BioAsia 2026
TechBio Unleashed
AI, AUTOMATION & THE BIOLOGY REVOLUTION

Pharma's new architecture

Where novel science meets AI and manufacturing power

February 2026

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Foreword

The global life sciences sector is no longer evolving; it is being rewritten. For decades, the industry operated under a linear discovery model—one where science, manufacturing and commercialization functioned in silos. Today, that fragmentation is a liability. As pipelines shift toward complex biologics and cell therapies, the "traditional way" of sequential development is resulting in costly delays and missed opportunities for patients.

In this new era, integration is the only path to survival. Value is being redefined by real-world impact and success is measured by the speed at which we can bridge the gap between a laboratory breakthrough and a scalable, global solution.

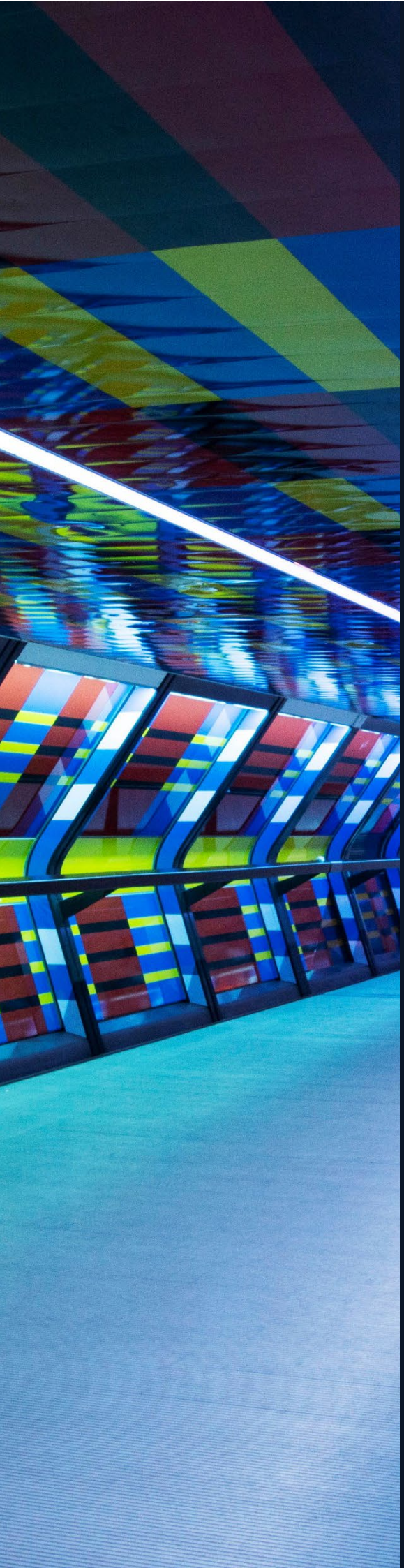
The future belongs to the bio-weavers—enterprises that do not just own capabilities but orchestrate them with surgical precision. To win, a new architecture that prioritizes execution at every stage needs to be adopted:

- Upstream integration: Moving manufacturing and supply chain constraints into the design phase to eliminate bottlenecks before they occur.
- AI-driven decision making: Leveraging machine learning not just for research, but to predictively navigate the "valley of death" in clinical scale-up.
- Platform-based agility: Transitioning from standalone assets to repeatable development ecosystems that allow for faster movement from research to testing.

India stands at a pivotal point in this transformation. With its unique blend of scientific talent, digital depth and large-scale manufacturing capacity, India is the natural home for this integrated model. It is no longer just the "pharmacy of the world"; it is becoming the world's laboratory and digital engine.

The winners of BioAsia 2026 and beyond will be those who stop building in silos and start weaving. By harmonizing novel science with AI and manufacturing power at the start of the journey, we are not just improving the industry—we are accelerating the future of global health.

Daniel Mathews
EY Global Life Sciences Leader; EY EMEIA Life Sciences Market Lead



The global pharmaceutical industry is experiencing a significant transformation, evolving from traditional linear discovery pipelines and scale-driven manufacturing to a new architecture of innovation. This emerging paradigm integrates cutting-edge biology, artificial intelligence and digitally enabled manufacturing, fundamentally reshaping how medicines are discovered, produced and scaled, while redefining competitive advantage.

This thought leadership piece delves into how this convergence is restructuring the pharmaceutical value chain. It posits that future success will depend on the seamless integration of three critical domains: innovative therapeutic science, data-driven intelligence across R&D and clinical development and advanced manufacturing systems capable of reliably scaling complex products. From AI-driven target discovery to the use of digital twins in bioprocessing and the implementation of Quality 4.0 on the factory floor, the industry is transitioning from isolated innovations to interconnected systems of discovery and delivery.

For India, this transition represents both a pivotal moment and a generational opportunity. The country's pharmaceutical sector is globally recognized for its manufacturing excellence and cost efficiency, providing a robust foundation for a shift toward higher-value innovation. Indian companies are increasingly investing in proprietary biologics, new modality platforms and digital R&D capabilities, leveraging strengths in engineering, data science and scalable production. Future growth will be characterized not just by volume, but by the ability to build platforms, intellectual property and resilient innovation ecosystems.

The Union Budget 2026 reinforces this direction through the Biopharma Strategy for Healthcare Advancement through Knowledge, Technology and Innovation (SHAKTI) initiative, an INR10,000 crore, five-year program aimed at positioning India as a global biopharma manufacturing hub. Investments in new and upgraded National Institute of Pharmaceutical Education and Research (NIPERs), a national network of over 1,000 accredited clinical trial sites, and the enhanced Central Drugs Standard Control Organisation's (CDSCO) scientific-review capacity signify a shift from mere capacity creation to capability building—encompassing talent development, clinical research, regulatory science and manufacturing execution. Other measures, such as duty relief for select high-value and rare-disease therapies and expanded allied health training, further bolster the sector ecosystem. Over time, these initiatives can shorten development timelines, enhance regulatory confidence and deepen India's integration with global biopharma networks.

Realizing this potential will require reimagined collaboration among industry stakeholders, policymakers and research institutions. Regulatory frameworks must evolve alongside scientific advancements; talent development must integrate biology, computation and industrial engineering; and technology adoption must extend beyond pilot projects to enterprise-wide transformation. Collaboration among startups, global partners, academia and manufacturers must become the standard.

BioAsia 2026 embodies this moment, uniting global science, industry leadership and policy dialogue to translate ambition into action. It reflects India's commitment to shaping the next era of pharmaceutical innovation.

The future of pharma will not be defined by isolated breakthroughs, but by an architecture that connects discovery, development and delivery. By integrating novel science, AI and manufacturing into a cohesive system, the industry can create medicines that are faster to develop, smarter in design and more reliable in production. Through this publication, we invite leaders across the ecosystem to engage with this vision and work collaboratively toward a future where innovation and impact advance together.

Suresh Subramanian
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The life sciences sector is entering a period of significant change, driven by closer interaction between biology and digital technologies. As research becomes more data-intensive, traditional approaches are no longer sufficient. New ways of working are shortening the distance between discovery and application, enabling scientific insight to translate more steadily into healthcare practice. Science remains central to this shift, with research increasingly focused on drug classes and methods that can be applied across multiple programs, shaping early development decisions.

Across R&D, companies are using AI, including large language models (LLMs), to enable greater speed and scale. In discovery and preclinical stages, these tools support structure- and-function analysis across small molecules and proteins and improve laboratory workflows by learning from experimental data. As programs advance, similar approaches support clinical activities such as digital marker development, site selection, patient recruitment and study-data preparation. They also support safety and regulatory work to review information and identify signals, with expert oversight remaining essential.

These capabilities are extending into manufacturing and operations, helping teams better understand processes, test alternatives and manage growing complexity while keeping human judgment at the center of decisions.

In response, Telangana's life sciences sector focuses on connecting research, development and manufacturing. Through its Next-Gen Life Sciences Policy, the state is strengthening innovation-led growth across advanced biologics, platform-based research and digitally supported development, supported by continued investment in specialized infrastructure and innovation hubs.

This perspective underpins the theme of BioAsia 2026, TechBio Unleashed: AI Automation & the Biology Revolution. Organized by the Government of Telangana in collaboration with EY, the 23rd edition of BioAsia continues its long-standing role in convening leaders across the life sciences ecosystem.

Shakthi Nagappan
CEO, Telangana
Lifesciences

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What lies next for pharma?

The pharmaceutical industry continues to advance scientific innovation, with new therapies expanding treatment options across many diseases. However, translating these discoveries into scalable, high-quality medicines remains challenging as pipelines move toward complex molecules, biologics and advanced therapies. This shift places greater emphasis on how research, technology, and manufacturing work together. Strengthening alignment across these areas has become essential to support consistent development, reliable scale-up, and timely delivery of therapies to patients.

The therapeutics frontier is expanding

Scientific progress continues to reshape pharmaceutical development. Small molecules remain important, but their structure and production requirements have evolved. New chemical entities involve complex synthesis steps and require tighter control during manufacturing. Alongside this, biologics and biosimilars now form a substantial share of global pipelines. Vaccines also play a wider role, supporting rapid response and preparedness in addition to routine immunization. Advanced therapies, including targeted cancer treatments and gene-based approaches, are adding new options while introducing greater development and manufacturing demands. Together, these shifts create a broader mix of therapies with behaviors beyond the laboratory. As a result, complexity now sits at the core of development rather than appearing only in select programs. Organizations must therefore build systems that can support multiple pathways at the same time.

Innovation is moving toward platform thinking

As scientific programs become more complex, companies are rethinking how they structure research and development. Rather than building each medicine as a standalone effort, many now rely on platforms that support multiple programs overtime. These platforms provide stable foundations for discovery. Teams apply shared knowledge, common data and established development pathways across assets. Learning carries forward from one program to the next, reducing repetition and improving continuity. This approach does not remove scientific uncertainty, but it brings greater clarity to execution. Development timelines become easier to plan, and transitions between programs become smoother.

Key characteristics of this approach include:

- Reuse of tools and workflows across programs
- Common development pathways for multiple assets
- Faster movement from early research to testing
- Stronger learning across portfolios

As a result, progress depends less on isolated breakthroughs and more on systems that support steady and repeatable development.

Small molecules continue to adapt alongside new therapies

Small molecules remain a central part of global treatment options, even as new therapies expand the pipeline. What has shifted is the way these medicines move from design to production. Higher potency compounds and more complex synthesis routes place pressure on traditional methods that rely on manual handling and fixed batch processes. These approaches often struggle to maintain consistency and safety at scale. In response, manufacturers are adjusting how they design and operate production systems, with greater focus on control, predictability, and continuity from laboratory development through commercial manufacturing. This shift supports stable output while maintaining required quality standards. Rather than losing relevance, small molecules are adapting to fit modern development models that demand precision and reliability.

India's role in scientific development is widening

As global pipelines become more complex, India's position within pharmaceutical development is also changing. The country has long supported global supply through generics and vaccines, and this foundation remains important for access to medicines. Alongside this, Indian organizations are participating in higher-value research, including proprietary molecules, biologics programs, and oncology-focused work. Partnerships with global companies point to growing confidence in domestic scientific capabilities.

Progress, however, remains uneven. While talent and ideas are available, movement from laboratory research to scalable development often faces constraints. Gaps in validation depth, consistency in quality practices, and coordination between research and manufacturing continue to limit translation. India's next phase depends less on shifting away from manufacturing strength and more on strengthening the systems that connect science with execution.

Software is changing how decisions take shape

As scientific programs grow more complex, organizations increasingly rely on digital systems to support earlier and better-informed decisions. Software now plays a role in reviewing evidence, guiding molecule design, and shaping development plans before major resources are committed. Artificial intelligence (AI) and machine learning (ML) help identify patterns across biological, clinical and real-world data. Large and small language models assist teams in synthesizing scientific literature, prior study results and internal knowledge. Deep learning methods support the interpretation of complex datasets that are difficult to assess manually. These tools allow teams to test assumptions through simulation and scenario analysis before physical work begins.

Clinical development is becoming more connected

Clinical development is moving toward a more continuous way of working. Design, execution, and monitoring are now more closely linked, allowing

teams to follow progress as studies run rather than waiting for final outcomes. This approach supports earlier decisions and clearer visibility during trials. It helps address long-standing issues such as slow recruitment, incomplete data, and late identification of operational risks.

Practices shaping this shift include:

- Earlier use of simulation during trial planning
- Broader inclusion of real-world evidence when shaping protocols
- Ongoing review of data quality during execution

Together, these changes help reduce uncertainty during development and shorten the time between insight and action.

Manufacturing enters earlier into development

Manufacturing now plays a role much earlier in development. Biologics and advanced therapies place higher demands on production, including precise process control, flexible facility design, secure handling and reliable temperature management. As a result, manufacturing teams engage earlier to guide scale-up planning, cost expectations and quality readiness. Research decisions influence production outcomes, while manufacturing constraints shape development choices. This shift improves reliability but increases interdependence across functions. Manufacturing has become part of innovation planning rather than a downstream step.

Supply continuity shapes development outcomes
Development programs depend on steady access to materials and logistics. Gaps in inputs can delay progress even when scientific results remain strong. Advanced therapies increase this sensitivity. Availability of vectors, enzymes and specialized single-use components directly influences development timelines. Dependence on limited suppliers adds pressure as programs move from early studies toward scale. As a result, supply planning now begins earlier in development. Organizations focus on diversification, selective localization, and closer coordination across regions rather than waiting until commercialization. Supply resilience has become a design requirement rather than a corrective step.

Where progress still breaks down

Despite advances across science, software and manufacturing, many programs continue to struggle during scale-up. The underlying issue is fragmentation. Work often moves in sequence rather than in coordination. Decisions pass through handoffs instead of shared systems. Constraints surface late when changes carry higher costs and risks.

Common gaps include:

- Limited visibility across functions
- Delayed recognition of manufacturing or supply limits
- Misalignment between development timelines and execution readiness

As a result, promising therapies stall not because science falls short, but because execution lacks alignment. This pattern appears across organizations and regions, pointing to a structural issue rather than an isolated failure.

Integration becomes essential

The next phase of biopharma requires integration across discovery, development, manufacturing, quality and supply. Organizations that align these areas early gain clearer visibility into risk. They adjust programs sooner and scale successful assets with greater confidence.

Integrated models support:

- Earlier identification of constraints
- Smoother movement between development stages
- Consistent quality across portfolios
- Better cost control for complex therapies

Integration does not guarantee success, but it reduces avoidable failure.

India's opportunity in the integrated model

India brings together several important capabilities, though not all at the same level of maturity. The country has a growing base of scientific activity, strong digital engineering depth, and large manufacturing capacity built over decades. CRDMOs increasingly support global programs across research, development and production, and select

licensing agreements indicate rising confidence in Indian-origin science.

At the same time, challenges remain. Progress across the ecosystem is uneven, and coordination often depends on individual organizations rather than shared systems.

Key gaps include:

- Limited depth in late-stage translation and validation
- Variation in quality practices across institutions
- Weak linkage between research, development and scale

India's opportunity lies in connecting what already exists. Clear pathways, consistent practices, and stronger integration between science, software and manufacturing can help convert capability into repeatable execution.

Policy and ecosystem signals

Policy developments are increasingly fostering integration with global biopharma networks. Initiatives such as the Biopharma SHAKTI program announced in Budget 2026 allocate INR10,000 crore over five years to establish India as a global pharmaceutical manufacturing hub. The program aims to enhance capabilities across the value chain, including improved biopharma research through upgraded National Institutes of Pharmaceutical Education and Research (NIPERs), a national network of over 1,000 accredited clinical trial sites, and strengthened regulatory capacity through dedicated scientific review teams. Additional measures such as customs duty relief on select high-value drugs and expanded health training can further bolster the ecosystem.

These efforts mark a shift from creating capacity to building capabilities—investing in talent, clinical infrastructure, regulatory science and translational pathways. This approach can shorten the time from lab to market, enhance regulatory confidence in Indian programs and attract global biopharma partnerships.

However, coherence remains a challenge. Fragmentation across institutions and systems limits effectiveness. The success of these initiatives will depend on their ability to connect academic science with Contract Development and Manufacturing Organization (CDMOs), clinical sites with digital platforms, and regulatory reforms with advanced manufacturing practices. Aligning these efforts into a unified model can help India transition from a cost-competitive producer to a globally trusted hub for advanced biopharma innovation.

Looking ahead

The next phase of biopharma will depend less on individual breakthroughs and more on the ecosystems built around them. Science opens new possibilities, but decisions, development and delivery determine whether those ideas reach patients. Progress now relies on alignment across research, digital tools, manufacturing and supply. When these parts work together, innovation moves with greater predictability. When they remain disconnected, delays and cost pressures persist. The direction forward is clear. Sustainable progress will come from integration, discipline and execution across the full lifecycle of medicine development.

Chapter

01

Science: Innovation shifting to novel drugs and platform biology

The pharmaceutical industry is being re-architected, globally and in India. For decades, small-molecule generics and established portfolios drove growth, delivering affordability and access at scale. That model remains foundational for India, but may no longer sufficient for the next wave of therapeutic complexity and competitive differentiation.

While small molecules account for ~46% of global prescription sales by revenue in 2025; biologics represented 54%, up from 50% in 2022. By 2028, biologics are expected to account for nearly 60% of global prescription sales revenue[1]. The industry is expanding into advanced modalities such as biosimilars and next-generation biologics, peptides, antibody-drug conjugates (ADCs), oligonucleotides, bispecific and multifunctional biologics, and cell and gene therapies, where precision, outcomes and durable IP increasingly define value.

This shift is not just a change in molecules. It is a change in how innovation is produced. Biopharma is moving from one-off products to platform-led discovery, where reusable technology engines such as antibody engineering systems, mRNA toolkits, gene editing frameworks, synthetic biology design loops and AI-enabled experimentation can generate multiple assets, faster and with compounding learning.

