recently acquired by Infosys, uses artificial intelligence to provide impact assessment and execute automated testing of their enterprise solutions. As a result, it can achieve 75-80% reduction in time and resource consumption. This is now being utilized across a number of large organizations with substantial time and resource savings. Automation is also being effectively utilized in executing the many repetitive tasks in application support services resulting in greater than 35% efficiency savings for organizations.

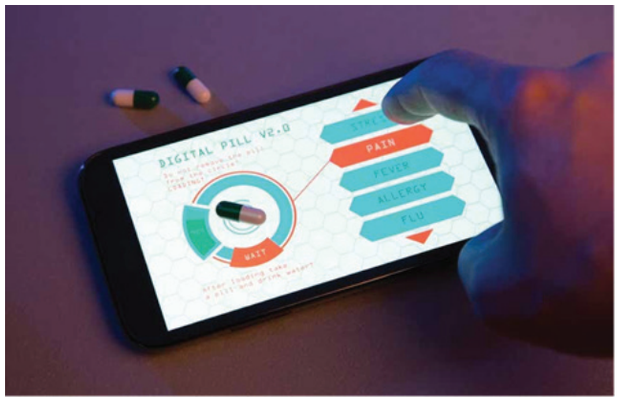
We envision that the automation of IT processes will soon become a key component of the life sciences operations and new-generation leaders will mandate these efficiency savings within their lean organizations.

New opportunities for life sciences

Populations are aging. Chronic illnesses are increasing. New disease strains are emerging at an alarming rate. Add to this mix, the soaring number of patients in a greater spread of geographies. Top it with global regulatory mandates. Then, factor in the variable dosage needs. Think about the shelf life of pharmaceutical drugs and medications. And, we are looking at skyrocketing global healthcare costs. At the same time, there is pressure to develop innovative drugs to save more lives.

Here are the opportunities that await the life sciences industry:

- Connected patients and partners: In today's socially connected world, pharmaceutical companies have a clear opportunity to play a greater role in delivering a better experience for patients and their providers. Patients are becoming demanding about how they want their care. This has precipitated a major transformation in business and technology and has led organizations to adopt a patient-centric model. Earlier attempts at creating these solutions were exclusively focused on adherence to the medication. However, an emphasis on continuity of care provides an opportunity for pharma companies to play a bigger role. Digital solutions are facilitating patient education,



behavioral change, and better communication with clinicians. There is also a wide variety of solutions that facilitate this connect including web portals, body sensors, and apps. These help the patient self-monitor and get needed support, between visits to the physician.

These solutions now provide health advice anytime, anywhere, by developing patient-centric smart tools and devices. These devices also detect and track data regularly and accurately and relay the same to physicians.

Mobility is another key feature of these solutions, making it easier for the patient to communicate. A hospital network in Boston empowers patients to use their home devices to track and report data to their doctors. Patient and physician- centric portals, where comprehensive information about treatments and drugs is actively shared, are also on the rise.

In the future, pharma companies will design holistic Medical-health (M-health), platforms that connect the patients and physicians across the globe, drive patient and physician engagement, and activation – all with the objective of improved care experience for patients, better clinical outcomes, and lower total cost of care. In the new collaborative, omni-access data world, this will be a key factor in attracting and retaining patients, partners and clients. To keep pace with a rapidly changing technology landscape, organization, would need to develop a deeper integration, collaboration, and synchronization of activities across all channels.

- Adoption of IoT and wearables across the value chain: Ubiquitous presence of smartphones and substantial investments in Internet-of-things (IoT) are providing an exciting opportunity to reduce the gap between the patients and the pharmaceutical industry. While still in its nascent stage, higher adoption of IoT has already started to facilitate at-home diagnostic testing, self-management of chronic diseases, and remote patient-health care provider interaction in the healthcare industry.

