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Organisation of Pharmaceutical Producers of India

Fueling innovation, advancing equity

The power of partnerships and digital-first strategies driving Indian pharma's global dominance

November 2025

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The better the answer.
The better the world works.

EY Parthenon

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Foreword

India today stands at the cusp of an extraordinary transformation. From being one of the world's fastest growing large economies to aspiring to become a US$30 trillion to US$35 trillion economy by 2047, the nation's journey is marked by resilience, innovation and an unrelenting pursuit of progress. The pharmaceutical industry has been a vital force in this journey—fueling economic growth, enabling global health equity and ensuring that India remains a trusted partner to the world.

Over the past decade, the industry has evolved from its traditional strengths in generics and vaccines to embrace a future defined by research, innovation and digital excellence. This transition is not just an economic imperative; it reflects India's growing role in shaping the future of global healthcare. The three pillars that define this transformation—pharmaceutical manufacturing at scale, the rise of CRDMOs/CDMOs and the expansion of Global Capability Centers—together symbolize India's shift from being the "Pharmacy of the World" to becoming a global innovation powerhouse.

The findings from the OPPI–EY study, conducted through in-depth dialogues with industry leaders, underscore this momentum. Indian pharma's scale and scientific depth are now being matched by value-led innovation, while the CRDMO sector is emerging as a key partner for global R&D and manufacturing. Simultaneously, the next generation of GCCs are embedding cutting-edge digital, analytical and R&D capabilities, transforming India into a global knowledge and innovation engine.

This report captures not just data and trends, but the spirit of an industry that is reimagining its role in India's growth story. It highlights how collaboration, capability-building, and commitment to quality are driving India's life sciences sector toward a new horizon of global leadership. Anchored in science, strengthened by partnerships and powered by talent, India's pharmaceutical ecosystem stands ready to lead the world in delivering health, hope and innovation for all.

Bhushan Akshikar

President OPPI and Vice President & Managing Director, GlaxoSmithKline Pharmaceuticals

India's pharmaceutical and healthcare sectors are at a defining juncture—an inflection point marked by rapid transformation, both in scale and in strategic ambition. This report captures the sector's journey from generics dominance and cost leadership to embracing innovation, resilience and value-driven partnerships, reflecting our commitment to align with the nation's vision for a US$30 trillion to US$35 trillion economy by 2047.

The collective strength of our pharma ecosystem is anchored in three interlinked pillars: generics and vaccines leadership, a rising CRDMO/CDMO sector driving innovation partnerships, and the expansion of Global Capability Centers (GCCs) harnessing world-class digital, analytical and R&D talent. Over the past decade, these pillars have positioned India as a global health engine—supplying safe, affordable medicines, responding with agility during the pandemic, and shaping the future with advanced research and development. Our progress has been enabled by collaborative partnerships with government, academia, patient advocacy groups and multinational industry leaders—a synergy at the heart of every chapter in this report.

Yet, the path ahead is not without challenges. The sector must move beyond short-term volume gains and cost efficiencies to invest in next-gen therapies, digital transformation, regulatory agility and a robust talent pipeline. To sustain and accelerate this journey, every stakeholder—industry, government, academia, investors and start-ups—must converge and act cohesively. Strong public-private alliances, purposeful digital integration and ecosystem-wide investment in R&D are essential to building a future-ready healthcare sector that serves India and the world.

This report is both a reflection of our achievements and a call to action. Through candid dialogue with CXOs, exhaustive research and ground-level industry insights, it charts a roadmap for transforming India from the "pharmacy of the world" to an innovation-led life sciences leader. The foundation is laid; now is the time to work together with renewed resolve, shared responsibility, and an unwavering focus on quality, equity and patient-centricity.

I extend sincere gratitude to every colleague and visionary who contributed to this report and the sector's journey. With collaborative spirit and strategic ambition, we will deliver on the promise of a resilient, innovative and globally trusted Indian pharma sector.