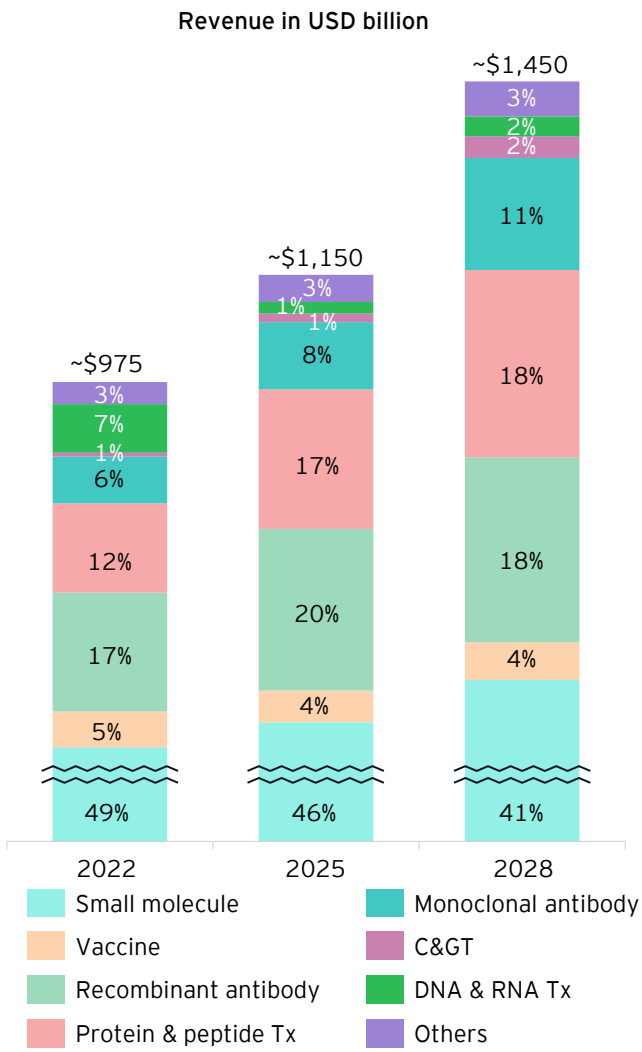
Historically, target identification and lead optimization followed a largely manual and sequential process. Drug targets were chosen from known biological pathways, compound screening relied on large laboratory experiments conducted in batches, and disease classification was based on fixed diagnostic categories. Lead optimization typically focused on refining one molecule at a time, with limited ability to reuse learnings across programs. This linear model meant long timelines, high failure rates and massive development costs that exceeded US$2.5 billion per approved drug in some cases[2].

Today, platform-led and AI-enabled discovery models are replacing the earlier approach. Advances in machine learning, robotics and computational biology allow teams to identify targets, design molecules, and improve leads in parallel rather than sequentially. Using reusable foundations such as gene editing systems, mRNA technologies and AI-driven antibody design, platform science enables learning from one program to inform many others.

[1] https://resources.pharmalinkage.com/industry-news/analyzing-the-global-pharma-industry-growth-trends-and-strategic-outlook-for-2024/
[2] https://greenfieldchemical.com/2023/08/10/the-staggering-cost-of-drug-development-a-look-at-the-numbers/

1.1 The modality shift: What is changing and why it matters

Global prescription sales by modality (US$ billion), 2022-28F



	Modality	CAGR (25-28F)
Emerging	Cell and Gene Therapy	35%
	DNA & RNA Tx	20%
	Monoclonal antibody	19%
	Protein & peptide therapeutics	10%
	Recombinant antibody	5%
	Others	8%
Conventional	Small molecule	4%
	Vaccine	6%

Others include oncolytic virus, PROTACs, plant extracts, plasma-derived therapies

Source: Evaluate Pharma. Data as of December 2025. Not reviewed by Evaluate analysts

Heading: Global number of assets in pipeline by modality and stage, 2026

Modality	Pre-clinical	Phase 1	Phase 2	Phase 3	Launched / Filed
Small molecule	5,471	2,149	2,109	802	722
Vaccine	632	271	280	122	722
ADCs	559	177	105	49	26
Antibodies	1,466	619	550	254	549
Protein and peptides	395	182	230	110	123
Nuclei acid	1,827	566	572	100	123
Cell and gene therapy	1,406	535	470	92	263

Source: Citeline. ADCs: antibody-drug conjugates. Data as of January 2026

Small molecules are currently the larger chunk in the development pipeline across all stages, with the highest absolute number of launched products. EY analysis of Evaluate data shows that in 2025, the top five small-molecule products (Eliquis, Biktarvy, Jardiance, Trikafta and Farxiga) generated more than US$58 billion in combined revenue, with the top 10 reaching US$94.4 billion. By 2028, a refreshed cohort of small molecules is expected to enter the top ranks. There are increased investments in biologics, next-generation therapies and a vibrant biotech start-up landscape, supported by deeper collaborations, licensing and acquisitions.

This strategic shift in the industry is not primarily about the number of assets, but about value concentration, scientific complexity and long-term differentiation. As programs advance into later clinical stages and commercialization, advanced modalities, particularly biologics, nucleic acid-based therapies and cell and gene therapies, account for a growing share of clinical and commercial focus, despite higher attrition rates driven by scientific, manufacturing and regulatory challenges.

1.1.2 Biologics and biosimilars: The "industrialization" of complexity in India

Biologics and biosimilars are increasingly becoming important to the advancement of India's biopharmaceutical sector, signifying a transition from conventional small-molecule generics to high-value, complex therapies. On a global scale, biosimilars are gaining momentum as patents for significant biologic drugs expire, presenting opportunities for cost-effective alternatives that enhance accessibility and lower healthcare expenses.

India is evolving from a generics leader to a more diverse biopharma hub. Over the past few years, Indian pharma companies have steadily increased their investments in novel biologics and next-generation therapies, marking a clear shift from volume-driven generics toward innovation-led growth. Biologics and biosimilars now represent a critical bridge between India's manufacturing-led legacy and the next phase of innovation.

To achieve revenue growth and margin improvement, leading pharma companies are pivoting toward complex formulations including injectables, biosimilars, peptides and modified-release drugs, as well as advanced and specialty therapies that demand significantly higher levels of technical sophistication, regulatory rigor and capital commitment. Biosimilars industrialize complexity. They demand analytics-heavy comparability, robust quality systems and consistent biologics manufacturing — capabilities that translate directly into next-generation biologics and emerging modalities.

Currently, biosimilars constitute a rising proportion of biologic utilization worldwide, especially in oncology and chronic disease management, bolstered by supportive regulatory frameworks and a growing number of approvals[3].

Beyond oncology and immunology, monoclonal antibody (mAbs) drugs are expanding into cardiovascular, metabolic and gastroenterology. Pharma companies are securing antibody platforms that offer durable differentiation and can scale across multiple indications.

India is emerging as a significant player in the biosimilars market, with over 100 biosimilars approved domestically, including insulin, monoclonal antibodies, and various other therapeutic classes[4]. Leading companies such as Biocon, Zydus and Intas are at the forefront of development and global commercialization efforts[5]. Recent achievements, including the launch of the world's first nivolumab biosimilar in India[6], underscore the nation's scientific capabilities and increasing global significance.

India's leaders in biosimilars have already built deep experience across regulated-market development, quality systems and global regulatory filings. The next step is a strategic shift from biosimilar execution to proprietary biologics and platform-enabled assets, where differentiation is created upstream in discovery and engineered into manufacturability from the outset. For instance, initiatives such as Ichnos Glenmark Innovation's (IGI) trispecific antibody platform illustrate how platform science can efficiently produce multiple differentiated candidates instead of relying on one-off therapies[7]. IGI's proprietary BEAT® Multispecific™ platform allows for the engineering of antibodies that engage multiple

[3] https://www.amecoresearch.com/market-report/vaccines-market-277122
[4] https://www.biospectrumindia.com/features/18/26042/25-transformative-years-of-biosimilars.html?utm_source=chatgpt.com.
[5] https://www.ihealthcareanalyst.com/global-infectious-disease-vaccines-market/
[6] https://www.zyduslife.com/investor/admin/uploads/21/83/Zydus-launches-the-world-s-first-biosimilar-of-Nivolumab---Tishtha----in-India-to-treat-multiple-cancers.pdf
[7] https://news.abbvie.com/2025-07-10-AbbVie-and-Ichnos-Glenmark-Innovation-IGI-Announce-Exclusive-Global-Licensing-Agreement-for-ISB-2001,-a-First-in-Class-CD38xBCMAxCD3-Trispecific-Antibody

targets simultaneously. Its lead product, ISB 2001, is a trispecific T-cell engager that targets BCMA and CD38 on multiple myeloma cells and CD3 on T cells, currently in Phase 1 clinical trials. The platform's design logic, which utilizes common light chain libraries and optimized heavy chain pairing, facilitates the creation of structurally complex immune engagers with improved target binding, manufacturability, and stability.

Beyond ISB 2001, the platform is being positioned as a reusable discovery engine capable of generating next-generation multispecifics across multiple oncology and autoimmune targets, illustrating how a single engineering framework can underpin a portfolio of assets rather than a solitary program. According to the company, IGI's multispecific antibody pipeline consists of three assets. This includes ISB 2301, which is in the discovery stage for application in solid tumors. ISB 2001 and ISB 1442 are orphan drugs designated by the US Food and Drug Administration (FDA). ISB 2001 is currently in Phase 1 clinical study for relapsed/refractory multiple myeloma. ISB 1442 development has been discontinued and the asset prepared for out-licensing [8][9].

Approaches such as IGI's trispecific antibody platform and the out-licensing of its lead oncology candidate highlight India's potential to develop complex biologics with global significance and its evolution into a broader innovation base, capable of supporting differentiated biologics, attracting global partners and engaging more in high-value segments of the biopharma value chain.

1.1.3 Vaccines: Moderate growth rate with emerging therapeutic areas

Pandemic preparedness and the need for rapid-response capabilities, rather than routine immunisation alone, is shaping vaccine innovation. Traditional vaccine development models, which often spanned a decade or more, are poorly suited to fast-evolving pathogens. In contrast, plug-and-play vaccine platforms reuse validated biological backbones across pathogens, reducing repetitive safety, formulation and manufacturing steps, and enabling faster regulatory review and deployment.

Advances in Artificial Intelligence (AI) further accelerate this shift by improving antigen design, immunogenicity prediction, and candidate optimization through computational modelling. Combined with mRNA and recombinant platforms, these capabilities support rapid antigen redesign, scalable manufacturing and combination approaches, expanding vaccine pipelines into areas such as RSV, flu-COVID combinations and other respiratory and endemic threats. These trends mark a transition from product-led vaccine development to platform-driven preparedness.

The platform-driven principles are now being applied to advanced therapeutic modalities, where biological complexity and narrow therapeutic windows amplify the need for integrated design and execution.

1.1.4 The frontier: Advanced modalities (ADCs, bispecifics, oligos, CGT, PROTACs)

Advanced modalities such as antibody-drug conjugates (ADCs), RNA therapies and cell and gene therapies are reshaping drug development, with precision medicine and unmet clinical needs driving demand.

Gene and cell therapies highlight both curative potential and the importance of delivery, quality and regulatory discipline, while CAR-T therapies are emerging as early proof points in oncology. Nucleic acid-based therapeutics are entering a more balanced growth phase after their pandemic peak, with renewed momentum across cardiometabolic, neurological, and inflammatory diseases, reflected in strategic transactions such as Novartis' acquisition of Avidity Biosciences[10]. In parallel, targeted protein degradation approaches such as proteolysis targeting chimeras (PROTACs) are expanding the druggable universe, positioning India to participate in globally relevant, platform-enabled innovation.

[8] https://news.abbvie.com/2025-07-10-AbbVie-and-Ichnos-Glenmark-Innovation-IGI-Announce-Exclusive-Global-Licensing-Agreement-for-ISB-2001,-a-First-in-Class-CD38xBCMAxCD3-Trispecific-Antibodyhttps://news.abbvie.com/2025-07-10-AbbVie-and-Ichnos-Glenmark-Innovation-IGI-Announce-Exclusive-Global-Licensing-Agreement-for-ISB-2001,-a-First-in-Class-CD38xBCMAxCD3-Trispecific-Antibody

[9] https://glenmarkpharma.com/gpl_pdfs/investors/announcement/2025/BSE_NSE_PRMDA_signed.pdf#:~:text=ICHNOS%20GLENMARK%20INNOVATION%20(IGI)%20IGI%20features%20a,orphan%20drug%20designation%20from%20the%20U.S.%20FDA.

[10] https://www.ddw-online.com/novartis-acquires-avidity-biosciences-for-12-billion-38522-202511/

The potential of emerging modalities

Modality	Description
ADCs	Next-gen ADCs using controlled conjugation and advanced linker systems can deliver higher efficacy with lower off-target toxicity[11] Bispecifics: Next-gen pipeline and successful products highlight these off-the-shelf alternatives to more complex cell-based therapies
Cell and gene therapy	While CAR-T anchors cell therapy growth, T-cell Receptor or TCR T, Tumor-Infiltrating Lymphocytes or TIL therapies and stem cell products are expanding[12]. Advances with CRISPR are getting regulatory approvals[13]
Nucleic acids	siRNA and antisense therapies are expanding beyond rare diseases. mRNA pipeline is stabilizing and shifting to long-term infectious diseases[14]
Targeted protein degradation	PROTACs and molecular glues are enabling targeting more disease relevant proteins, including those without traditional binding pockets[15]

Indian companies driving new modalities

India now has a sizeable group of companies delivering advanced modalities across high-potency, peptides, ADCs, antibodies and RNA/Oligonucleotides

High potency drugs	Sai Life Sciences Aurigene Cipla Aurobindo Dr. Reddy's Lab Piramal Sun Pharma
Peptides	Piramal Syngene Sai Life Sciences Biocon Aurigene Aragen Dr. Reddy's Lab Strides
ADCs	Syngene Piramal Shilpa Biologics Aragen Cohance Sun Pharma
Antibodies	Syngene Aurigene Biocon Biologics Intas CuraTeQ Lupin Dr. Reddy's Lab Zydus
Oligo and RNA Therapeutics	Aragen Syngene Cohance Chemo India

Source: Company websites

1.2 Platforms powering the shift

The life sciences sector is evolving from a traditional product-by-product R&D approach to a platform-driven model. In this new paradigm, technologies such as AI/ML, CRISPR gene editing, mRNA constructs and advanced antibody platforms are not merely isolated innovations; they serve as repeatable engines that can generate multiple therapeutic candidates across various disease areas. This shift fundamentally transforms the processes of drug discovery, development, and scaling, like how

[11] Antibody–Drug Conjugates (ADCs): current and future biopharmaceuticals | Journal of Hematology & Oncology | Springer Nature Link
[12] CAR T and Beyond: The Expanding Pipeline and Promise of Cell Therapies | Pharmacy Times
[13] https://www.pharmacytimes.com/view/car-t-and-beyond-the-expanding-pipeline-and-promise-of-cell-therapies
[14] https://www.cas.org/resources/cas-insights/sirna-therapeutics
[15] https://www.technologynetworks.com/cancer-research/blog/molecular-glues-meet-precision-discovery-to-advance-oncology-treatments-402140

software platforms facilitate app ecosystems rather than standalone applications.

1.2.1 AI/ML for target discovery, design, optimization

AI and ML are now deeply embedded across the drug discovery pipeline, evolving from isolated analytical tools into integrated platforms that connect biological data, generative modelling and automated experimentation. This transition enables faster design-test-learn cycles, more reliable early-stage insights, and improved predictability in research outcomes. Rather than supporting individual steps, AI-driven platforms increasingly function as reusable discovery engines, allowing learnings from one programme to inform multiple assets and indications.

These capabilities are being delivered through collaborative ecosystems involving technology providers, biotech innovators and pharma companies, reflecting a broader shift toward platform-led innovation. (The new R&D tech stack architecture, components and operating models of AI-native R&D platforms are examined in detail in Chapter 2, where the focus moves from scientific possibility to scalable system design.)

1.2.2 mRNA platforms

The success of mRNA vaccines during the past few years has demonstrated that platform science can deliver results at scale and speed. Companies like Moderna have structured their business models around mRNA platforms[16], allowing multiple programs to utilize the same manufacturing processes and digital design tools, with only the mRNA sequence changing akin to software updates.

How mRNA platforms help discovery, prediction and modeling

- Faster discovery through digital design: mRNA platforms allow scientists to design and test many drug ideas on computers before going into the lab. By changing only the mRNA sequence, researchers can quickly predict which versions are likely to work best, saving time and reducing trial-and-error in early discovery.
- Better prediction of drugs' effect on bodies: Scientists can better predict how the protein made by an mRNA drug could behave, including the immune system's likely respond, before testing it in animals or people[17]. This helps teams choose safer and more effective candidates earlier in development.
- Learning improves with every new program: mRNA drugs use the same delivery and manufacturing approach, which is why data from one project helps improve the next. Over time, companies build better models that make future drug development faster and more reliable[18].

1.2.3 CRISPR and gene editing platforms

CRISPR-Cas9 emerged as a programmable gene-editing technology in 2012. Within five years, it gave rise to venture-backed platform companies such as Editas Medicine (2013) and Intellia Therapeutics (2014).

By 2018–2020, CRISPR-based therapies had entered human clinical trials in the US and Europe[19]. This momentum culminated in 2023–24, when the first CRISPR-based treatments for sickle cell disease Casgevy (exagamglogene autotemcel) from Vertex received regulatory approvals in the US and the UK, marking a historic validation of gene editing as a therapeutic platform rather than an experimental tool[20].

Multiple CRISPR/Cas9 programs have advanced into late-stage development, underscoring growing clinical maturity. These include exa-cel in Phase 3[21] for transfusion-dependent β-thalassemia, NTLA-2001 (Intellia) progressing toward registrational studies for transthyretin amyloidosis[22], among others, collectively reinforcing CRISPR's transition from platform validation to scalable therapeutic deployment[23].

Globally, CRISPR platforms have attracted multi-billion-dollar partnerships and collaborations focused

[16] https://www.modernatx.com/power-of-mrna/modernas-mrna-platform
[17] https://www.nature.com/articles/s41587-022-01386-1
[18] https://www.science.org/doi/10.1126/science.abg4045%5d(https:/www.science.org/doi/10.1126/science.abg4045
[19] First CRISPR Clinical Trial Begins in Europe - Scienceline
[20] FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease | FDA
[21] https://crisprtx.com/about-us/press-releases-and-presentations/fda-accepts-biologics-license-applications-for-exagamglogene-autotemcel-exa-cel-for-severe-sickle-cell-disease-and-transfusion-dependent-beta-thalassemia
[22] https://marketchameleon.com/PressReleases/i/2203055/NTLA/intellia-therapeutics-presents-positive-longerterm-phase-1
[23] https://crisprtx.com/about-us/press-releases-and-presentations/crispr-therapeutics-reports-positive-results-from-its-phase-1-carbon-trial-of-ctx110-in-relapsed-or-refractory-cd19-b-cell-malignancies

on in-vivo genetic therapies, diagnostic tools (e.g., Cas12/13-based sensing platforms), and innovative therapeutic constructs. A notable example is Intellia Therapeutics, a pioneer in CRISPR-based genome editing, which has developed programs targeting hemoglobinopathies like sickle cell disease, demonstrating the use of the same platform across diverse indications[24].