For life sciences companies, the adoption of IoT can improve medication adherence and reduce time by capturing critical clinical indicators directly and sending them to the EDC system, produce better outcomes based on analytic insights such as in clinical trials where patient data through wearables has been found to be useful for tracking recovery from cardiac surgery, judiciously replace physical interaction with digital intervention, and lower the cost of treatment. Doctors are turning to wireless devices such as Fitbits to understand the factors that help the recovery of patients. A report published in the Annals of Thoracic Surgery says, "Wireless monitoring of mobility after major surgery was easy and practical. This opens the door for changing recovery models and improving outcomes in surgical practice."

Early market movers already see the use of pill-shaped micro-cameras that traverse the human digestive tract, sensors in pills that track concordance, hip replacements that detect falls and send messages to care providers, and thousands of health-monitoring applications that send messages and data from the home to the hospital or patient to the HCP to improve early diagnosis and treatment solution.

One critical innovation in this area is the advancement by Proteus Digital Health. It has created an FDA-approved small pill that consists of a pinhead- sized sensor embedded in the pill and a battery-powered patch that monitors various health indicators such as sleep, activity, respiration, and heart rate. The recent announcement by Novartis of partnering with Google on developing contact lenses that will monitor blood sugar levels and even correct impaired vision will further transform eye care and exemplify another frontier in adoption of IoT.

The adoption of IoT is yet to pan out in the life sciences industry. The industry must work cohesively to overcome the barriers to wearable

technology adoption – concerns of security and privacy, data sharing and protection, regulatory compliance, among others – to take life sciences to the next level. In our view, companies that are proactive in using IoT will be the leaders of the future.

- Effective big data utilization to generate insights: From next-generation sequencing data and patient information to supply chain monitoring, pharmaceutical firms have been managing massive amounts of data for years. In recent years, rapid digitization has made access to larger volumes of data (EMR, clinical, genomics, wearables), an everyday reality. The need to design solutions that will systematically analyze and generate real-time insights from these mountains of data more effectively is critical for success. To develop and deliver the next generation of successful therapies, the industry must simultaneously minimize the cost of processing / managing data while maximizing its value. This is complicated by the need to continue integrating new data types and sources from around the globe and to glean insights from unstructured data, while complying with multiple complex regulations governing drug safety, supply chain security, patient privacy, and other sensitive information.

  Since early 2000, research units within biopharmaceutical organizations have been actively harnessing the powers of big data by leveraging the advancements in next-generation sequencing. This includes a variety of studies including whole-genome sequencing, targeted re-sequencing, discovery of transcription factor binding sites, and noncoding RNA expression profiling, among others. Organizations are now able to leverage the vast library of available molecular and clinical data, utilize predictive modeling techniques, and identify new potential candidate molecules with a high probability of being successfully developed into drugs while ensuring efficacy and safety.

  Clinical development now is also benefiting from big data solutions. We have already mentioned earlier how a large pharmaceutical company is creating a cloud-based aggregated clinical data solution that will house results from all of its global trials.

  Faster access to and analysis of this data will reduce the time-to-market and enable rapid decision-making capability. We envision that a further integration of clinical operations data with safety data will allow near real- time monitoring of trials and provide the ability to rapidly identify safety or operational signals demanding action to avert adverse events and unnecessary delays.

  We believe that the need to uncover valuable relationships within the existing data is the key to boosting innovation and driving new value. With computing power and storage becoming cheaper, as well as increase in cloud adoption, the life sciences industry stands to benefit tremendously from big data solutions.

Conclusion

There are several reasons for the conservatism of the life sciences industry. But given the current dynamism in the sector, occasioned by regulatory, market, and technological forces, life sciences companies can no longer hold back. We believe this is a time of great opportunity, albeit with some challenges, for this industry. As the industry looks to grow while managing existing investments, it must adopt a dual strategic approach towards technology- renew existing systems and processes for greater efficiency while adopting completely new technologies and practices for value creation ■

Article Courtesy: Infosys - Published earlier in PBW October 2022

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Building a Sustainable Pharma Future

In the evolving healthcare landscape, India's pharmaceutical industry stands tall as a beacon of innovation, affordability, and scale. Rightly referred to as the "pharmacy of the world," the sector contributes more than 20% of the global supply of generic medicines, and 60% of vaccines, to over 150 countries. The COVID-19 pandemic reinforced India's leadership, as pharma companies ensured uninterrupted access to essential medicines. However, this defining moment also prompted scrutiny of the industry's environmental impact, from excessive water use to waste discharge and emissions.

Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA), emphasizes that India's pharmaceutical industry is increasingly embracing sustainability as a core operational principle, with a strong focus on ESG performance.

India's pharmaceutical production has grown rapidly, expanding at roughly 8% annually over the past decade, more than twice the global average.

As the world confronts the environmental costs of this rapid growth, India's pharma sector faces an opportunity to broaden its leadership beyond quality, cost, and access. The new frontier of global leadership lies in environmental sustainability.

It is no longer sufficient to focus solely on healing people; we share a fundamental responsibility to heal and protect the planet as well. The question posed by Jonas Salk, the developer of the first successful polio vaccine, remains as urgent as ever: "Are we being good ancestors?" With this, Salk challenged us not only to cure diseases but to consider the impact of our actions on future generations.

The Strategic Shift Toward Sustainability

This perspective by Salk now finds tangible expression in the industry's strategic shift towards environmental sustainability, which has emerged as a critical business imperative—no longer merely a regulatory checkbox but a core tenet of corporate responsibility, strategic positioning, and long-term competitiveness. Sustainability is rapidly evolving into the currency of trust in an increasingly conscientious global healthcare market. Across international markets, Environmental, Social, and Governance (ESG) criteria are becoming essential determinants of investment decisions, partnerships, and corporate reputation.

Indian pharmaceutical companies are proactively embracing this shift, aligning their operations with India's net-zero goals for 2070, the United Nations Sustainable Development Goals (UNSDGs), and the Business Responsibility and Sustainability Reporting (BRSR) mandates issued by SEBI. Testament to this progress, the Dow Jones Sustainability Index now ranks seven Indian pharmaceutical companies among the world's top eleven, affirming their growing global stature in sustainability performance.

While these achievements signify meaningful progress and reflect the sector's readiness to evolve with the times, much more remains to be done. India's leadership in the global pharmaceutical industry must now be defined by its capacity to innovate sustainably, adopt greener production practices, and build resilient supply chains that minimize environmental impact throughout the entire value chain.

From Molecule to Market: Aligning the Value Chain with Sustainability

Sustainability in pharmaceuticals demands a holistic approach. It is not the responsibility of any single department or phase but a continuous mandate

spanning the entire value chain. From research and development to manufacturing, logistics, and equitable distribution, each stage offers unique opportunities to drive sustainability.

a. Greening R&D: Starting with Innovation

The journey of every molecule begins in the laboratory. Indian pharmaceutical companies are increasingly embracing green chemistry principles, striving for less hazardous and more resource-efficient formulations. Cleaner synthesis processes for Active Pharmaceutical Ingredients (APIs) and eco-friendly excipients are gaining momentum. However, challenges remain in underfunded R&D ecosystems, regulatory frameworks that inadequately incentivize sustainable investments, and technical hurdles requiring novel synthetic pathways, solvents, and reaction conditions. These substantial obstacles can be overcome through government-backed incentives, public-private partnerships, and innovation clusters focused on green pharmaceutical technologies. Collaborative platforms and increased investment in research infrastructure will be essential to catalyse systemic change and accelerate progress toward sustainability.