Anil Matai

Director General,
OPPI

India's pharmaceutical industry stands at a pivotal moment, from being the world's trusted supplier of affordable, high-quality medicines, the country is now poised to emerge as a global hub for drug discovery and innovation. The foundation is strong – world-class chemistry and manufacturing capabilities, digital excellence and an expanding talent base. The next phase of evolution will be driven by translating these assets into high-value innovation and scientific breakthroughs.

The shift from volume to value marks a profound transition that demands bold thinking, sustained investment and collective ambition. As the boundaries between science and technology blur, India's success will depend on how effectively the ecosystem converges – linking academia and industry, global and local partners, established players and emerging innovations, and deep science and digital technology. These partnerships are no longer peripheral; they are the core mechanism through which new therapies will be discovered, technologies commercialized and healthcare reimagined.

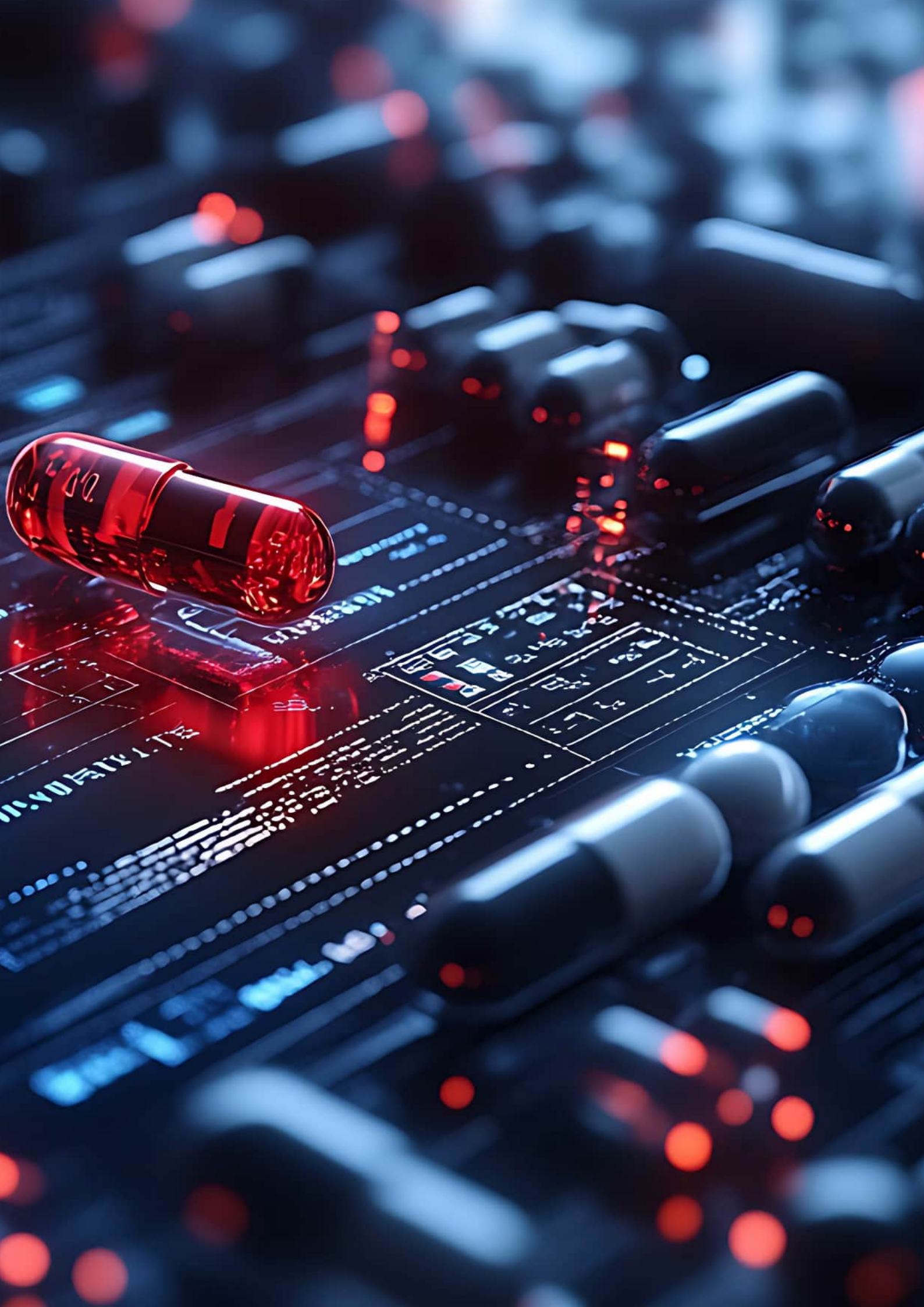
The time to act is now. India's aspiration to become the world's innovation engine is within reach – but it will take courage to invest, trust to collaborate and vision to lead collectively. If we move forward together – with ambition and alignment – India will not only deliver for the world but redefine what it means to innovate for humanity.