1.2.4 Synthetic biology platforms

Instead of relying solely on complex chemical synthesis or extraction from natural sources, scientists are now designing biological pathways in engineered microbes to efficiently and sustainably manufacture compounds, including pharmaceuticals, fine chemicals and specialty products. Synthetic biology integrates genetic engineering, metabolic pathway design, computational modeling and systems biology to create or rewire biological systems. This approach enables the construction of entirely new biosynthetic pathways in microorganisms, leading to the production of small molecules that were previously difficult, expensive or inefficient to manufacture using classical methods.

Beyond small molecules, several recombinant proteins, peptides, vaccines, mAbs and hormones are being manufactured using synthetic biology. Synthetic biology enabled the engineering of yeast and bacteria with a multigene biosynthetic pathway to produce artemisinic acid, the key precursor to the antimalarial drug artemisinin. This microbial process replaced the historically variable and costly extraction of artemisinin from Artemisia annua. As a result, semisynthetic artemisinin can now be reliably and efficiently produced on a commercial scale, significantly improving supply stability and reducing costs.

Biosynthesis pathway

Another frontier enabled by synthetic biology is the activation of cryptic biosynthetic gene clusters (BGCs), dormant clusters in microbial genomes that encode pathways for potentially valuable small molecules that have never been observed under normal laboratory conditions. By employing genome mining, pathway refactoring and heterologous expression techniques, researchers can unlock this hidden metabolic potential to discover new compounds and establish entirely new biosynthetic routes[25].

Advances in synthetic biology are transforming the production of traditional molecules by designing and implementing new biological pathways in engineered microbes. By combining metabolic engineering, computational design and modular biological parts, synthetic biology is enabling sustainable, scalable and economically viable routes to valuable compounds[26].

1.2.5 Data ecosystems and digital twins

Data ecosystems and digital twins act as the connective tissue across the new pharma architecture, enabling discovery and development programs to learn across portfolios through connected, governed data foundations spanning genomics, laboratory outcomes and early clinical signals. Digital twins allow teams to simulate biological, clinical and manufacturing scenarios before committing costly experiments or scale-up decisions, improving predictability, and reducing risk. (Their role in reshaping AI-native R&D and clinical development is explored in detail in Chapter 2, while their extension into manufacturing and quality systems is examined in Chapter 3.)

1.2.6 Antibody platforms

Therapeutic antibodies were among the first biologics to display the advantages of platform science. Once a production and optimization platform is established, companies can quickly generate families of antibodies with enhanced specificity, reduced immunogenicity and improved manufacturability.

Recent innovations have integrated AI into antibody discovery and optimization, accelerating discovery cycles and increasing success rates. AI-driven platforms can predict antibody-antigen interactions and identify high-potency candidates, significantly reducing time and costs compared to traditional trial-and-error methods.

In addition to traditional monoclonal antibodies, newer platform variations include bispecific antibodies, ADCs, and programmed immune cell engagers, all built on reusable discovery and engineering frameworks.

[24] https://www.nature.com/articles/d43747-024-00001-1
[25] Discovery of microbial natural products by activation of silent biosynthetic gene clusters | Nature Reviews Microbiology
[26] Synthetic Biology Strategies for Activating Cryptic BGCs in Streptomyces: Engineering Native and Synthetic Promoters for Antibiotic Discovery - PMC

- Genmab has built a reusable antibody engineering platform (DuoBody, HexaBody) that underpins multiple approved and pipeline assets, including Darzalex and next-generation engineered antibodies with enhanced complement activation and effector functions[27].
- Amgen's BiTE platform pioneered T-cell-engaging bispecific antibodies, leading to approved products such as Blincyto and a broad pipeline of next-generation immune engagers[28].
- IGI's proprietary trispecific antibody platform utilizes its BEAT® protein engineering technology. Its lead candidate, ISB 2001, is a first-in-class trispecific T-cell engager that targets BCMA, CD38 and CD3 for treating relapsed or refractory multiple myeloma. Early clinical data and the subsequent global out-licensing to AbbVie demonstrate the scientific strength of the platform and its potential to produce multiple differentiated assets[29].

> "India is still in the early stages of developing next-generation therapeutic platforms such as ADCs, mRNA and CRISPR, though companies are increasingly recognizing their future importance; oligonucleotides are emerging with early activity from several Indian players, placing these technologies today at a maturity level similar to peptides roughly a decade ago.
>
> *Dr. Ganesh Ramachandran, Head-Peptide Purification, Biocon*

1.3 Ecosystem actors: Partnerships, Venture Capital and M&A

Big Pharma and technology partnerships are reshaping innovation

Pharma companies are increasingly joining forces with technology and AI organizations to strengthen discovery and development engines by integrating AI models, real world data resources and simulation tools directly into their core scientific and operational workflows. Examples include:

Sanofi / Open AI / Formation Bio: Aim is to build AI-powered systems that support end-to-end drug development by combining Sanofi's data resources with advanced model building capabilities. AI tool Muse was developed to speed clinical trial recruitment by rapidly analyzing scientific literature, patient demographics and real-world evidence[30].

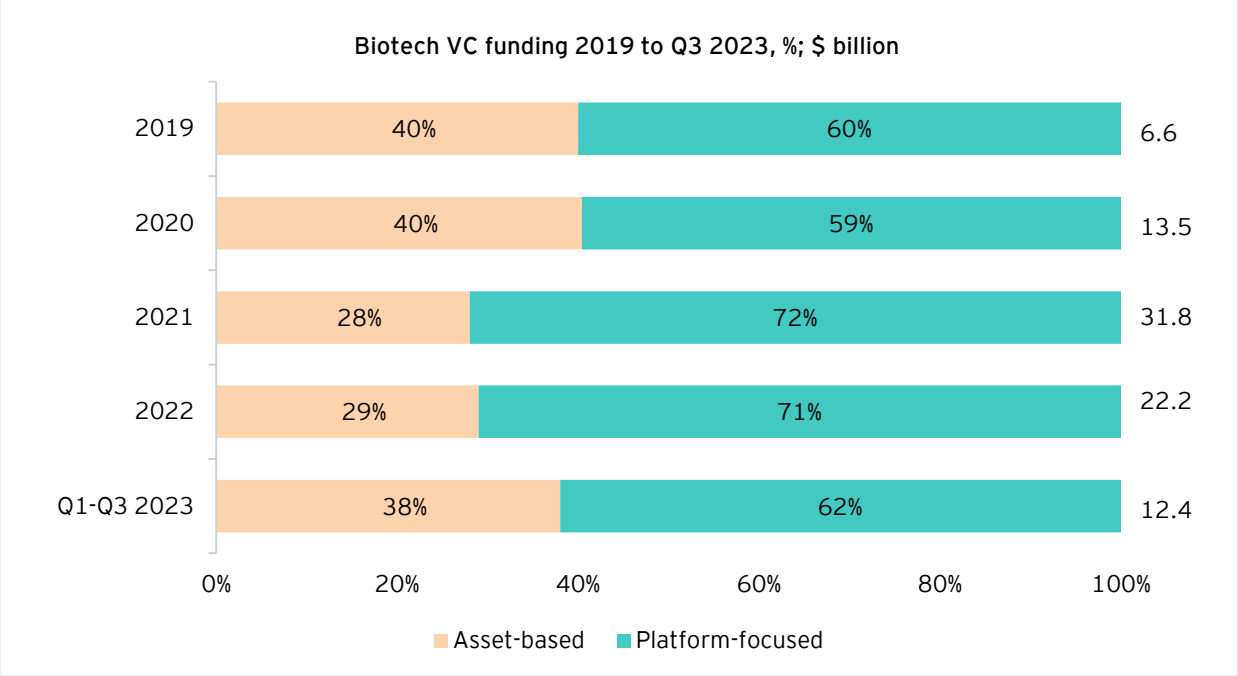
Roche / Flatiron: Roche purchased Flatiron for its oncology-focused electronic health record platform and deep expertise in generating regulatory-grade real world evidence to support precision oncology[31].

Bayer / Recursion: Recursion's massive phenotypic dataset and ML infrastructure are being applied to Bayer's precision oncology research, with the potential to launch multiple new oncology programs under the partnership[32].

[27] https://www.genmab.com/antibody-science/antibody-technology-platforms
[28] https://www.amgen.com/stories/2024/12/ten-years-of-blincyto---celebrating-the-history-impact-and-future
[29] https://www.prnewswire.com/news-releases/abbvie-and-ichnos-glenmark-innovation-igi-announce-exclusive-global-licensing-agreement-for-isb-2001-a-first-in-class-cd38ObcmaOcd3-trispecific-antibody-302501835.html
[30] https://www.formation.bio/blog/introducing-muse
[31] https://resources.flatiron.com/press/press-release/roche-completes-acquisition-of-flatiron-health
[32] https://www.bayer.com/en/us/news-stories/bayer-and-recursion-focus-research-collaboration-on-oncology

Pharma's new architecture

Heading: Platform concentration in VC funding



Source: Pitchbook. Data as of October 2023. Not reviewed by Pitchbook analysts

Venture funding in biotech has tightened in recent years, but capital is concentrating around companies that offer platform breadth rather than single therapeutic assets. While total deal value remains below peak levels, investors continue to commit significant capital to companies with discovery, delivery or computational engines that can generate multiple programs.

Later-stage rounds have grown as investors double down on established platforms with clearer development paths. Examples include major 2025 financings such as MapLight's pre-IPO round, Kriya Therapeutics' large Series D, and additional rounds supporting gene therapy, AI-enabled discovery and advanced RNA platforms[33] [34]. These patterns reflect a flight to quality, where platform companies with repeatable pipelines and differentiated technology attract the strongest support.

M&As move toward securing modality platforms

Across the M&A landscape, large pharma companies are increasingly acquiring entire modality platforms to futureproof their pipelines. A recent example is Novartis' agreement to acquire Avidity Biosciences for approximately US$12 billion for its antibody oligonucleotide conjugate platform and late-stage programs for genetic neuromuscular diseases[35]. This acquisition strengthens Novartis' RNA therapeutics strategy and demonstrates how platform assets can justify transactions at large-cap scale.

Across the industry, platform-centric transactions are gaining momentum as buyers also seek technological engines that can produce future pipelines. These strategic acquisitions reflect a shift toward long-term capability building rather than one-off asset purchasing.

[33] https://finance.yahoo.com/news/maplight-251m-ipo-sees-schizophrenia-114539789.html
[34] https://kriyatherapeutics.com/news/kriya_announces_320_million_series_d_financing_to_advance_pipeline_of_gene_therapies_for_chronic_diseases_of_high_unmet_need/
[35] https://www.ddw-online.com/novartis-acquires-avidity-biosciences-for-12-billion-38522-202511/

1.4. India's position in the new architecture: From volume to value and integration

From "pharmacy of the world," supplying affordable generics and APIs to global markets, India's pharmaceutical ecosystem is leveraging its strengths in scale manufacturing, talent availability and digital capabilities to move towards deeper innovation in complex modalities and platforms. While pharma companies, GCCs, CRDMOs, government strategy and public-private collaborations represent manufacturing capacities, a large talent pool of 900,000-plus people employed across pharmaceuticals and related industries[36] adds to innovation capabilities.

New Chemical Entities (NCEs)

While generics remain economically vital, Indian firms are making significant strides in novel small molecule discovery:

- Wockhardt has built one of India's most advanced innovative anti-infective pipelines, led by Zaynich® (cefepime–zidebactam) — a novel β-lactam/β-lactamase inhibitor (BL/BLI) combination for multidrug-resistant Gram-negative infections that has received US FDA Fast Track and Qualified Infectious Disease Product (QIDP) designations and has progressed to Phase III trials for complicated urinary tract and serious hospital-acquired infections. This is complemented by WCK 4282 (high-dose cefepime/tazobactam, Phase III) aimed at Extended-Spectrum Beta-Lactamase (ESBL) producers as a carbapenem-sparing option, and WCK 6777 (ertapenem/zidebactam), a once-daily Beta-lactam and Beta-lactamase Inhibitor (BL/BLI) regimen with FDA Fast Track status following Phase I completion, to support outpatient treatment of resistant infections. Earlier innovations such as WCK 771 (levonadifloxacin) and WCK 2349 (alalevonadifloxacin) are already approved in India for difficult Gram-positive infections including Methicillin-resistant Staphylococcus aureus (MRSA) and also carry QIDP status.
- **Zydus Lifesciences' Desidustat (Oxemia):** Desidustat is a novel oral hypoxia-inducible factor (HIF)-prolyl hydroxylase inhibitor for anaemia associated with chronic kidney disease, launched in 2022[37].
- **Rhizen's Umbralisib:** Approved by the US FDA in 2021, Umbralisib is an oral PI3Kδ/CK1ε inhibitor for relapsed or refractory lymphoma. Discovered by Rhizen Pharmaceuticals and out-licensed to TG Therapeutics, it is recognized as the first NCE discovered by Indian scientists to secure US FDA approval[38].
- **Orchid Pharma's Enmetazobactam:** This novel β-lactamase inhibitor has been approved in multiple markets, highlighting India's ability to develop clinically valuable NCEs that meet international regulatory standards[39].

Biologics: From biosimilars to proprietary platforms

The biologics segment, historically dominated by multinational firms, is now a key area for Indian innovation. Indian pharma is increasingly building and owning proprietary complex biologics and biotherapeutic platforms:

- **Glenmark Pharma's IGI:** The company's innovation arm entered a US$700 million exclusive licensing deal with AbbVie in 2025 for its cancer candidate ISB 2001, targeting refractory multiple myeloma. This agreement could lead to total milestone payments exceeding US$1.2 billion, reflecting strong global validation of Indian oncology research. This is among India's first success stories on platform-led discovery[40].
- **Biocon Limited**: Proprietary products like Biomab EGFR (a monoclonal antibody for head-and-neck cancer) and Alzumab (Itolizumab) demonstrate innovation capability in complex molecule classes[41]. Biocon collaborated with the Cuban company CIMAB S.A., the commercial arm of the Center of Molecular Immunology

[36] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2085345&reg=3&lang=2
[37] Press_Release_Zydus_to_launch_Oxemia_a_breakthrough_treatment_for_Anemia_in_patients_suffering_from_CKD.pdf
[38] First new chemical entity discovered by Indian scientists gets USFDA approval - BusinessToday
[39] https://www.pharmabiz.com/NewsDetails.aspx?aid=166575&sid=2
[40] https://www.icicidirect.com/research/equity/blog/glenmark-pharma-abbvie-licensing-agreement-watershed-movement-in-indian-pharma
[41] https://journals.sagepub.com/doi/10.1177/2277977918803186#core-collateral-purchase-access

(CIM) in Havana, to develop and market BIOMAb EGFR®[42].

- **Bharat Biotech:** It has recently established CRDMO Nucelion Therapeutics to focus on cell and gene therapy manufacturing and development[43].

CRISPR: India's expanding capabilities and ecosystem

Scientific breakthroughs and an emerging industry ecosystem are adding momentum to India's CRISPR efforts. One of the most notable advances is the development of FnCas9 by researchers at Council of Scientific and Industrial Research (CSIR) Institute of Genomics & Integrative Biology (IGIB). Unlike the widely used SpCas9 enzyme, the Indian FnCas9 offers several advantages in higher mismatch sensitivity, smaller size (efficient delivery into cells, particularly using viral vectors), broader protospacer adjacent motif (PAM) sequence range and improved efficiency and therapeutic potential[44].

FnCas9 has already powered practical applications such as FELUDA, a paper strip CRISPR diagnostic capable of detecting SARSCoV2 variants quickly and cost effectively. CrisprBits[45] is an early pioneer developing platforms for diagnostics and precision medicine.

1.4.2 CRDMOs and Global Capability Centers: India as an innovation hub

India's outsourcing ecosystem is undergoing a structural shift from traditional Contract Research Organization (CRO) and Contract Development and Manufacturing Organization (CDMO) models to fully integrated CRDMOs that combine discovery, development and Good Manufacturing Practice (GMP) manufacturing. Together, they are raising the bar of pharma innovation in India, shifting from simple small molecules to high-value segments like ADCs, biologics, peptides, oligonucleotides and cell and gene therapy.

Many of the Big Pharma in India such as Lupin[46], Alkem[47] and Sun Pharma[48] are also entering this space while some are making larger investments, indicating the focus and shift towards the new areas of opportunity.

New entities and carve-outs driving R&D focus

Over the past two decades, India has seen the emergence of specialized research and development arms and integrated CRDMO platforms:

- **Syngene International:** Biocon's subsidiary has grown into a global CDMO and discovery services provider with integrated small molecule and biologics capabilities[49].
- **Aurigene Pharmaceutical Services:** Biologics and therapeutic protein development firm offers advanced discovery-to-commercial services, including antibody and vector development[50].
- **Cohance Lifesciences / Suven Pharma:** The merged entity creates a multimodality CRDMO platform that brings together ADC payload chemistry, US-based linker and bioconjugation expertise through NJ Bio, and oligonucleotide building block capabilities via Sapala[51].
- **Jubilant Biosys:** Expanded its footprint into Europe by acquiring Pierre Fabre's SaintJulien R&D site, establishing a European center of excellence for biologics and ADC development, integrated with its India-based discovery and CDMO operations[52].

Global Capability Centers (GCCs) are another key pillar of innovation. As a recent EY report points out, out of the top 50 global life sciences organizations, 23 have established GCCs in India[53]. Major areas of innovation include drug discovery and digital therapeutics, in addition to clinical trial operations, pharmacovigilance, regulatory affairs and real-world evidence (RWE) analytics. GCCs are embedding AI for molecule design, predictive diagnostics and virtual

[42] https://www.biocon.com/docs/PR_Biocon_CIM_270910.pdf
[43] https://www.thehindu.com/business/Industry/bharat-biotech-sets-up-crdmo-arm-to-focus-on-cell-and-gene-therapies/article70235291.ece
[44] https://pmc.ncbi.nlm.nih.gov/articles/PMC8571677/
[45] https://crisprbits.com/
[46] https://www.lupin.com/LMS/
[47] https://scanx.trade/stock-market-news/stocks/alkem-labs-unveils-ambitious-growth-strategy-targets-rs-450-500-crore-from-cdmo-business/10121412
[48] https://sunpharma.com/crams/
[49] https://www.syngeneintl.com/
[50] https://www.aurigeneservices.com/
[51] https://njbio.com/2025/06/cohance-lifesciences-and-suven-pharmaceuticals-announce-strategic-merger-to-expand-cdmo-capabilities/
[52] https://www.jubilantbiosys.com/wp-content/uploads/2025/02/Jubilant-Biosys-seals-deal-with-Pierre-Fabre.pdf
[53] Fueling innovation, advancing equity : The power of partnerships and digital-fi rst strategies driving Indian pharma's global dominance

clinical trials, apart from digital twins and immersive technologies across the value chain.