b. Cleaner Manufacturing: Scaling Responsibly

Post-R&D, the focus shifts to cleaner manufacturing, where the Indian pharma sector has made notable strides. Initiatives such as the Production Linked Incentive (PLI) scheme and the development of dedicated pharma clusters encourage the adoption of global best practices. Several companies have integrated Zero Liquid Discharge (ZLD) systems, automated pollution control technologies, and renewable energy solutions into their operations. Yet, significant challenges persist - effluent discharge from bulk drug production, emissions from aging facilities, and inconsistent waste management practices continue to impact environmental outcomes. Industry-wide adoption of cleaner technologies, supported by robust regulatory frameworks and voluntary self-regulation, will be critical to reducing the sector's environmental footprint.

c. Greener Supply Chains: Logistics for a Low-Carbon Future

India's pharmaceutical supply chain, encompassing manufacturing hubs, cold storage, transportation, and last-mile delivery, is among the most complex worldwide. While operational efficiency and scale have improved, environmental concerns have mounted due to energy-intensive cold chains, excessive plastic packaging, and emissions from long-distance transport. Building a sustainable supply chain is not only an environmental imperative but also enhances resilience against disruptions and improves cost-effectiveness. Key enablers for this transformation include decentralized manufacturing hubs, adoption of electric or hybrid transport fleets, biodegradable packaging solutions, and digital tools for optimized route logistics.

d. Equitable Access: The Social Sustainability Dimension

At the heart of India's pharmaceutical leadership lies its unwavering commitment to affordability and access. Programs spearheaded by the National Pharmaceutical Pricing Authority (NPPA) and the Standing Committee on Affordable Medicines and Health Products (SCAMHP) have brought essential medicines within the reach of millions. Environmental sustainability must never come at the cost of social equity. The transition toward greener processes and materials should not compromise drug affordability or accessibility. Innovation must be inclusive, ensuring sustainable healthcare remains synonymous with equitable healthcare.

e: Driving Change: Pharma Industry Embracing Sustainable Practices

India's pharmaceutical industry is increasingly embracing sustainability as a core operational principle, with a strong focus on ESG performance. Companies are implementing forward-looking strategies to reduce carbon emissions, boost energy efficiency, and adopt responsible water and waste management practices.

One of the most impactful transformations has been the widespread adoption of Zero Liquid Discharge (ZLD) systems. These advanced technologies treat, recycle, and reuse wastewater within manufacturing facilities, significantly minimizing ecological footprints. The treated water is repurposed for non-potable applications such as cooling towers and cleaning operations, thereby improving overall resource efficiency.

In pursuit of clean energy, pharmaceutical firms are turning to renewable sources like solar power. Rooftop solar installations, biomass utilization, and renewable energy procurement have become common initiatives

contributing to long-term decarbonization goals. Energy efficiency efforts extend beyond power generation—LED lighting, motion sensors, and smart timers are being installed to optimize electricity use. Additionally, Heating, Ventilation, and Air Conditioning (HVAC) systems are being upgraded with variable-speed blowers, programmable thermostats, and automated controls to maintain indoor air quality while reducing energy consumption. The adoption of smart metering further enhances operational efficiency by enabling precise energy monitoring and management.

Moreover, companies are investing in employee training and awareness programs to foster responsible behavior and effective greenhouse gas (GHG) management. Aligning with global transparency standards, many Indian pharmaceutical companies publish dedicated ESG or Sustainability Reports that detail key achievements, ongoing initiatives, and future targets. This commitment to openness reinforces accountability and strengthens the industry-wide pledge toward a greener future.

Bridging Gaps: Navigating the Challenges

The path to sustainability is not without obstacles. Legacy infrastructure, capital constraints, and fragmented regulatory compliance remain significant roadblocks. Moreover, while leading firms have made substantial progress, smaller companies often lack the resources to follow suit.

Overcoming these challenges requires a multi-dimensional strategy. This includes strategically mainstreaming ESG principles by embedding sustainability into core business models with clearly defined metrics, targets, and accountability mechanisms. Innovation must focus on circularity—redesigning product life cycles to prioritize reusability, recyclability, and minimal environmental impact. Additionally, building collaborative ecosystems that involve government, academia, startups, and multinational corporations is critical to scaling sustainable innovations across the entire value chain.