I would like to thank the Organisation of Pharmaceuticals Producers of India (OPPI) for their continued partnership and shared vision in developing this report, and my EY colleagues for their commitment and insight. Together, we hope this publication services not merely as a reflection of progress, but as an invitation to think bolder, collaborate deeper and act faster.

India's journey toward global life sciences leadership is well underway, and through purposeful partnerships and collective resolve, we can turn this vision into enduring impact for patients and for the world.

Suresh
Partner
National Life Sciences Leader
EY India

Table of Contents



Executive Summary

India's pharmaceutical sector stands at a pivotal moment of transformation. Having built its reputation as the 'pharmacy of the world' through high-quality affordable medicines and vaccines, the industry is now shifting from a value-driven growth story to one centered on innovation and scientific leadership. Pivotal to this transition is the continued strengthening of capabilities and capacities across the ecosystem — spanning research and development (R&D), advanced manufacturing, digital health and data-driven science. The next wave of growth will depend on creating a more integrated, innovation-ready ecosystem – one that harnesses purposeful partnerships, strategic alliances, and cross-sector collaboration to position India at the forefront of global healthcare innovation.

The foundation of India's pharmaceutical leadership rests on three converging pillars that together hold the potential to chart its course toward global prominence – pharma and vaccines majors manufacturing at scale, Contract Research Development and Manufacturing Organizations (CRDMOs), and Global Capability Centers (GCCs).

Armed with the strength of the country's strong foundation in chemistry, formulation development, large-scale manufacturing and digital leadership, the Indian Pharmaceutical industry is evolving into a broader ecosystem of innovation. Over the past decade, the combined efforts of all ecosystem players, including the industry, government, academia, research institutions and start-ups have led to steady progress in complex generics, biosimilars, biologics and next-generation therapies. Supporting initiatives from the Department of Biotechnology (DBT), Biotechnology Industry Research Assistance Council (BIRAC) and Department of Science and Technology (DST) – alongside academic institutions such as IITs, NIPERs and C-CAMP – have accelerated translational research, incubation and technology development.

India's contract research, development and manufacturing (CRDMO/CDMO) ecosystem has also undergone a profound transformation, evolving into a global innovation engine. Indian CRDMOs are investing heavily in advanced manufacturing, analytics platforms and biologics capabilities, while adopting AI-enabled tools to accelerate drug discovery and development. This convergence of scientific depth and digital sophistication has enabled India to move beyond its traditional outsourcing role toward a model of integrated, value-based partnership with global biopharma companies.

Parallelly, Global Capability Centers (GCCs) established by the leading global pharma companies are emerging as critical enablers of India's innovation landscape. Of the top 50 life sciences organizations globally, around 50% already have their GCCs in India. The GCC landscape continues to advance and expand rapidly, driven by continued investments by the global MNCs across the value chain.

Once perceived as back-end support units built on cost advantages, these centers have evolved into strategic assets that serve as integral extensions of global business functions. Leveraging India's deep technology expertise, data analytics capabilities and scientific talent, these centers have transitioned from executing tasks to owning end-to-end capabilities that shape enterprise-wide strategies and drive innovation at a global scale.