1.4.3 What India must do

In the Indian context, capability is not the constraint; integration and coherence are. From a volume manufacturing base, it is increasingly a part of the global innovation and execution chain across discovery services, development and complex manufacturing. The opportunity now is to convert these strengths into a coherent system: discovery linked to Chemistry, Manufacturing and Controls (CMC) early, digital evidence linked to regulatory credibility, and manufacturing linked to real-time quality and resilient inputs. Building integrated platforms across science, software and supply can determine whether India becomes a supplier to the world or a platform for the world's next wave of biopharma innovation.

1.5 Global integration and ecosystem support

Beyond company-led innovation, India's growing reputation as a hub for clinical trials and R&D services enhances its evolution. Global firms, such as Takeda exploring trial hubs in India and Amgen establishing a US$200 million innovation center focused on data science and drug discovery, signal increased integration into the global life sciences innovation landscape.

Institutional support from organizations like BIRAC, DBT, ICMR and World Bank-backed initiatives like the National Biopharma Mission (NBM), biotechnology parks and incubators, and Centers of Excellence (CoEs) are creating a more supportive environment for startups and biotech innovators, fostering advancements in novel therapeutics and diagnostics.

While generics and volume manufacturing remain foundational to India's pharmaceutical strength, the country is clearly transitioning toward an innovation-led momentum. Supported by policy vision, public-private collaboration, breakthrough NCEs, proprietary biologics and significant oncology research partnerships, India is emerging as a credible contributor to global drug discovery and advanced therapeutics.

Platform science changes the innovation frontier but it also raises the bar on execution. As modalities become more complex, the limiting factors shift to decision speed, evidence quality, manufacturability, and reliable scale-up. This is where software becomes central: AI-native R&D and clinical development create faster feedback loops and move uncertainty upstream. In the next chapter, we examine how software is redefining the economics and speed of development, and why the winners will be those who build governed data foundations, validated AI workflows, and continuous decision systems across the lifecycle. As complexity rises, the limiting factor in delivering therapies is no longer discovery alone; it is how decisions are made, how evidence is synthesized, and how programs execute reliably.
Increasingly, leading organizations are responding through platformization: building reusable scientific, digital and manufacturing platforms that standardize execution while accelerating learning across programs. These platforms convert fragmented efforts into repeatable systems, enabling faster iteration, shared infrastructure and portfolio-level risk management. The shift from product-led to platform-driven models is becoming a defining trend in biopharma, allowing companies to move multiple assets forward in parallel, shorten development cycles, and scale innovation with greater consistency and confidence.

Our next chapter explores how software and AI are reshaping these decision systems across discovery and clinical development.

> "A standalone algorithm is a science project, and a platform without intelligence is just expensive plumbing; the value comes from integrating specialized AI into a governed, scalable platform.
>
> *Dr. Olga Kubassova, CEO and President, Image Analysis Group*

Chapter

02

Software: AI-native R&D and clinical development are redefining speed and scale

Therapeutic research is undergoing a major transformation, and this shift is influencing how medicines are discovered, tested and brought to market. Traditional development followed a fixed, linear sequence; first discovery, then preclinical work, followed by trials and launch planning. Today, this path is becoming more connected and flexible. Digital tools link activities across research, clinical development and regulatory preparation, allowing teams to work with greater speed, clarity and coordination.

Software is changing how therapeutic research is planned and carried out by helping teams address risks much earlier. Instead of waiting until later stages, teams can plan, make estimates, run tests and learn from the beginning. This approach allows discovery, Chemistry, Manufacturing, and Controls (CMC), clinical development and regulatory work to move forward at the same time rather than in sequence. As these activities progress together, decisions can be made sooner and with clearer information. Speed is no longer only about finishing tasks faster. It now depends on how quickly teams can make the right choices. Together, these shifts point to a new way of building and managing the drug development process; one grounded in this new architecture.

> “
>
> AI rapidly designs novel, highly selective small-molecule drug candidates. For example, a strong-scaffold, druggable JAK2 inhibitor that outperforms early-stage comparators, with accuracy validated through wet-lab testing, and a workflow (AI → MD simulation → lab) that compresses preclinical discovery from 5–6 years to a fraction of the time.
>
> *Prof. Kil To Chong, Jeonbuk National University, South Korea*

2.1 The AI-native R&D stack: From scientific intelligence to execution

The entire drug development journey is shifting across the full continuum, from lead selection and optimization to preclinical studies, clinical trials and regulatory review.

A modern ecosystem for AI-native R&D technology stacks can reshape how next-generation drug discovery and clinical development can evolve. With six-point interconnected layers it supports the entire R&D lifecycle through a layered, end-to-end architecture that integrates intelligence, design, simulation, execution, evidence generation and regulatory enablement into a unified system. Rather than operating as isolated functions, these six discrete yet tightly connected layers form a coherent, data-driven pipeline that accelerates scientific insight, improves experimental efficiency, and strengthens regulatory readiness across the continuum of research and development.

- The Scientific intelligence layer brings together literature mining, patent analytics, multi-omics interpretation, and knowledge graphs to transform vast, high-dimensional biomedical data into actionable hypotheses.
- The Design layer applies generative chemistry, protein and molecule design, Quantitative Structure-Activity Relationship (QSAR) modeling, ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) prediction, and molecular docking to rapidly create and prioritize high-quality therapeutic candidates.
- The Simulation layer leverages digital twins, mechanistic models and in-silico experiments to predict molecular behavior, optimize compounds and reduce costly wet-lab iterations.
- The Execution layer orchestrates laboratory automation, robotic experimentation, electronic lab notebooks (ELN), laboratory information management systems (LIMS), and workflow engines to translate computational designs into reproducible experimental outcomes at scale.
- The Evidence layer integrates clinical trial analytics, real-world evidence, pharmacovigilance, safety monitoring and quality signals to generate robust, longitudinal proof of efficacy, safety, and value.
- The final Regulatory layer enables structured submissions, full data traceability, model governance, and audit-ready documentation to enable credibility, compliance and trust in AI-driven R&D decisions.

Six layers of an AI-native R&D technology stack
It can steer the progress of next-generation drug discovery and clinical development

Scientific intelligence	Converts large volumes of high-dimensional biomedical data (literature mining, patent analytics, multi-omics interpretation, knowledge graphs, etc.) into actionable hypotheses.
Design	Helps rapidly create and prioritize high-quality therapeutic candidates using generative chemistry, protein and molecule design, Quantitative Structure-Activity Relationship (QSAR) modelling, ADMET prediction, etc.
Simulation	Helps predict molecular behavior, optimize compounds and reduce costly wet-lab iterations using digital twins, mechanistic models and in-silico experiments.
Execution	Translates computational designs into experimental outcomes that can be used at scale, using lab automation, robotic experimentation, electronic lab notebooks (ELN), workflow engines, etc.
Evidence	Generates robust, longitudinal proof of efficacy, safety, and value based on clinical trial analytics, real-world evidence, pharmacovigilance, safety monitoring and quality signals.
Regulatory	Builds credibility, compliance, and trust in AI-driven R&D decisions through structured submissions, full data traceability, model governance, and audit-ready documentation.

The Indian government's Budget 2026 positions AI and digital transformation as national priorities, with higher investment expected in interoperable platforms, data governance and AI-assisted tools to support real-time analytics, clinical decision-making, and digital health delivery, including deeper integration of Ayushman Bharat Digital Mission (ABDM) and Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) ecosystems.

As a result, the drug lifecycle is becoming more coordinated and responsive. This chapter examines how modern tech stack ecosystem is reshaping the journey from early scientific ideas to therapies reaching patients. The shift is driven mainly by progress in digital capabilities and data ecosystem, which now allow tasks to run in parallel, reduce repeated failures, and lower both time and risk in testing new medicines.

> "AI has the strongest potential in three areas: discovery using genomics and omics data, translation from pharmacology to clinical readiness, and late-stage manufacturing operations.
>
> *Dr. Narendra Chirmule, Co-founder, Symphony Technologies and Visiting Professor, IIT Mumbai*

2.2 Scientific intelligence copilots: Evidence-first hypothesis generation

Instead of assessing one compound at a time, teams can now evaluate multiple options simultaneously using shared and dynamic datasets. Large language models (LLMs) and agents give researchers deeper insight into which targets are most viable and how proteins behave under different conditions.

Modern tools are removing traditional R&D bottlenecks to deliver faster, smarter results using GenAI, graph-based approaches, Natural Language Processing (NLP) and physics-driven simulations to help researchers assess targets, design stronger molecules and lower preclinical risks. Across the value chain, drug research is changing as digital tools reshape how work is planned and carried out.

Two broad categories of LLMs are evolving to serve distinct purposes across the R&D value chain: Scientific Copilots and Operational Copilots. The cognitive burden of synthesizing millions of scientific

publications is a significant bottleneck that AI-native blueprints address through knowledge graphs and LLM copilots. Scientific Copilots support this core discovery and innovation activities such as hypothesis generation, target identification and molecular and protein design, enabling faster and more informed scientific decision-making. These systems are designed to reduce the burden associated with documentation-heavy and compliance-driven workflows. While human researchers struggle to forge connections among disparate diseases and genes, advanced models like BioGPT and ChatPandaGPT are pre-trained on extensive text data to identify potential drug targets faster.[54]

In contrast, Operational Copilots focus on downstream execution by enhancing laboratory operations, clinical documentation, quality processes, regulatory workflows and compliance, thereby improving efficiency, traceability and operational rigor across R&D and clinical development.

Traditional Computer-Aided Drug Design (CADD) often failed to capture the adaptability of biological targets. New deep learning models and Generative Adversarial Networks (GANs) can create optimized molecular structures that target specific biological activities while improving safety profiles.

Knowledge graphs act as a structured semantic network, connecting disparate dots between genes, proteins, diseases and drugs. When integrated with LLMs through Retrieval-Augmented Generation (RAG), these "copilots" allow scientists to query in natural language. LLM copilots can synthesize decades of research into a validated hypothesis in minutes. Many leading industry players are experimenting with LLM assistants. For example, Google DeepMind's recently announced AI co-scientist for biomedicine can analyze vast bodies of scientific literature and generate novel research hypotheses. In preliminary experiments, it suggested multiple promising approaches to inhibit liver fibrosis, a condition marked by scarring that has long lacked effective treatments, by synthesizing insights faster and at a scale beyond traditional manual review[55]. This capability suggests that AI systems can augment expert researchers and accelerate early discovery workflows. Companies like Atomistic Insights[56] enhance understanding of protein dynamics by revealing cryptic binding sites and dynamic transitions in half a day on a single GPU. Traditional simulations used to take months to a year on a supercomputer to reveal only shallow binding sites and dynamic changes.

New AI platforms with embedded copilots are emerging that enable precise engineering of therapeutic molecules which selectively target tumors while minimizing off-target effects, addressing one of the most pressing challenges in cancer treatment. Beyond discovery, these copilots guide decisions across research, clinical development and regulatory preparation, helping teams operate in a more connected, data-driven and coordinated manner across the R&D lifecycle.

LLMs can also map several potential targets, enabling pharmaceutical researchers to explore hypotheses more efficiently. The impact is improved disease classification through technology-driven analysis, enabling clearer diagnosis and more targeted treatment planning. It also supports faster and better-informed clinical decisions by simplifying complex medical data for healthcare professionals. A specialized LLM trained in the molecular Simplified Molecular Input Line Entry System (SMILES) language can support retrosynthetic planning and reaction outcome prediction.

Heading: LLMs and copilots: The shared and dynamic dataset advantage

Instead of sequential steps, researchers can evaluate different options together, which improves speed and accuracy of hypotheses, disease classification, clearer diagnosis, more targeted treatment planning, and faster and more-informed clinical decisions.

[54] Artificial Intelligence in Biopharmaceutical: Revolutionizing Drug Discovery Amidst Industry Challenges; https://www.researchgate.net/publication/392201814_Artificial_Intelligence_in_Biopharmaceutical_Revolutionizing_Drug_Discovery_Amidst_Industry_Challenges/citations
[55] https://www.reuters.com/technology/artificial-intelligence/google-develops-ai-co-scientist-aid-researchers-2025-02-19/
[56] Atomistic Insights

Tool/Capability	Purpose	Impact
Scientific Copilots	Synthesize millions of scientific publications and literature for core discovery, hypothesis generation, target identification, molecular and protein design	Higher efficiency
Operational Copilots	Streamline downstream execution in lab ops, clinical documentation, quality, regulatory workflows	Improved traceability, compliance rigor across R&D/clinical
Deep learning models, Generative Adversarial Networks (GANs)	Create improved, data-driven molecular structures that target specific biological activities	Reduced time and cost of drug discovery; improved safety
Knowledge graphs	Link genes, proteins, diseases and drugs. If integrated with LLMs through Retrieval-Augmented Generation (RAG), allow queries in natural language	Faster discovery, structured reasoning

> Generative AI can now unlock intelligence hidden in physician notes, scans and unstructured clinical records.
>
> *Ajay Nyamati, Co-founder and CEO, Kitsa*

2.3 In silico design: molecules, proteins, and properties before synthesis

GenAI is transforming nearly all aspects of the pharmaceutical industry. With the rise of AI-powered generative chemistry, researchers can now design molecules more rapidly, simulate chemical properties with greater accuracy, and optimize molecular structures far more intelligently than in traditional workflows. Next-generation LLMs contribute by learning to predict the next substructure within complex molecules, such as nucleic or amino acid sequences, and by generating deeper insights into large-molecule chemistry. These capabilities enable insilico design of novel drug vectors and improve early predictions of efficacy across multiple drug discovery assays. Insilico Medicine's AI-discovered fibrosis drug entered Phase II trials in only 12-18 months[57].

A similar leap is occurring in protein design. Traditional drug discovery pipelines have long been constrained by limited and incomplete protein structure data, as experimental methods often struggle to capture full structural and conformational complexity, leading to uncertainty in downstream design. LLMs, adapted to proteomics as protein language models (pLMs), treat amino acid sequences as a language, allowing them to computationally model structure, function and interactions. This approach is accelerating the discovery of high-affinity drug candidates by enabling more accurate protein engineering and reducing reliance on slow, trial-and-error experimental cycles.

Drug discovery is increasingly shaped by AI-driven approaches that help guide scientific decisions before laboratory work begins. Tools such as Quantitative Structure-Activity Relationship (QSAR) models and molecular docking allow researchers to assess whether a new molecule is likely to perform as intended prior to synthesis. Molecular docking simulations offer deep insights into the biological activity of novel compounds with impressive accuracy. This stage focuses on creating new chemical structures using molecular modelling, generative algorithms, fragment linking, activity prediction and chemical space exploration

AI models can also assist chemists in designing new molecules guided by desired properties, such as improved binding affinity to specific targets. In addition, these models can aid ADMET prediction (assessing absorption, distribution, metabolism, excretion and toxicity), to filter out compounds with unfavorable characteristics early in drug discovery.

[57] First Generative AI Drug Begins Phase II Trials with Patients | Insilico Medicine

2.4 Digital twins and simulation: Narrowing uncertainty with context-of-use models

The Fourth Industrial Revolution has reshaped biopharma through greater use of data, automation and connected digital systems. Among these advances, digital twins are emerging as a powerful tool in drug discovery and clinical research. A digital twin is a virtual model of a biological system that is continuously refined using real-world data, allowing researchers to study complex behavior without relying solely on physical experiments. While the concept originated in engineering, its application is now expanding rapidly within biomedical research.[58]

Most digital twins used in biopharma today are narrow twins rather than full organism-level models. These are built for a clearly defined context of use, such as mechanism-of-action simulation, pharmacokinetics and pharmacodynamics (PK/PD) modeling, or specific trial operations.

In discovery, digital twins allow scientists to simulate disease pathways, predict how molecules interact with biological targets, and evaluate potential safety signals before laboratory testing begins. By integrating genomic, proteomic, and clinical data, these models support faster hypothesis testing and more informed candidate selection. At the discovery stage, a digital twin can be used to predict target binding alongside potential off-target toxicity risk, helping researchers compare candidate molecules earlier.

In clinical development, digital twins can model patient responses, simulate trial scenarios, and help anticipate variability across populations. In early kinase discovery, cardio-toxicity due to hERG inhibition remains a major cause of late-stage failure. A Discovery Twin integrates ML-based kinase affinity prediction with dedicated hERG risk models, supported by docking and uncertainty scoring[59]. High-risk analogs are removed before synthesis, while candidates with strong predicted potency and low cardio-risk advance to wet-lab testing. This approach mirrors published ML-led hERG screening patterns and supports safer, earlier design decisions. At the clinical stage, digital twins can simulate trial arms, estimate patient dropout, test endpoint sensitivity, and assess site-level performance before trials begin. This enables more focused study design, earlier risk identification and reduced reliance on lengthy trial-and-error cycles.[60] In Phase II oncology, a Clinical Twin simulates ORR@Week 12 and PFS@Week 24 (Overall Response Rate and Progression-Free Survival)[61] under estimand-aligned frameworks while accounting for ~20% patient dropout. Virtual trials incorporate intercurrent events, Missing Not At Random (MNAR) sensitivity, and external benchmarks to test design robustness. Results support a hybrid strategy with ORR as the primary endpoint and PFS as a key secondary, achieving required power with fewer patients and a faster readout while remaining aligned with regulatory expectations. While challenges remain around data quality and biological complexity, continued collaboration between computational scientists, biologists, and clinicians is steadily strengthening these models and expanding their role across the research continuum.

During early-stage simulation and modeling, molecular dynamics (MD) are used to understand how molecules and proteins behave in realistic conditions. Atomistic molecular dynamics helps check whether a binding pose is stable, and enhanced sampling methods explore additional shapes and movements that molecules may adopt. Free energy methods are used to estimate how strongly a molecule may bind, which supports decisions on which molecules should advance. To keep the environment realistic, membrane proteins are simulated in proper lipid bilayers, and flexible proteins and antibodies are treated as moving ensembles. Docking results are validated with molecular dynamics to remove false positives and confirm stability. In silico trials are also used to test many possible outcomes on a computer before any real experiment takes place. Together, these simulation-driven insights form the foundation for decisions that later shape clinical trial design, execution, and risk planning.