A particularly complex challenge is addressing 'Scope 3' emissions - indirect greenhouse gas (GHG) emissions occurring throughout a company's value chain. Industry leaders are adopting an integrated "dual mission" approach that simultaneously optimizes costs and reduces Scope 3 emissions. To achieve this, pharmaceutical companies can focus on three key **levers:** decarbonizing the raw material value chain, improving process and energy efficiency, and promoting recycling and circularity.

Decarbonizing the raw material value chain requires a detailed analysis of both the cost and carbon footprint of products and components, enabling more informed procurement decisions and adoption of lower-impact alternatives. Enhancing process and energy efficiency through measures such as transitioning to renewable energy sources and implementing robust energy management systems can reduce emissions by 30–40% while cutting energy costs by up to 20%. Embracing recycling and circularity by redesigning packaging to reduce material use, eliminating single-use plastics, and simplifying packaging processes can also substantially lower the industry's overall environmental impact

A Future-Ready Vision for Indian Pharma

India has already redefined global healthcare leadership through its scale, efficiency, and commitment to access. Now, it stands poised to redefine leadership once more by setting new benchmarks in environmental sustainability. Pharma companies must prioritize adopting green technologies in legacy and new facilities, invest in bio-based APIs and green chemistry platforms, conserve energy and water across all operations, and ensure transparent ESG reporting with meaningful stakeholder engagement.

India's pharmaceutical sector is at a crossroads of immense opportunity and responsibility. The decisions made today will shape not only the future of healthcare but also the future of the planet. Environmental sustainability is no longer optional—it is essential to secure health for both people and the planet. The Indian pharmaceutical industry has the scale, capability, and vision to lead this transformation boldly, holistically, and irreversibly. ■

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BIO-India World Expo & Conferences 2026
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Industry Automation & Control 2026
PVF Pumps, Valves & Fittings World Expo 2026
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- Water Treatment Chemicals
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FACT & FIGURES 2024

- **750** EXHIBITORS FROM 15+ COUNTRIES
- **25871** VISITORS FROM 53 COUNTRIES
- **8** TECHNICAL CONFERENCES
- **1500+** BUSINESS DELEGATES
- **250+** GLOBAL SPEAKERS
- **2500+** ENGINEERING PHARMA & SCIENCE STUDENTS AT STUDENT OUTREACH PROGRAM FROM 28 STATES & UNION TERRITORIES
- SCALE@ CHEMTECH World Expo 2024: 60+ GLOBAL CLIMATE TECH STARTUPS FROM 20 COUNTRIES; 40 TECHNICAL PRESENTATIONS
- BRICS WORKING GROUP BRAIN STORMING SESSION

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R.N.I. No.: MAHENG/2002/08502. Date of Publication: 26th of every month. Poster Registration No: MCS/207/2023-25
Posted at Patrika Channel Sorting Office, Mumbai 400001. On 27th every month. Total Pages 48

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Bio-X India World Expo & Conference 2026

HIGHLIGHTS OF BIO-PHARMA WORLD EXPO 2024

Bio Pharma World Expo 2024

NAVIGATING THE PATH TO LEADERSHIP IN BIOPHARMA EXCELLENCE

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

Biotech is one of the fastest-growing industries in the world right now, especially in India. The Indian bioeconomy registered a remarkable 28% growth in 2022. The past three years have been enormously successful, especially considering the challenges posed by the COVID-19 pandemic. The Indian bioeconomy is forecasted to reach USD 300 billion by 2030, a significant increase from its current valuation of USD 140 billion, which constitutes 4% of the total GDP of our country's growth. The BioPharma industry contributes approximately 43% to the economy and extends beyond pills; it encompasses aspects of healthcare, wellbeing, and cognitive enhancement. To capitalize on green growth and the bio economy, we are establishing Bio enablers in the form of Bio manufacturing hubs through Public-Private Partnerships.

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

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