As development moves molecular simulation into human testing, these predictive principles extend into the clinical trial lifecycle through Clinical Trials 4.0. This model reframes from trials as a connected sequence of design, recruitment, execution, monitoring, analysis and reporting.

[58] Frontiers | The digital twin in neuroscience: from theory to tailored therapy
[59] https://link.springer.com/article/10.1186/s13321-020-00479-8
[60] Enhancing randomized clinical trials with digital twins | npj Systems Biology and Applications
[61] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e9r1-statistical-principles-clinical-trials-addendum-estimands-and-sensitivity-analysis-clinical?trk=public_post_comment-text

Multimodal AI and quantitative models

In the biopharma industry, multimodal AI is fundamentally reshaping drug discovery and clinical development. Unlike traditional single-source analytics, these platforms integrate genomic, imaging, clinical and real-world data into unified models, delivering insights that improve speed, were previously impossible. This is not just about speed; it is about precision and confidence in decision-making. Platforms are using **explainable AI** to detect biological signals and predict patient outcomes with unprecedented accuracy.

Large Quantitative Models (LQMs) can act as a quantitative engine within multimodal systems, enriching predictions with robust numerical insights while multimodal AI provides contextual depth across biological and clinical dimensions. This synergy enables drug developers to move beyond isolated datasets, creating holistic models that improve accuracy in target validation, trial design and patient stratification. LQMs also help design new drug molecules faster, using huge amounts of chemical and biological data to predict how a molecule will behave, check its safety and improve its structure before any lab work starts. A partnership between SandboxAQ and UCSF's Institute for Neurodegenerative Diseases (IND)[62] leveraged LQMs to speed up Alzheimer's and Parkinson's research, compressing timelines from years to a few months, significantly reducing reliance on animal models and expanding access to potential treatments for rare and complex disorders.

> "By replacing manual iteration with multimodal AI modeling, we cut time and cost while generating higher-quality constructs, enabling faster, more confident progression from pre-validation to the lab.
>
> *Amit Mookim, Board Director and CEO, Immuneel Therapeutics*

2.5 Clinical trials 4.0: Design → Recruit → Run → Monitor → Analyze → Report

Clinical research is moving through a steady period of change as data-driven methods become part of routine planning and execution. Many tasks that once depended only on manual judgment now draw support from structured information, predictive science and algorithmic reasoning. This shift helps trial teams to look at patterns earlier, adjust study plans with more clarity, and prepare for hurdles that might appear during a trial.

During the design stage, protocol simulation, endpoint selection and site feasibility assessment help teams test different trial structures before finalizing study plans. Earlier research relied heavily on expert judgement and isolated studies, limiting the ability to anticipate outcomes with confidence. Now, integrated systems analyze data across prior clinical trials, safety signals, biological responses and real-world patient outcomes in parallel. Predictive models and validated biomarkers operate along with clinical observation, enabling earlier assessment of efficacy and safety. This allows risks to be identified and refined upstream, reducing dependence on prolonged, expensive, and multi-arm trials. When evaluated collectively across large datasets, these signals reveal consistent biological patterns, lowering bias and uncovering relationships that individual studies are unable to detect.

Electronic health record (EHR) screening, genomic stratification and diversity-focused enrollment models support faster and more representative patient recruitment. AI improves patient recruitment and stratification by screening electronic health records (EHR) and genomic data at scale. It automatically matches patients with trial inclusion criteria and identifies geographic clusters where eligible participants are concentrated. This approach reduces recruitment delays and helps teams reach suitable patients faster, leading to smoother trial planning and execution.[63] GenAI tools now integrate multi-omics data with real-world evidence to help research teams streamline recruitment, personalize dosing strategies, and reduce costly trial failures. Advanced patient-stratification solutions identify the genetic and clinical markers most predictive of treatment response, enabling sponsors and Contract Research

[62] World Economic Forum Annual Meeting 2026 | World Economic Forum
[63] AI Applications in Streamlining Clinical Trial Participant Recruitment

Organizations (CROs) to enroll the right participants, in the right trials, at the right time.

Hybrid and remote trial operations, including eConsent, virtual visits and wearable devices, allow studies to continue with greater continuity and patient participation. At the same time, better study planning is becoming important. Early testing helps teams understand how choices may affect patient enrolment, safety, and timelines. These insights also highlight where delays or dropouts may occur, allowing teams to adjust plans early and keep studies on track.

Risk-Based Quality Management (RBQM), anomaly detection and risk-based monitoring help trial teams focus attention on high-risk sites, patients, and data patterns. Interim analytics, adaptive decision-making and subgroup analysis allow teams to respond to emerging signals while trials are still in progress.

As these insights move from analysis into action, they need to be translated into reliable and repeatable operational workflows. This transition is enabled through the execution layer.

The execution layer supports day-to-day laboratory work through a controlled and connected operating environment. It brings together instruments, robotics and software so that samples, methods, and results move through the laboratory without disruption. Electronic Lab Notebooks (ELN) capture experiments in a structured format, while Laboratory Information Management Systems (LIMS) manage samples, methods, worksheets and reports across studies.

A workflow engine coordinates activities across instruments and teams, converting written protocols into automated actions. Data flows directly from laboratory instruments into connected systems, reducing manual entry and limiting errors. The execution layer applies version-controlled methods, defined user access, audit trails, and electronic signatures to meet compliance requirements.

Operational continuity is maintained through automated scheduling, instrument reservation and workload balancing, which reduce waiting time and improve throughput. Inventory, reagents and calibration activities are monitored to keep laboratory runs consistent and ready. Real-time dashboards provide visibility into execution status, exceptions, and emerging trends, allowing issues to be identified and addressed early. At the same time, these systems connect upstream design and simulation outputs with downstream analysis and reporting, allowing laboratory execution to remain aligned with broader development goals.

Automated reporting, submission-ready outputs, audit trails, and end-to-end traceability support smoother regulatory review and stronger inspection of readiness. As trials progress, execution models increasingly combine physical sites with digital capabilities.

> “
> India has the population, cost advantage, and digital infrastructure, yet captures only a small fraction of global clinical research value.
>
> *Ajay Nyamati, Co-founder and CEO, Kitsa*

2.6 Quality and integrity in the clinical data layer: From scattered tools to governed systems

The evidence layer focuses on how clinical trial data, real-world evidence and safety analytics are brought together to support continuous oversight and decision-making. Rather than relying on isolated reviews, this layer creates a connected view of patient outcomes, operational quality, and emerging risks.

Modern clinical review systems strengthen trial quality by bringing clinical data and real-world evidence together and applying safety analytics to spot irregularities early. They help reviewers detect unusual patterns and unexpected adverse events, reporting inconsistencies and quality signals through real-time visualizations and automated checks. Centralized access to clean, analysis-ready data reduces manual verification and supports quicker, more confident decisions.

When traditional trial data is limited, rapid assessment methods use real-world data to add clarity and confirm or dismiss potential safety signals. This combination improves the accuracy of safety evaluations by comparing patient trends, timelines and event rates. Standardized digital workflows guide teams from issue detection to review and documentation, reducing delays and limiting

opportunities for errors or fraud. By merging clinical data with real-world insights and applying focused safety analytics, these technologies make it easier to detect quality problems, reveal patient experience more clearly, and strengthen ongoing oversight throughout development and post-approval monitoring.

Together, this evidence layer enables continuous detection of quality signals across clinical development and post-approval monitoring, supporting timely and well-informed safety decisions.

Clinical trials often face quality risks from manual oversight, delayed reporting and fragmented data review. Early approaches mostly relied on rule-based checks and periodic audits with limited visibility. Machine learning models later began tracking enrollment patterns, duplicate records and reporting delays to flag anomalies. Deep learning added deeper pattern analysis across longitudinal data, identifying subtle inconsistencies. Building on these, AI now supports real-time monitoring, compliance checks and adverse event reporting, improving data integrity and patient safety across trial operations.[64]

As mentioned earlier, the government has introduced Biopharma SHAKTI initiative, allocating INR10,000 crore over five years to bolster India's pharmaceutical manufacturing sector in Budget 2026. This initiative aims to achieve its goals by expanding the NIPER network, establishing more than 1,000 accredited clinical trial sites, and implementing significant reforms within the Central Drugs Standard Control Organization (CDSCO) to enhance regulatory efficiency, quality, and international standards alignment.

Clinical data tools: Bringing clinical trial data, real-world evidence and safety analytics together

Early detection of quality issues	Identifying irregularities, inconsistencies, and emerging risks early through real-time analytics and automated checks
Centralized, connected view of data	Unified view of patient outcomes, safety data, and operational signals
Stronger data integrity	Automated cleaning, de-duplication, standardization, and entity matching in datasets
Improved safety monitoring	Detecting unexpected adverse events, unusual patterns, and reporting issues using machine learning and deep learning
Enhanced workflow efficiency	Reduced manual effort, faster reviews, and quicker documentation from issue detection
Real-time, closed-loop decision systems	Data flow from EHRs, labs, and devices enabling real-time protocol adjustments and dynamic monitoring
Consistent governance and shared models	Standardized formats and governance frameworks providing a trusted data foundation
Greater transparency and operational control	Integrated data systems enhance visibility, especially with hybrid/insourced models

2.6.1 Creating a single, structured data foundation

With a large and growing volume of data, it is no longer sufficient to rely on isolated digital tools for tighter expectations around speed and quality. Integration matters because future leaders are expected to move away from scattered projects toward connected systems where clinical data, analytical models, and automated workflows operate together. This alignment allows insights to flow into action, reduces manual effort, improves data consistency, and supports timely, well-informed decisions across trial design, monitoring and reporting.

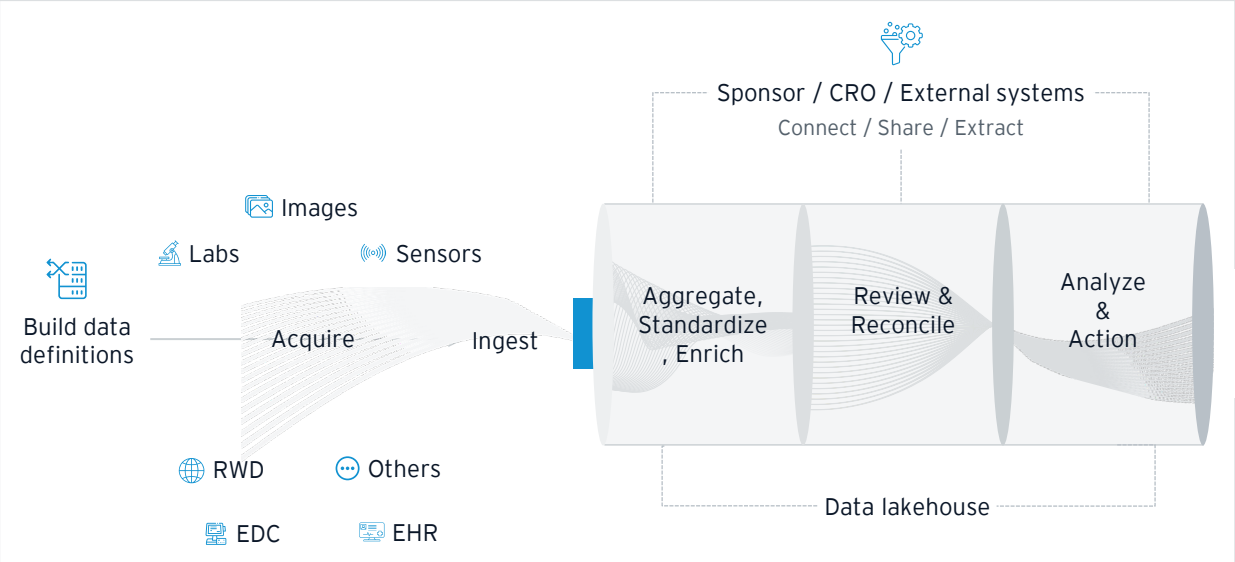
A unified clinical data layer brings together customer data, historical trial records, safety reports, genomics, supply chain inputs and real-world evidence into a single structured view. Data from EHRs, labs, devices and external partners are first mapped to consistent formats using shared data models and standards. AI supports data cleaning, de-

[64] View of Leveraging AI-Driven Anomaly Detection for Enhanced Data Quality and Regulatory Compliance in Clinical Studies

duplication and entity matching, while machine learning helps classify records and detect gaps or anomalies. Data science methods link datasets across time and sources, creating usable trial-ready datasets. Common access rules and governance ensure teams work from the same trusted data foundation throughout the clinical trial lifecycle[65].

Large pharmaceutical companies are strengthening internal delivery models. There is a move away from full-service outsourcing toward hybrid and insourced models, driven by the desire for closer control over data, higher operational transparency, and faster decision-making.

Heading: Structured data foundation for clinical trial: Clinical data, analytical models and automated workflows



Source: Clinical Data Integration: Everything You Need to Know

> Instead of testing drugs on broad populations, we now use data to identify which patients are most likely to respond, making trials smaller, faster and more successful.
>
> *Dr. TS Balganesh, President, GangaGen Biotechnologies and former Head of Research, AstraZeneca India*

2.6.2 From automation to autonomy: Real-time decision loops

Clinical trials operate with an active feedback loop where data does not stop at reporting. Real-time inputs from EHRs, labs and devices flow into a unified data layer, where automation flags patterns and feeds insights back into discovery and formulation models. This allows protocol or dosage adjustments during the trial itself. Several companies actively run closed feedback loops across clinical trials. Some are using data of millions of patients to generate regulatory-grade real-world evidence refreshed daily. For instance, one company is applying agent-based AI across 23 million patient records to identify responder subgroups during ongoing trials[66]. Another player uses automated loops to compare trial outcomes with real-world performance for post-market surveillance.

[65] Enhancing clinical trial outcome prediction with artificial intelligence: a systematic review - ScienceDirect
[66] nference Establishes AI Initiative with Takeda to Advance Precision Medicine in Inflammatory Bowel Disease

2.7 AI in regulatory review and compliance frameworks

Across the globe, regulators are effectively mandating a new architecture. While AI use is permitted, it must operate within traceable, governed systems where data provenance, model validation, and full lifecycle controls are auditable. This shift is pushing pharmaceutical companies beyond isolated experimentation toward engineered, platform-based AI environments built for compliance, credibility, and scale. That means AI adoption is acceptable only when embedded within controlled, auditable systems rather than isolated experimentation.

In India, the Central Drugs Standard Control Organization (CDSCO) is using AI both as a regulatory tool and as a subject of regulation. On the regulatory side, draft guidelines for medical device software explicitly cover AI and machine learning systems. Diagnostic tools such as AI-based cancer detection software are classified as Class C devices. This classification requires clinical validation, documented lifecycle management, and post-market performance monitoring for approval.

AI can also alleviate many problems in regulatory affairs. For instance, AI tools enable faster compliance gap analysis by comparing company policies and SOPs with new regulations. They automatically flag discrepancies, identify outdated statements, and support structured gap assessments. In some cases, LLMs also recommend remediation actions, helping teams update documents quickly and align with evolving regulatory requirements. Globally, regulatory submissions now increasingly reference AI for specific, validated uses such as imaging-based endpoints, patient stratification, and trial optimization. Low-impact applications such as early-stage discovery tools remain outside of formal regulatory evaluation.

In January 2025, the US FDA issued draft guidance for AI models referenced in regulatory submissions such as Investigational New Drug Applications (INDs), New Drug Applications (NDAs) and Biologics License Applications (BLAs)[67]. The guidance applies a risk-based credibility framework. AI systems must be validated for a defined context of use, supported by performance evidence, and maintained through documented lifecycle controls. The FDA does not assess AI based on novelty but on whether the model produces reliable and reproducible outputs that affect regulatory decisions.

The European Medicines Agency outlined its expectations in the 2024 Reflection Paper and the 2025 to 2028 AI Workplan. These documents require early engagement with regulators, explicit risk management plans, and transparency across development, deployment, and post-market phases. The approach aligns with the EU AI Act, which classifies most health-related AI systems as high risk and enforces mandatory compliance from August 2026. Regulators are converging in a common position. AI is acceptable in regulatory pathways only when its role is clearly defined, performance is proven and risks are actively managed over time. The regulatory bar for AI in healthcare is not experimental but operational.

India has also addressed intellectual property implications. The July 2025 Computer Related Inventions (CRI) Guidelines[68] allow patent protection for AI-generated drug candidates when a demonstrable technical effect is established. This supports pharmaceutical innovation while regulatory authorities continue to examine questions of inventorship and accountability.

[67] FDA Proposes Framework to Advance Credibility of AI Models Used for Drug and Biological Product Submissions | FDA
[68] Guidelines for examination of computer related inventions (CRIS)- 2025.pdf

Overcoming critical barriers: Data, accuracy, computational capacity, regulations

Despite their potential, integrating AI and LLMs into drug development faces significant hurdles. These models depend on high-quality data; incomplete or biased datasets can produce misleading predictions and inequitable outcomes. General-purpose LLMs lack true biomedical reasoning, relying on statistical patterns rather than mechanistic understanding, which can yield superficial or incorrect conclusions. Life sciences demand accuracy and context-aware reasoning for patient safety, yet current AI struggles with complex decision-making beyond pattern recognition. Also, excessive reliance on AI may weaken critical scientific judgement. Human expertise remains essential for hypothesis generation, experimental design, and ethical decision-making.

LLMs also require substantial computational resources and careful data management, though developers are addressing this through more efficient training methods and smaller models to reduce costs and biases. As protein sequence databases expand, models like pLMs will continue improving, uncovering disease-pathway connections that accelerate drug discovery and provide proteome-scale insights for experimental validation.

Regulatory frameworks remain inadequate for evaluating AI-generated insights, particularly around model validation, accountability and data provenance.

2.8 India's emerging digital pharma ecosystem

While India's pharmaceutical manufacturing process is well established — with North America and Europe sourcing over 60% of their generic medicines from the country to help control healthcare costs — the rapidly evolving R&D ecosystem presents a new opportunity. India can emerge as a preferred destination for clinical trials and a global-scale testbed for evidence generation, digital and decentralized trials, and cost-efficient drug development.

This transition is actively enabled by a converging set of national policies and digital public infrastructure initiatives. Programs such as the BioE3 Policy, which links AI, biotechnology, and manufacturing through Bio-AI hubs, biofoundries, and advanced biomanufacturing facilities — with an ambition to build a US$300 billion bioeconomy by 2030[69] — are creating the foundation for AI-native life sciences innovation. In parallel, platforms such as India Stack, the evolving Health Stack, and the Ayushman Bharat Digital Mission (ABDM) are establishing consent-based data sharing, personal health records, and interoperable digital rails that pharmaceutical companies increasingly rely on for clinical trials, real-world evidence generation, and regulatory-grade data exchange.

Further reinforcing this shift, the Department of Pharmaceuticals outlined its Pharma 4.0 agenda in December 2025, embedding AI, machine learning and blockchain across research, manufacturing, and supply chains through the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme. These initiatives signal a deliberate move from manufacturing-led leadership to an integrated, digitally enabled R&D and innovation ecosystem.

To convert momentum into sustained advantage, three priorities stand out for India's next phase.

- First, common data models and governed real-world evidence frameworks are needed, supported by clear standards, defined access mechanisms and privacy-by-design principles.
- Second, India requires dedicated validation infrastructure for AI, including benchmark datasets, credibility frameworks aligned with global regulators, and controlled sandboxes where models can be tested before use in regulatory submissions.
- Third, stronger talent and translation pathways are essential, bringing together clinical

69 https://www.pib.gov.in/PressReleasePage.aspx?PRID=2161247&utm_source&reg=3&lang=2

operations, data science, and regulatory science so that AI insights can move efficiently from experimentation into approval-ready evidence.

A clear trajectory is visible. India's pharma sector is no longer just digitizing processes. It is building an integrated system where policy, public digital infrastructure, research institutions and startups move in the same direction, turning AI and data into core drivers of drug discovery, development, and delivery.

2.9 Strategic outlook: AI's impact on go-to-market and economics

AI is quietly changing how pharmaceutical companies take medicines to market through clearer pricing, better demand planning and reaching the right patients at the right time, while reducing waste across the system. Globally, AI is becoming a core economic lever for pharma.

Early decisions in drug design, such as solubility, stability and impurity control, strongly influence how smoothly a medicine can be scaled, stored and released. These decisions follow ICH guidelines and standard impurity-profiling practices. Quality by Design (QbD) helps link these product attributes to process steps, allowing teams to build strength and consistency early so that the process performs reliably at full scale.

As processes mature, digital models and Process Analytical Technology (PAT) turn batch data into real-time signals. These tools create feedback loops that allow teams to adjust mixing, crystallization and content uniformity while the process is running. This supports continuous quality and reduces late corrections that often lead to time loss and lower yield.

Supply realities are also influencing R&D earlier than before. Recent disruptions have shown why planning for raw-material risks, developing diversified sourcing and connecting production and distribution choices from the start is essential. New planning approaches now bring R&D, manufacturing and logistics together so that teams can balance feasibility, cost and speed in uncertain conditions.

Together, strong manufacturing systems, real-time quality tools and resilient supply chains are becoming strategic advantages. These capabilities help speed up launches, protect margins, and increase confidence as production moves to a larger scale.


15.7
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Chapter

03

Supply: Manufacturing and quality as strategic differentiators

3.0 The strategic reinvention of manufacturing

As therapeutics become more complex and global demand for speed, resilience and precision grows, manufacturing is no longer a downstream function; it is a strategic asset. Modern manufacturing sits at the intersection of scientific complexity, data integration, and operational precision, powered by modular design and digital infrastructure.

The convergence of platform-driven science (Chapter 1) and software-native systems (Chapter 2) enables a new model of manufacturing: one that is flexible, data-rich and quality-embedded. This chapter explores how forward-looking companies are reimagining manufacturing and supply execution, and how India can lead this transformation.

3.1 From batch to flow: Reengineering small molecule production

Traditional batch-based manufacturing systems are increasingly falling short to the scale, consistency, and safety required for next-generation active pharmaceutical ingredients (APIs). As molecules become more complex and regulatory scrutiny increases, manufacturers are being pushed to adopt more precise, controllable and resilient production models.

Emerging players are therefore moving toward advanced manufacturing approaches that improve efficiency while embedding quality and sustainability into the process itself:

- **Continuous flow chemistry:** Continuous flow systems replace large batch reactors with smaller, continuously operating units, allowing for tighter control over temperature, pressure, and reaction conditions. This improves yields and reduces variability, shortening reaction times from hours to minutes, and enhancing safety by minimizing hazardous intermediates. Flow chemistry also facilitates faster scale-up from lab to plant by extending run time instead of redesigning the entire process[70].
- **Biocatalysis and synthetic biology:** Enzyme-based and engineered biological pathways facilitate highly selective reactions under milder conditions, reducing energy consumption and minimizing toxic solvents and by-products. These methods promote greener manufacturing and enable efficient synthesis of complex or chiral molecules that are challenging to produce with traditional chemistry. Additionally, synthetic biology allows microorganisms to be programmed as "cell factories" for producing pharmaceutical intermediates, merging sustainability with process robustness[71].
- **Modular reactor design:** Modular systems enable rapid reconfiguration of production units for different compounds and scaling by adding parallel modules. This flexibility supports multi-product facilities and accelerates transitions between clinical and commercial manufacturing. Additionally, modular design reduces capital intensity by eliminating the need for large, fixed plants and allows capacity to be located closer to demand, enhancing supply-chain resilience[72].

These shifts collectively help reduce the physical footprint of manufacturing, lower production costs and shorten development-to-commercialization timelines. Real-time monitoring and automation improve responsiveness to quality deviations, enabling faster corrective action and more consistent output compared with end-of-batch testing.

Beyond enzymes, advances in synthetic biology (synbio) are expanding the range of molecules that can be produced through engineered biological pathways. By redesigning microbial strains to produce complex intermediates or key building blocks, manufacturers can bypass long chemical synthesis routes. While still emerging for commercial APIs, synbio approaches are gaining traction for high-value intermediates and specialty molecules, particularly where traditional chemistry faces yield or sustainability constraints. Over time, the convergence of flow chemistry, biocatalysis and synthetic biology is expected to reshape how complex small molecules are designed and manufactured[73].

[70] https://www.contractpharma.com/library/continuous-flow-chemistry-revolutionizing-pharma-manufacturing
[71] https://www.cell.com/cell-reports/fulltext/S2211-1247(25)00486-3
[72] https://www.tandfonline.com/doi/full/10.1080/00207543.2025.2575844
[73] https://www.nature.com/articles/nrg2775

Heading: Manufacturing approaches reshaping small molecule production

Manufacturing platform	Usage	Gains
Continuous and flow manufacturing	Complex and high-potency APIs; multi-step reactions such as hydrogenation, oxidation, and nitration; sensitive chemistries requiring tight process control	Better reaction control and consistent quality; safer closed-system operations; easier scale-up from laboratory to commercial production; lower contamination and handling risk
Biocatalysis	Stereoselective reactions; chiral synthesis and complex transformations; multi-step API production routes	Fewer processing steps; reduced solvent and energy use; improved selectivity and yield; lower waste generation
Integrated flow plus biocatalysis	Continuous enzyme-based reactions; stable production of complex intermediates; closed-loop manufacturing systems	Steady and predictable output; reduced process variation; improved reproducibility across sites; stronger foundation for global technology transfer
Synthetic biology (emerging route)	Production of high-value intermediates; specialty molecules difficult to synthesize through conventional chemistry; pathways with sustainability constraints	Shorter synthesis routes; improved yield potential; reduced dependence on complex chemical steps; long-term sustainability benefits

Strategic implications for India

For India's contract development and manufacturing organizations (CDMOs) and generics manufacturers, this transformation represents an opportunity to leapfrog legacy batch infrastructure and establish leadership in efficient, green small-molecule production.

By investing early in continuous processing, biocatalysis, and modular manufacturing platforms, Indian firms can move beyond cost-driven competition toward differentiated capabilities that appeal to global innovators seeking safer, faster and more sustainable API supply.

In India, the adoption of continuous and flow chemistry platforms among CDMOs is still nascent, but progress is evident. A Karnataka-based CDMO has a Flow Chemistry Centre of Excellence in Bengaluru, integrating continuous reactor technologies into process development and commercial manufacturing[74]. This facility combines proprietary flow platforms with a team of over 100 specialists, successfully developing and transferring multiple flow-based reactions to pilot and production scales, showcasing the potential of industrial flow adoption to accelerate complex synthesis and reduce hazards.

However, most Indian CDMOs have yet to fully industrialize continuous platforms, limiting their competitiveness in advanced process intensification and supply services for global innovators. Reports indicate that investment in newer processes like flow chemistry, green chemistry and biocatalysis is essential for capturing downstream opportunities as global biopharma increasingly outsources specialized chemistry work[75]. Strengthening these capabilities would enable Indian CDMOs to transition from traditional API and generic manufacturing to high-value, integrated process services.

Targeted investments and global technology partnerships are crucial for bridging this gap, particularly where advanced manufacturing and development capabilities are required. In practice, several collaborations are already strengthening India's CDMO infrastructure. DRILS[76], through its Flow Chemistry Technology Hub in partnership with Corning, is enabling hands-on adoption of flow reactors, process analytics, and continuous manufacturing practices[77]. Thermo Fisher has established a Bioprocess Design Center in Hyderabad, supporting bench-to-pilot single-use systems,

[74] https://www.indiapharmaoutlook.com/news/shilpa-medicare-opens-flow-chemistry-centre-in-bengaluru-nwid-4409.html
[75] https://www.aragen.com/news/indias-cdmos-crdmos-to-benefit-from-global-biopharmas-increased-outsourcing-report
[76] Sridhar Babu opens India's first single-use bioprocess facility – Hyderabad Mail
[77] Telangana launches Telangana 1 Bio to support biologics scale-up and innovation - Express Pharma

process-control training, and biologics scale-up[78]. Sai Life Sciences is expanding CMC R&D capacity to support peptides and oligonucleotides, while ALS has set up a cGMP biologics[79] testing laboratory in Genome Valley to enhance quality testing and digital monitoring[80].

Such partnerships can accelerate knowledge transfer, reduce time-to-value, and enhance India's manufacturing ecosystem, making it more appealing to multinational clients seeking advanced chemistry solutions. By combining cost competitiveness with world-class continuous process capabilities, Indian CDMOs can strengthen their value proposition and emerge as leaders in next-generation pharmaceutical manufacturing.

3.2 From bespoke facilities toward repeatable systems: How modular, platform-based manufacturing is shifting biopharma production

The pharmaceutical and biotech industries are undergoing a foundational shift, from custom-built, product-specific plants toward modular, platform-based manufacturing systems. This transformation is based on growing complexity and diversity of therapeutic modalities, particularly biologics, RNA-based therapies, and cell/gene therapies. These products demand greater flexibility, speed and control in manufacturing — needs that traditional infrastructure cannot easily meet[81].

To address these challenges, leading companies are investing in three core manufacturing innovations:

1. Single-use modular systems for rapid scale-up and multi-product flexibility

Single-use bioreactors and modular production units allow manufacturers to adjust capacity quickly without lengthy cleaning and validation steps, supporting greater flexibility in how facilities are used. This enables:

- Faster clinical-to-commercial transitions by reducing downtime between batches and avoiding lengthy cleaning and changeover processes.
- Support for multi-product manufacturing in the same facility, allowing different products to be produced using a shared setup with minimal disruption.
- Lower contamination risk and capital intensity, as disposable systems cut cleaning steps and reduce the need for large upfront investments.

These systems are particularly well-suited for emerging biologics and RNA therapies, which often require fast adaptation and parallel production streams.

2. Continuous bioprocessing for yield, quality, and control

Continuous upstream and downstream processing keeps cell growth and purification running under stable conditions over extended periods. This approach:

- Improves batch-to-batch consistency by keeping cells and purification steps operating under stable conditions over time.
- Raises overall yields by reducing losses that occur during repeated start and stop cycles.
- Enables tighter process control through continuous monitoring and adjustment during production.

These advantages are critical when dealing with complex biologics, viral vectors, and cell-based therapies products where consistency is not only a regulatory requirement but a therapeutic necessity.

3. Digital control layers for real-time monitoring and release

Advanced digital platforms that combine sensors, analytics, and automation are improving quality control. These systems enable:

[78] Aragen Life Sciences expands its operations from Hyderabad - 24/7 BIOPHARMA
[79] global-companies-to-open-new-centres-in-hyderabad-across-life-sciences-and-tech-sectors.pdf
[80] Sai Life Sciences set to double Process R&D capacity with new facility in Hyderabad |
[81] https://www.bioprocessonline.com/doc/biopharma-facility-modular-design-construction-key-considerations-0001#:~:text=Does%20a%20modular%20approach%20work,%2C%20safety%2C%20or%20regulatory%20compliance.&text=A%20key%20concept%20to%20maximize,exact%20combination%20of%20grid%20units.

- Real-time monitoring of critical quality attributes (CQAs) by continuously tracking key parameters during production rather than checking them only at the end.
- Predictive maintenance and early deviation detection, helping teams address problems before they affect product quality or timelines.
- Acceleration toward real-time release testing (RTRT), reducing delays caused by extended post-production quality checks.

This digital layer shortens production cycles, improves data integrity and strengthens regulatory compliance, which are key enablers for high-throughput, high-value manufacturing[82][83].

Platform-based models working at scale

Companies are already demonstrating the viability of this approach:

- WuXi Biologics has deployed its WuXiUP system, a fully integrated continuous bioprocessing platform across multiple global sites, enabling more predictable, scalable production across diverse biologics programs[84].
- Cytiva's KUBio modular biomanufacturing units provide pre-engineered facilities that can be deployed worldwide within months, supporting the manufacture of monoclonal antibodies, viral vectors, and mRNA-based products[85].

Strategic implications

This shift from bespoke infrastructure to flexible, repeatable systems enables faster innovation cycles, global harmonization and better risk management across increasingly complex portfolios. As advanced modalities continue to dominate pipelines, modular manufacturing platforms will be critical in achieving speed-to-market, enabling consistent product quality and maintaining global competitiveness.

These platform-based strategies not only enhance production agility but also enable decentralized, globally harmonized manufacturing, an increasingly critical enabler for pandemic response, personalized medicine, and scalable gene therapy pipelines. This opportunity aligns directly with India's strength in manufacturing depth, engineering capability, and cost-efficient scale. As a result, we should expect accelerated investment flows toward modular platforms, digital quality systems, and continuous processing across Indian CDMOs and large pharmaceutical companies over the next five years, which would position India as a key execution hub in the next phase of global biopharma.

India's opportunity in modular biologics

Modern biologics plants increasingly utilize single-use systems and modular layouts, which reduce cleaning validation time and minimize cross-contamination risks. These designs facilitate faster product changeovers and support multi-product portfolios, offering India a practical opportunity to leapfrog legacy infrastructure. Instead of replicating large, fixed biologics plants, India can scale smaller, GMP-grade modular units that can be easily reconfigured as pipelines evolve. Such facilities are particularly suited for cell and gene therapies and niche biologics, where batch sizes are smaller, but process complexity is higher[86].

However, infrastructure alone is insufficient; the talent pool must also evolve. The complexity of biologics and cell and gene therapies necessitates skills in bioprocess engineering, sterile operations, digital quality systems and regulatory science. As manufacturing becomes more data-driven, operators need training in real-time monitoring, digital batch records and predictive quality tools. The rise of integrated digital quality systems and compartmentalized facility designs increases the demand for multidisciplinary expertise across biology, engineering[87].

India's opportunity lies in leveraging its existing strengths in biosimilars while building the next layer of capability. Such scale would create a strong foundation for adapting proven global models within the CDMO and CRDMO ecosystem. India is already beginning to show tangible progress in biologics manufacturing through its CDMOs. Companies such as Aurigene, Aragen and Enzene Biosciences have made strategic investments in specialized, sterile, and

[82] https://blog.siemens.com/2025/12/smart-manufacturing-in-pharmaceuticals-why-it-matters-and-how-it-transforms-production/#:~:text=By%20enabling%20detailed%2C%20real%2Dtime,through%20execution%20and%20production%20optimization.
[83] https://pmc.ncbi.nlm.nih.gov/articles/PMC8234957/?utm_source=chatgpt.com
[84] https://www.wuxibiologics.com/press-release/wuxi-biologics-wuxiup-accomplishes-automated-continuous-drug-substance-production-at-pilot-scale/
[85] https://www.cytivalifesciences.com/en/us/solutions/bioprocessing/products-and-solutions/enterprise-solutions/kubio
[86] https://www.sciencedirect.com/science/article/pii/S1465324924009411
[87] https://ispe.org/pharmaceutical-engineering

biologics-focused infrastructure across key biotech hubs, including Bengaluru and Hyderabad.

For example, Aurigene's facility integrates therapeutic protein and viral vector production within a single site – an emerging benchmark for the kind of advanced biological inputs required for cell and gene therapies. These capabilities mark a shift in India's biomanufacturing approach from capacity-driven scaling to quality-driven specialization, aligned with global trends prioritizing process reliability, contamination control and modular flexibility over raw output volume[88].

By aligning infrastructure investments with targeted workforce development, India can transition from being primarily a biosimilar producer to a trusted global hub for complex biologics and cell and gene therapy manufacturing.

3.3 Quality 4.0: Embedding assurance into the system

Legacy quality systems relied on retrospective batch reviews, identifying deviations only after production was complete. This often resulted in delayed product releases, increased rework and heightened compliance risks, especially as processes grew more complex.
In contrast, Quality 4.0 integrates quality directly into manufacturing through real-time analytics, digital batch records, and AI-enabled monitoring. These systems continuously assess critical process parameters and quality attributes, allowing for early detection of deviations and enabling corrective actions before issues escalate. By shifting from inspection to prevention, Quality 4.0 shortens release timelines, enhances consistency, and boosts regulatory confidence, facilitating faster and more reliable manufacturing at scale. Key shifts include:

- Real-time process analytics for monitoring CQAs – Process Analytical Technology (PAT) allows continuous measurement of critical quality attributes during manufacturing, enabling early detection of variability and tighter process control, thereby reducing reliance on end-stage testing[89][90].
- Digital twins and predictive models for deviation prevention – Virtual replicas of processes leverage historical and real-time data to simulate outcomes, helping teams anticipate deviations and test adjustments in silico, preventing failures before they affect production[91].
- Integrated LIMS and Manufacturing Execution System (MES) for automated documentation and release – Connected laboratory and manufacturing systems streamline data capture, batch records, and review workflows, minimizing manual errors and accelerating batch disposition and regulatory documentation[92].
- AI/ML models to identify risk scenarios early – Machine learning analyzes equipment performance, process trends and quality signals to detect early risk patterns, enabling proactive interventions and reducing unplanned downtime or compliance issues[93].

Together, these advancements facilitate faster batch releases, fewer deviations and enhanced regulatory confidence by embedding quality into manufacturing workflows, improving transparency, traceability and consistency in complex production environments.

Despite advancements in manufacturing scale and GMP compliance, the adoption of digital quality infrastructure in India's pharmaceutical sector remains inconsistent in India. Many facilities still depend on paper-based batch records, manual deviation management, and retrospective quality reviews, limiting the advantages of real-time process control.

[88] India Targets $150B Bioeconomy With CDMO Growth
[89] https://www.forbes.com/councils/forbestechcouncil/2023/01/25/its-time-for-the-life-sciences-industry-to-embrace-quality-40/
[90] https://pmc.ncbi.nlm.nih.gov/articles/PMC8234957/
[91] https://ajprd.com/index.php/journal/article/download/1518/1535
[92] https://highresbio.com/blog/lab-automation-software/les-lims-mes#:~:text=An%20MES%20functions%20similarly%20to,and%20accelerate%20time%20to%20market.
[93] https://www.researchgate.net/publication/385885091_Artificial_intelligence-driven_predictive_maintenance_in_manufacturing_Enhancing_operational_efficiency_minimizing_downtime_and_optimizing_resource_utilization

Heading: Quality as a system: The new imperatives

Quality as a system: Core approaches in modern manufacturing

Process analytical technology (PAT)	Real-time release testing (RTRT)	Electronic batch records (eBR)	Predictive quality and equipment monitoring
Role: Enables continuous monitoring of critical quality attributes during manufacturing. **Impact:** Supports early detection of variability, improves process control, and strengthens consistency across production runs.	**Role:** Uses live process data to verify product quality during manufacturing rather than after completion. **Impact:** Reduces reliance on end-stage testing and shortens product release timelines.	**Role:** Digitizes batch documentation and captures data directly from manufacturing systems. **Impact:** Improves data accuracy, reduces manual intervention, and accelerates batch review and audit readiness	**Role:** Analyzes process and equipment data to identify potential deviations before they occur. **Impact:** Improves operational stability and reduces unplanned downtime.

However, the shifts outlined earlier, such as PAT, RTRT, electronic batch records and AI-enabled deviation detection, illustrate how Quality 4.0 can shorten release timelines, reduce variability and enhance regulatory confidence. Targeted incentives can expedite this adoption. Policy support for electronic batch records, PAT and integrated LIMS-MES platforms, along with procurement preferences for digitally enabled facilities, would motivate manufacturers to transition from compliance to prevention-driven quality.

For CDMOs, establishing Quality 4.0 benchmarks as part of client qualification criteria can further encourage investment in real-time monitoring, predictive analytics, and automated documentation. These measures can embed digital quality as a standard capability, positioning India's manufacturing base for complex biologics and advanced therapies at a global scale.

3.4 Rethinking resilience: The supply chain imperative

Post-pandemic disruptions have revealed vulnerabilities in global pharmaceutical supply chains, making resilience a board-level priority. As biologics, cell and gene therapies and RNA-based medicines enter mainstream production, supply networks face new challenges, including reliance on single-use components and stringent cold-chain requirements. In response, manufacturers are rethinking their supply strategies to enhance continuity, visibility and control. Key investments include:

- Localized production of key inputs: Companies are establishing regional capacity for critical biological inputs like vectors and enzymes to reduce reliance on imports. Aurigene's integrated facility in India, which combines therapeutic protein and viral vector production, exemplifies this shift[94].
- Redundant sourcing strategies: Manufacturers are qualifying multiple suppliers for high-risk materials and APIs, enabling rapid substitutions during disruptions. Aurobindo Pharma's vertically integrated API network, with multiple manufacturing sites and extensive warehousing, illustrates how redundancy enhances supply continuity[95].
- Digital visibility platforms: Cloud-based systems integrate real-time data on supplier performance, inventory, and logistics, allowing for early identification of bottlenecks and

[94] https://manufacturingchemist.com/aurigene-expands-cdmo-facilities-for-viral-vectors-209143
[95] https://www.aurobindo.com/api/uploads/annualreports/AurobindoPharmaLimited-AnnualReport2023-24.pdf

coordinated responses across distributed networks[96].

- Cold chain intelligence systems: Advanced monitoring technologies continuously track temperature, location, and handling conditions. B Medical Systems' facility in Mundra, Gujarat, strengthens India's cold-chain capabilities by producing refrigeration units for vaccine and biologics distribution[97].

Heading: Key shifts shaping supply chain resilience

Focus area	What is changing	Why it matters	Response
Localized input production	Regional capacity is being built for critical biological inputs such as vectors and enzymes	Reduces import dependence and limits disruption risks for advanced therapies	Develop local production hubs for high-risk biological inputs
Redundant sourcing	Multiple suppliers are being qualified for critical materials and APIs	Enables faster substitution during supply disruptions	Implement dual- or multi-supplier sourcing strategies
Digital supply visibility	Real-time data on suppliers, inventory, and logistics is being integrated	Improves early risk detection and coordinated response	Deploy digital visibility and monitoring platforms
Cold-chain intelligence	Continuous tracking of temperature, location, and handling conditions	Protects product quality for biologics and vaccines	Strengthen cold-chain monitoring and compliance systems

These investments are shifting manufacturers from reactive logistics to proactive supply orchestration, combining localization, digital oversight, and redundancy to safeguard product integrity and ensure reliable delivery of complex therapies in domestic and global markets.

Policy support for Indian manufacturing

India's bulk drug parks, Production-Linked Incentive (PLI) schemes and incentives for domestic input production enhance the resilience of the pharmaceutical supply chain by localizing APIs, Key Starting Materials (KSMs) and intermediates, while also reducing costs through shared infrastructure[98]. However, mere capacity expansion is insufficient. As manufacturing evolves to become more modular, digital, and quality-focused, these facilities must implement real-time controls, electronic records, and Quality 4.0 practices. Without this transformation, increased scale may not translate into improved global competitiveness.

The Budget 2026 Biopharma SHAKTI initiative announcement underscores the transition by positioning manufacturing capability at the core of India's biopharma strategy. Investments in new and upgraded NIPERs can bolster process development and biomanufacturing specialization, while a national network of accredited clinical trial sites would expedite the journey from development to commercial production. Additionally, enhancing the CDSCO with dedicated scientific review teams can mean faster and more predictable regulatory pathways. Duty exemptions on select high-value drugs may further enhance access to specialized inputs and lower landed costs, thereby supporting niche and high-complexity manufacturing. Over time, these initiatives can enable closer integration between R&D, clinical development, regulatory approval, and manufacturing execution, shifting India toward platform-based production rather than isolated facilities[99].

To accelerate progress, policy incentives should prioritize capability outcomes rather than just output. Bulk drug parks can adopt digital manufacturing practices while aligning PLI incentives with data integrity, workforce skills and quality systems. Integration gaps among suppliers, as noted by the Directorate General of Foreign Trade (DGFT), still require attention.

[96] https://www.pharmafocusamerica.com/articles/pharma-supply-chain-digitalization-trategies#:~:text=Digital%20supply%20chain%20pharma%20strategies,risks%20and%20proactively%20managing%20them.
[97] B Medical Systems inaugurates its manufacturing facility in Mundra, Gujarat - India Press Release
[98] https://www.pib.gov.in/PressReleseDetailm.aspx?PRID=2197944&lang=2&reg&reg=3
[99] https://www.ey.com/content/dam/ey-unified-site/ey-com/en-in/services/tax/union-budget-2026/ey-pharma-and-life-science-sector-highlights.pdf

3.5 CDMO evolution and manufacturing as a service

India's CDMO sector, long recognized for cost efficiency and synthetic chemistry expertise, is entering a new competitive phase. As global pharma shifts toward platform-based innovation, complex biologics, and digitally enabled manufacturing, differentiation increasingly depends on innovation-readiness and regulatory confidence rather than price alone.

Clients now expect CDMOs to offer integrated development-to-manufacturing pathways, real-time quality assurance, and scalable production systems that can support advanced modalities. This requires Indian CDMOs to move beyond traditional capacity-led models toward technology-enabled, system-level execution. The global shift to integrated, tech-driven execution requires:

- Investments in modular and continuous platforms: As highlighted earlier, modular facilities and continuous manufacturing enable faster scale-up, multi-product flexibility and more predictable quality. Continuous flow and bioprocessing reduce variability and improve yield for complex molecules, while modular plants allow rapid reconfiguration across compounds and modalities. Various platforms illustrate shorter technology-transfer timelines and global deployment. For Indian CDMOs, adopting similar architectures offers a pathway to leapfrog legacy batch infrastructure and serve advanced programs more reliably[100].
- Digitally native quality and compliance systems: Quality is evolving from retrospective inspection to real-time prevention. Quality 4.0 capabilities are becoming essential for managing the complexity of biologics and advanced therapies. As noted earlier, digital quality systems shorten release cycles, reduce batch loss, and strengthen regulatory confidence. Indian CDMOs that embed these capabilities into operations will be better positioned to meet global expectations around data integrity, traceability, and audit readiness.
- Client integration capabilities across science and tech: Leading CDMOs increasingly function as extensions of their clients' R&D organizations. This requires tight integration across discovery, process development, manufacturing, and quality — supported by shared digital platforms and standardized data environments. Early alignment on Chemistry, Manufacturing and Controls (CMC), solubility, stability, and process design reduces rework and late-stage failures, enabling smoother progression from laboratory to commercial scale. Indian CDMOs that build these collaborative, platform-based interfaces can accelerate client programs while improving execution reliability[101].
- Talent models blending chemistry, automation, and data science: Advanced manufacturing demands multidisciplinary teams that combine traditional chemistry and bioprocess expertise with automation, analytics, and digital operations. As facilities become modular and quality data-driven systems, operators must understand both biological processes and real-time digital controls. Developing such hybrid talent pools spanning synthetic chemistry, sterile operations, digital quality, and predictive analytics is critical for sustaining performance in complex manufacturing environments.

Together, these shifts signal a transition from cost-led outsourcing to capability-led partnership. Indian CDMOs that invest early in modular infrastructure, continuous processing, digital quality, integrated client engagement, and cross-disciplinary talent can move up the value chain, positioning themselves as trusted global partners for next-generation pharmaceuticals rather than commodity suppliers.

> "India offers strong value in cost-efficient small-molecule development and manufacturing, but late-phase programs and complex modalities require partnering with CDMOs that have proven scale, regulatory-ready quality systems, and strong track records—supported by clear timeline expectations and permit alignment to manage program risks.
>
> *Akhil Ravi, CEO, Aurigene Pharmaceutical Services*

[100] https://www.bioprocessonline.com/doc/biopharma-facility-modular-design-construction-key-considerations-0001

[101] https://www.iconplc.com/insights/blog/2025/10/03/cmc-drug-development-and-life-cycle-management

Policy makers can play a catalytic role by:

- **Incentivizing adoption of advanced manufacturing systems:** Targeted fiscal support and performance-linked incentives can encourage investments in continuous processing, modular facilities, and automation, helping manufacturers modernize operations and build globally competitive production capabilities.
- **Creating regulatory sandboxes for digital QA/QC:** Controlled pilot environments can allow companies to validate AI-driven quality tools, PAT and real-time release systems with regulators, accelerating learning while ensuring compliance and building regulatory confidence.
- **Building centers of excellence for modular biologics manufacturing:** Shared facilities and training hubs can demonstrate best practices in single-use systems, continuous bioprocessing, and containment, while supporting workforce development and technology transfer across the ecosystem.
- **Mandating interoperability standards across MES/QMS systems:** Common data and system standards ensure seamless integration between manufacturing and quality platforms, enabling end-to-end traceability, reducing vendor lock-in, and supporting scalable digital transformation across CDMOs and innovators alike.

3.6 The new manufacturing paradigm can be a strategic lever to help India Pharma sustain its dominance

Today, manufacturing is no longer just a back-end operational function; it has become a strategic lever that shapes time-to-market, regulatory confidence, scalability, and commercial success.

Modern biopharma is shifting from fixed, product-specific plants to modular, platform-based factories. Standardized, prefabricated units and single-use systems allow for rapid reconfiguration across molecules and modalities, enabling capacity scaling through software and process adjustments rather than physical redesign. Digital systems provide continuous visibility throughout production, linking sensors, automation, and execution platforms to transition operations from periodic monitoring to real-time control. This approach aligns with the AI-native models discussed earlier, where data flows seamlessly across discovery, development, manufacturing, and supply, creating integrated learning systems.

Quality is also undergoing a significant transformation. Legacy batch reviews are being replaced by Quality 4.0, which incorporates real-time analytics, electronic batch records, digital twins, and AI-driven deviation detection directly into manufacturing workflows. This shift from inspection to prevention reduces release timelines, minimizes batch loss, and enhances regulatory trust, essential as therapies become more complex and valuable.

Manufacturing processes are being re-engineered as well. Small molecules are increasingly produced using continuous flow, biocatalysis, and synthetic biology, enhancing safety, yield, and sustainability. Biologics and advanced modalities depend on modular plants, continuous bioprocessing, enhanced containment, and intelligent cold chains to ensure consistent output and product integrity. Collectively, these changes transition the industry from scale-through-volume to scale-through-process-control.

As factories become modular and supply networks more distributed, success hinges on integration. CMC must begin at the discovery stage, and digital systems must connect science with execution in real time. Companies that excel will not only develop differentiated therapies but also create platforms that scale them reliably.
This convergence of AI, manufacturing, and quality paves the way for the next chapter: aligning policy, investment, and other capabilities to thrive in this new era of biopharma innovation. As the manufacturing paradigm evolves—from batch to flow, from analog to digital, and from volume to quality—India's ability to orchestrate these shifts at a national scale will define its global role. The next chapter outlines ways to align policy, talent and ecosystem design to translate these manufacturing capabilities into strategic sovereignty.


Living room
Temperature
24°C
75°F
Front door
Locked
Kettle
On
Oven
Off
Fan
Cooling
Done

Chapter

04

How India can play a bigger role in the global pharma landscape

As biopharma transitions to platform-based science, advanced modalities and software-enabled discovery, the criteria for global leadership are evolving. Success is determined by the ability to integrate discovery, development and delivery into a cohesive and repeatable system, rather than on manufacturing scale or low-cost production alone.

This chapter identifies key areas for focused efforts to accelerate India's transition from a volume-driven supplier to a globally relevant innovation and development hub. It explores how regulatory reforms, talent development, technology adoption, cost competitiveness and the implementation of global best practices can create a more resilient and future-ready ecosystem.

4.1. Regulations: What India can learn from other regions

Robust and forward-thinking policy and regulatory frameworks have been crucial in driving innovation and competitiveness in major pharmaceutical hubs like the US and the EU, providing valuable models for India as it aims to move up the value chain.

In the US, regulatory pathways such as Breakthrough Therapy, Priority Review and Fast Track designations are designed to expedite the development and review of therapies that address unmet medical needs, thereby shortening development timelines and enhancing patient access to innovative treatments. The Federation of Drug Administration's (FDA) Regenerative Medicine Advanced Therapy (RMAT) designation under the 21st Century Cures Act exemplifies this approach by facilitating early and expedited engagement for cell and gene therapies, thereby encouraging investment in next-generation biologics and advanced therapies.

Similarly, the EU's PRIME (PRIority MEdicines) scheme and accelerated assessment pathways aim to reduce evaluation periods for innovative products and foster early dialogue between developers and regulators, enabling companies to bring advanced therapies to market more swiftly.

In addition to approval of pathways, regulatory reforms that strike a balance between innovation and evidence-based oversight have had significant impact. The US FDA Modernization Act 2.0 eliminated the requirement for animal testing, allowing the use of computational modeling and alternative assay data in regulatory submissions, thus aligning regulatory science with contemporary R&D methodologies.

In the EU, recent pharmaceutical package reforms introduce tailored data and market protection periods for new medicines while allowing generics and biosimilar developers to prepare early, thereby striking a balance between access and innovation incentives.

The draft National Pharmaceuticals Policy 2023, proposed by India's Department of Pharmaceuticals, suggests that to improve regulatory efficiency and ease of doing research and business, India should move toward a simplified and coordinated licensing framework that minimizes duplication and strengthens alignment among key authorities such as Central Drugs Standard Control Organization (CDSCO), Drugs Controller General of India (DCGI), Ministry of Electronics and Information Technology (MeitY) and the Department of Animal Husbandry and Dairying (DAHD). A single-window clearance system for pharmaceutical licensing can enable faster approvals, clearer accountability and more consistent interpretation of regulations across agencies. This should be complemented by a stronger role for Indian standards bodies such as the Bureau of Indian Standards (BIS) in setting harmonized quality benchmarks, along with the development of a more coherent and predictable pricing framework. Together, these measures can balance patient safety with product innovation while reducing administrative burden on companies.

The Indian pharma industry will also benefit from faster turnaround times and stronger logistics capacity, including dedicated pharma corridors and logistics parks linking major hubs. Greater digitalization and automation can reduce delays and errors, while improved road infrastructure can increase the carrying capacity. Special focus is needed on rapid clearance and continuous temperature control for sensitive products to enable quality and regulatory compliance across the supply chain.

Collectively, these regulatory practices, ranging from expedited pathways to science-based flexibility, demonstrate that targeted policy frameworks can accelerate innovation, optimize development cycles and attract investment.

4.2. Talent: Closing the gap matters

Skilled human capital is essential for transforming India's biotech and pharmaceutical ecosystem from a volume-centric generics hub into a global participant in innovation and beyond.

While India's biotech workforce has grown rapidly, it remains largely concentrated in traditional areas such as manufacturing and routine R&D. Industry reports indicate that India ranks among the top 12 biotech destinations globally but lags behind peers like China and Singapore in the availability of specialist talent and research deep-skill roles[102]. According to India Decoding Jobs Report 2026, India's biotechnology sector employed over three lakh professionals as of the end of 2025[103]. The sector is transitioning from a focus on manufacturing dominance to high-value areas such as R&D, biotechnology, personalized medicine and digital healthcare ecosystems. This upward curve is expected to hold through FY27, with emerging roles like digital health specialists, AI analysts, pharmacovigilance experts and real-world evidence scientists[104].

Key challenges of India's pharmaceutical talent landscape

The pharmaceutical workforce is rapidly evolving, but the pace of scientific innovation, digital expansion and regulatory changes has created significant hiring and capability gaps.

- **Talent gap in advanced sciences and biotech:** Over 80%[105] of pharma companies report shortages in specialized areas such as clinical research, AI-driven drug discovery, regulatory sciences, gene editing and computational biology, leading to extended project timelines and aggressive talent poaching.
- **Increasing compliance complexity:** Evolving global regulatory standards, particularly for export-driven firms, result in longer onboarding cycles and constant retraining needs, creating gaps in regulatory job functions despite significant investment in learning programs.
- **Digital transformation disrupted by skill mismatch:** Approximately 43%[106] organizations struggle with digital maturity due to a lack of technology-integrated talent, with shortages in AI, automation, data modeling and cloud-based manufacturing delaying the transition to data-driven pharma operations.
- **High attrition in major pharma hubs:** Cities like Hyderabad, Bengaluru, Pune and Mumbai are experiencing rising retention challenges as salaries increase and hiring competition intensifies.
- **Reskilling efforts lag demand:** Despite growth in internal training programs, they are not matching the pace of industry transformation. Many employees are still unprepared for AI-driven research environments, limiting digital adoption across enterprises.

Initiatives such as India's National Biotechnology Development Strategy and Biotechnology Industry Research Assistance Council's (BIRAC) skilling programs are positive steps forward but require scaling and continuity to compete with ecosystems in the US and the EU, where tailored talent pipelines and lifelong learning frameworks foster rapid biotech innovation. By strengthening talent supply chains, from undergraduate curricula to advanced practitioner training, India can better position itself to meet the workforce demands of next-generation therapies and integrated R&D hubs that support global biotech leadership.

[102] https://www.ibef.org/industry/biotechnology-presentation#:~:text=India%20is%20the%20third%2Dlargest,(US$%203.04%20billion).
[103] https://taggd.in/industry-reports/idj/india-decoding-jobs-2026/
[104] https://taggd.in/blogs/pharma-hiring-trends/
[105] https://taggd.in/blogs/pharma-hiring-trends/
[106] https://taggd.in/blogs/pharma-hiring-trends/

> Sustained strength in small-molecule APIs and intermediates remains achievable with continuous improvements in capacity, quality and supply chain reliability, while long-term opportunities in cell and gene therapies will require India to close major gaps in infrastructure, quality systems, talent and regulatory agility.
>
> *Akhil Ravi, CEO, Aurigene Pharmaceutical Services*

4.3. Technology: Harnessing digital innovation for competitive advantage

Technology is a key pillar in the ongoing transformation of global life sciences and it will be essential for India to remain competitive in the discovery, development, manufacturing and commercialization of next-generation therapies. Worldwide, digital and computational tools, particularly AI, cloud computing, ML, automation and advanced digital twins, are revolutionizing drug discovery, testing, and production. These innovations are reducing timelines and costs while enhancing success rates and data quality.

What India can do to enhance its digital prowess for pharma:

- **Scale AI and data-driven drug discovery**
  India can expand the use of AI and machine learning in target discovery, toxicology prediction and clinical trial design by linking its IT strengths with its life sciences R&D. Companies such as Dr. Reddy's and Sun Pharma are already piloting AI-led discovery tools, showing early productivity gains[107][108][109].

- **Build cloud-based R&D infrastructure**
  India can expand the use of AI and machine learning in target discovery, toxicology prediction and clinical trial design by linking its IT strengths with its life sciences R&D. Companies such as Sun Pharma are already piloting AI-led discovery tools, showing early productivity gains.

- **Adopt digital twins and automation in manufacturing**
  India can improve quality and reduce batch failures by using digital twins, robotics and advanced process control in biomanufacturing and API production. Siemens already uses digital twins in bioprocessing, providing a model for Indian firms[110].

- **Strengthen synthetic biology and computational biology platforms**
  Investment in synthetic biology and programmable biology tools can help India move into advanced modalities such as engineered enzymes, cell therapies and gene editing. National programs such as Genome India and BIRAC's bio-innovation platforms provide an early foundation[111].

- **Encourage academia-industry technology transfer:**
  India can accelerate innovation by improving commercialization of academic research through shared labs, translational grants and faster IP licensing, similar to the US and EU biotech clusters[112].

> What used to take weeks to find the first patient can now be done in hours using AI-driven pre-screening.
>
> *Ajay Nyamati, Co-founder and CEO, Kitsa*

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[107] https://www.sify.com/ai-analytics/from-generics-to-genius-the-ai-revolution-reshaping-indian-pharma/#:~:text=MAJOR%20AI%20INITIATIVES%20IN%20INDIAN,to%20improve%20chronic%20therapy%20adherence.
[108] https://www.ey.com/en_in/newsroom/2025/02/india-s-pharma-and-healthcare-sectors-eye-30-40-percent-productivity-gains-with-gen-ai-adoption-ey-report.
[109] https://www.informatica.com/customer-success-stories/dr-reddys-success-story.html#:~:text=Perhaps%20most%20importantly%2C%20Dr.,the%20entire%20drug%20discovery%20process.
[110] https://www.siemens.com/global/en/products/automation/topic-areas/digital-enterprise/digital-twin.html?acz=1&gad_source=1&gad_campaignid=22226501403&gbraid=0AAAADEuPPN7Kf5pcvGd8Q7atk6fQbbDC&gclid=CjOKCQiAyvHLBhDIARIsAHxI6xqt-8zC9VVn0MKPCMb9KXTyj6N1HYy0kItD2d92AV3s9spuq3M2HWkaAknsEALw_wcB
[111] https://genomeindia.in/
[112] https://www.nature.com/articles/nbt.4328

4.4. Reducing costs to build India's self-reliance

India's pharmaceutical industry is globally recognized for supplying affordable medicines, yet a critical weakness persists upstream: heavy dependence on imported key starting materials (KSMs), drug intermediates (DIs) and active pharmaceutical ingredients (APIs), especially from China.
Bulk-drug and intermediate imports have continued to rise in value in recent years, with China's share exceeding 70% and dependence in certain segments such as antibiotics reaching nearly 87%.
On further analysis, materials required for bulk-drug production such as catalysts, reagents, intermediates and KSMs are still largely sourced from China. For example, in HIV and oncology bulk drugs where India is a dominant manufacturer, only the final steps are performed domestically[113].

This dependence exposes the industry to supply and price risks and at its core lies a cost-competitiveness challenge rather than simply a capacity shortage.

Progress underway: Policy measures al ready in motion

To address these vulnerabilities, the Government of India introduced the Production Linked Incentive (PLI) scheme and the Scheme for Promotion of Bulk Drug Parks in 2020. Progress under PLI scheme is visible:

- As of December 2024, 34 projects covering 25 bulk drugs have been commissioned, with investments exceeding their initial commitments[114].
- Key projects include Penicillin G in Kakinada, involving INR1,910 crore in investment and an expected annual import substitution of INR2,700 crore and Clavulanic Acid in Nalagarh, involving INR450 crore in investment and an expected substitution of INR600 crore annually[115]. These developments indicate domestic production revival in segments previously lost to imports.

The bulk drug parks initiative aims to directly correct these structural disadvantages by providing shared infrastructure, logistics networks and advanced testing centers. These shared facilities reduce compliance costs and enable economies of scale.

Structural actions recommended to close the cost gap:

- Provide demand assurance through procurement policies, prioritizing drugs manufactured using domestically produced bulk drugs and intermediates.
- Use calibrated tariff and security provisions where excessive import dependence creates a strategic vulnerability; for example, the recent minimum import prices for Pen-G.
- Expand public health procurement to create predictable production volumes required for cost-efficient operations.
- Strengthen technology capability through coordinated government-industry R&D programs and targeted funding for process innovation, especially in fermentation and complex APIs.

India's path to pharmaceutical self-reliance runs through cost competitiveness. Infrastructure, financing access, technology capability and assured market demand must converge to reduce structural production disadvantages. Only by solving the cost equation can India sustainably reduce import dependence and build a resilient pharmaceutical supply chain for the future.

[113] *DP 268 Prof Sudip Chaudhuri.pdf*
[114] Press Note Details: Press Information Bureau
[115] Press Note Details: Press Information Bureau

4.5. Raising quality standards in Indian pharma: From compliance to credibility

India hosts one of the largest numbers of manufacturing facilities approved for regulated markets outside the US, yet inspection outcomes and product quality failures show that performance across the ecosystem remains uneven. With global inspections returning to pre-pandemic levels and regulatory scrutiny intensifying, quality can no longer be treated as an audit event; it must become an operational capability embedded in manufacturing.

Recent inspection trends show both progress and gaps. Inspections by the US FDA have rebounded sharply, rising from only nine inspections in India in 2021 to around 256 inspections in 2024, nearly returning to pre-pandemic levels. Encouragingly, the share of inspections resulting in Official Action Indicated (OAI) outcomes has declined, reaching roughly 7% in 2024, the lowest in recent years (from 14% in 2022 and 10% in 2023), suggesting improved preparedness among leading firms. However, India's OAI rate still exceeds the global average and warning letters (with 12 warning letters out of 138 global warning letters) continue to highlight recurring quality lapses, particularly among small and mid-sized firms lacking resources to fully meet Current Good Manufacturing Practice (cGMP) expectations.

Why do quality gaps persist?

Inspection findings consistently point to structural drivers:

- A compliance mindset instead of a continuous quality culture
- Rapid capacity expansion without a proportional quality investment
- Cost pressure delaying automation and validation upgrades
- Weak supplier qualification and material controls
- Continued reliance on manual documentation systems

At the same time, regulators such as the European Medicines Agency (EMA) and the World Health Organization (WHO) are tightening expectations through global harmonization, Annex one updates and stricter data integrity and contamination standards, making continuous audit readiness essential.

Moving from compliance to quality leadership

1. Engineer quality into facilities

- Contamination control integrated into plant design
- Validated utilities and unidirectional flows
- Barrier technologies and redundancy in sterile zones

2. Digitize quality systems

- Electronic batch records and audit trails supporting real-time monitoring
- Digital logs for cleaning, calibration and change control

3. Strengthen CQV and lifecycle validation

- Qualification aligned with FDA/EMA expectations
- Continuous revalidation after changes

4. Build a quality culture

- Strong Corrective and Preventive Actions (CAPA) execution and deviation investigations
- Standard Operating Procedure (SOP) simplification and workforce empowerment

5. Improve supplier and Contract Manufacturing Organization (CMO) oversight

- Vendor qualification programs
- Shared quality metrics and audit readiness

India has already proven its manufacturing scale. The next competitive edge will come from consistent quality credibility. Firms that embed quality into systems, culture and technology will not only pass inspections but secure lasting global trust.

4.6. Expanding India's pharma services ecosystem

India's pharmaceutical services industry, encompassing Contract Research Organization (CRO), Contract Development and Manufacturing Organization (CDMO) and Contract Research Development and Manufacturing Organization (CRDMO) activities, has gained global relevance as pharmaceutical companies diversify supply chains and increasingly outsource research and manufacturing. Indian firms support global drug discovery, development and manufacturing programs, supported by cost competitiveness and a strong chemistry talent base. However, sustaining this momentum and moving into higher-value segments requires addressing structural constraints that still limit scale and capability expansion.

A central challenge lies in India's uneven capability mix, partially fueled by a talent shortage. While Indian companies are strong in small-molecule chemistry, the global drug pipeline is increasingly dominated by biologics, peptides and complex modalities where domestic expertise and infrastructure remain limited. As these therapies outpace traditional small molecules in growth, capability gaps risk excluding India from high-growth outsourcing opportunities. Compounding this issue, many firms operate either in early research or late-stage manufacturing, preventing the adoption of a "follow-the-molecule" strategy that captures value across development stages. Global CRDMO leaders have expanded through acquisitions and integrated capability building, while Indian companies have largely grown organically, leaving lifecycle participation fragmented.

Operational and regulatory frictions add further challenges. Sequential approvals, licensing delays, logistics bottlenecks and fragmented clearance systems delay project initiation relative to competing markets. Industry leaders frequently cite customs infrastructure gaps, cold storage shortages and regulatory delays as persistent ease of doing business concerns, eroding India's cost advantage by increasing execution uncertainty for global clients.

Clinical research services face additional hurdles. Historical concerns over data integrity, public mistrust of clinical trials, regulatory complexity and patient recruitment challenges have reduced India's attractiveness as a clinical trial destination. Although reforms have improved timelines and transparency, rebuilding global confidence remains essential for CRO growth.

Underlying many of these issues is the weak link between academic research and commercial development. Academic institutions often generate promising discoveries, yet commercialization pathways remain limited due to insufficient collaboration and shared infrastructure, which constrains innovation-led service growth.

Priority actions to accelerate growth

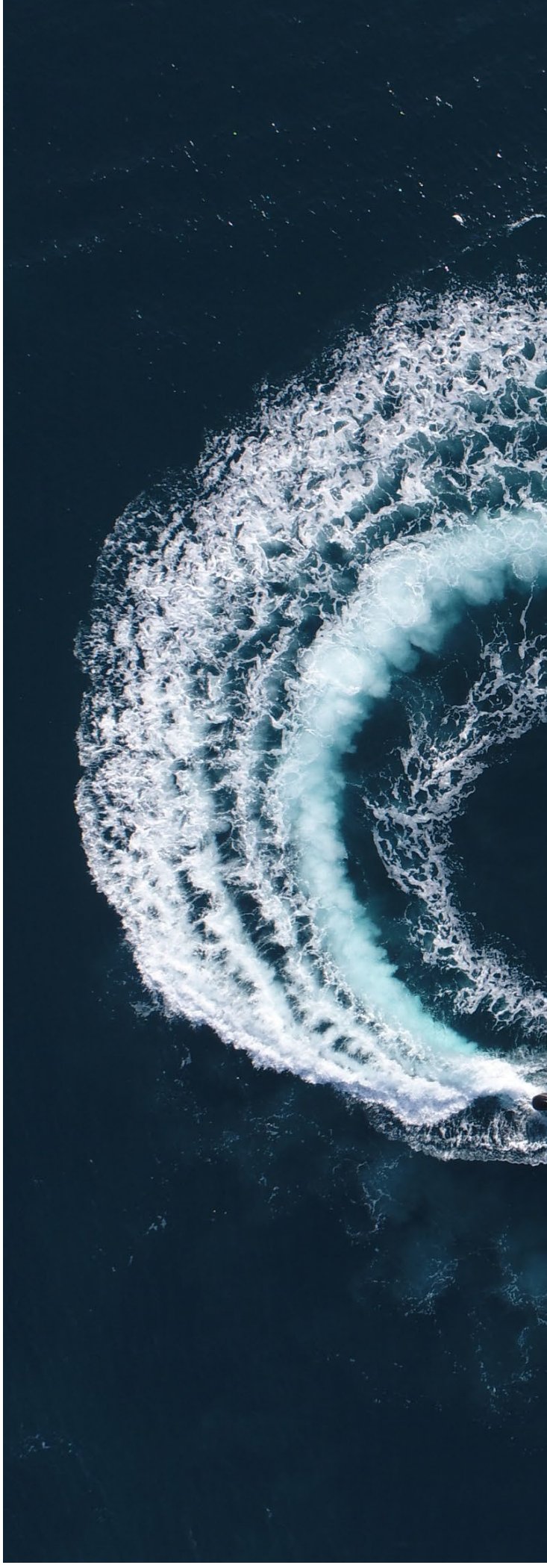
To unlock the next phase of expansion, coordinated policy and industry action is required:

- Expand biologics and advanced-modality infrastructure through targeted incentives and shared facilities, enabling participation in high-growth therapeutic segments.
- Encourage integrated service offerings and selective M&A so firms can follow molecules across development stages rather than remain limited to isolated services.
- Invest in workforce specialization via industry-academia partnerships, structured training programs and automation-driven productivity improvements.
- Develop dedicated CRDMO clusters with plug-and-play infrastructure and simplified regulatory processes to reduce operational complexity.
- Implement unified digital-clearance systems to streamline approvals, licensing and import-export processes.
- Strengthen regulatory efficiency and ethical-compliance frameworks to restore India's competitiveness in global clinical research.
- Expand commercialization support and shared research infrastructure to bridge the industry-academia gap.
- Improve access to long-term growth capital while promoting ESG-compliant infrastructure aligned with global client requirements.

India's pharmaceutical services sector stands at an inflection point. Global outsourcing demand remains strong and domestic capabilities are improving, but growth depends on faster capability building and ecosystem strengthening. Addressing structural frictions in time can enable India to evolve

from a cost-efficient outsourcing destination into a global innovation partner in pharmaceutical development.

India can adapt and enhance these models to strengthen its regulatory systems, promote global regulatory alignment and cultivate an ecosystem conducive to the development and commercialization of novel therapies at scale.



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With a record US$2.1 trillion in Firepower, the life sciences sector is prepared to accelerate dealmaking into 2026 and beyond. Discover more.

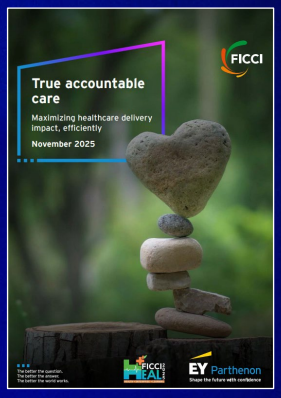
As India's OTC framework formalizes, top pharma players are redefining strategies to capture the next wave of consumer health growth.

Pharma packaging firms are redesigning for greater efficiency, safety and sustainability as compliance pressures intensify. Find put more.

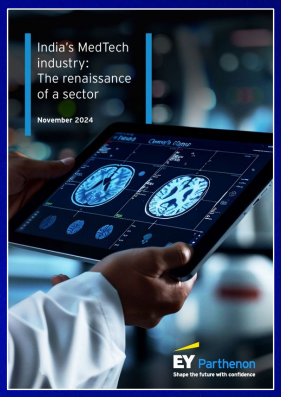
Future of healthcare in India is based on healthcare service providers that have connected platforms, real-time insights and user trust

Life Sciences GCCs in India are working in tandem with main decision centers of companies, co-owning global pipelines and outcomes. Explore more.

Find out how the power of partnerships and digital-first strategies driving Indian pharma's global dominance.



The future of accounntable healthcare in India must cater to evolving needs through strategies that deliver transparent and effective care.



The Indian MedTech market is witnessing a surge of creativity and innovation from start-ups, as they integrate pure medical technology with digital advancements, Find out more.

Notes

Notes

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