A defining feature of India's next wave of growth is the **rise of purposeful collaborations** that transcend licensing or supply partnerships. Global and Indian pharmaceutical companies, CRDMOs/CDMOs and GCCs are increasingly joining forces with each other and with academia, research institutions and start-ups to nurture talent, embed global best practices and raise the bar by building cutting-edge capabilities. These collaborations are strengthening the foundation of the ecosystem, enabling co-development of next-generation global platforms and accelerating the translation of science into market-ready innovations.

Digital transformation is another cornerstone of this journey. The integration of artificial intelligence, advanced analytics and automation across drug discovery, development, supply chain and commercialization processes is redefining how therapies are researched and delivered. AI-driven molecule design, predictive diagnostics, virtual clinical trials and real-world data analytics are improving speed, precision and cost efficiency across the value chain. With its inherent tech leadership, the intersection of life sciences, data and digital offers India an unparalleled opportunity to leapfrog traditional models and establish leadership in high-science, high-value innovation.

While progress has been significant, the path ahead calls for sustained and coordinated effort across all ecosystem stakeholders. Industry leaders emphasize that India's next leap toward becoming a global biotech and new modality innovation hub will depend on collective action in three high-impact priority areas: regulatory agility and policy leadership, R&D investment and innovation financing and talent and capability development. Advancing these areas through cohesive, ecosystem-wide partnerships will be critical to translating India's scientific and technology promise into global leadership.

> "Partnerships will be the currency of India's innovation decade— connecting scientific excellence with global opportunity. With the right alliances, bold investments and collaborative resolve, India can move from making medicines for the world to discovering the medicines that change it.
>
> *CXO, leading global biopharma MNC*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The current landscape – Strengths, shifts and signals

India today stands among the world's fastest growing large economies and is on the threshold of significant transformation. The nation's GDP has jumped from US$2.1 trillion to US$4.3 trillion over the past decade (2015-2025), occupying the fourth place in the world GDP order[1]. The Government of India aspires to transform the country into a US$30 trillion to US$35 trillion economy by 2047, which would elevate India to the status of the third-largest economy[2].

Of all the sectors critical to realizing this national ambition, the pharmaceutical industry holds a defining role in strengthening India's economic advancement not only through direct means such as Foreign Direct Investment (FDI) and job creation, but also indirectly by promoting public health. By ensuring a healthier population, the pharmaceutical industry enhances labor participation, mitigates the economic impact of diseases on industries and households and bolsters public finances.

EY-OPPI CXO survey

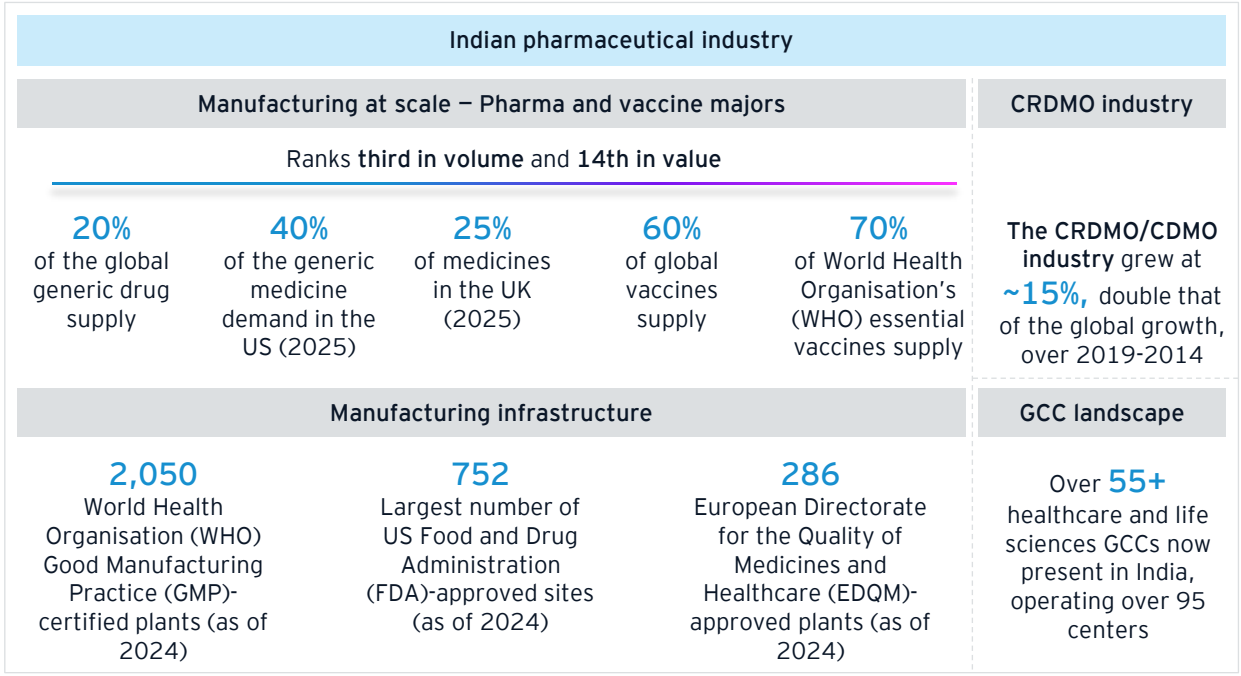
Three interlinked pillars defining the Indian pharma industry's global standing and future trajectory are:

1. Manufacturing at scale – Pharma and vaccine majors
2. CRDMO/CDMO industry
3. Global Capability Centers

During September and October 2025, OPPI and EY conducted primary research with the CXOs of the CXOs of pharma majors, Contract Research Development And Manufacturing Organizations (CRDMOs), Contract Development And Manufacturing Organizations (CDMOs), Global Capability Centers (GCCs), patient advocacy groups, academic institutions and other organizations to understand their perspective on the pivotal growth areas for the pharma and healthcare sectors in the country. From these discussions, India's pharmaceutical strength today rests on three interlinked pillars that together define its global standing and future trajectory. The first is the industry's **dominance in generics and vaccines manufacturing** that is now swiftly advancing toward innovation-driven growth. Second, the country's **rapidly advancing CRDMO/CDMO industry** is transforming India from a low-cost production hub into an integrated partner for global research, development and manufacturing, enabling participation in cutting-edge science and high-value innovation. Third, the **expansion of Global Capability Centers (GCCs)** by leading multinational pharmaceutical firms is embedding world-class digital, analytical and R&D capabilities within India, strengthening its position as a global innovation and knowledge engine. About 50% of leading life sciences and healthcare companies have already established their GCC in India in the last five years[3]. Together, these pillars not only reinforce India's competitiveness but also set the stage for the next phase of its growth journey.

Following sections of the report present a comprehensive overview of these three pillars, highlighting their current landscape, strengths and future growth potential.

[1] https://www.newsonair.gov.in/india-becomes-worlds-4th-largest-economy-surpasses-japan-niti-aayog/
[2] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2007105
[3] https://www.ey.com/content/dam/ey-unified-site/ey-com/en-in/pdf/2025/ey-reimagining-life-sciences-global-capability-centers.pdf



Sources: EY analysis, Press Information Bureau , globallegalinsights, PIB, aartipharmalabs , biospectrumasia, Times of India, The Print, Indian Pharma expands global focus with investments in infrastructure and operations: Report, ETPharma

Pharma and vaccine majors – Manufacturing at scale: The current snapshot

Macro indicators

The Indian pharmaceutical industry ranks as the fifth-largest contributor to manufacturing Gross Value Added (GVA). It plays a significant role in the economy, accounting for approximately 4% of India's FDI inflows. Notably, the sector recorded a cumulative FDI inflow of US$1.2 billion from Apr'25 to Jun'25 (Q1 of FY26)[4]. Additionally, the sector maintains a robust trade surplus of US$19 billion and supports approximately 2.7 million livelihoods, both directly and indirectly.[5]

Scale and global position

The industry, currently valued at US$55 billion[6], ranks **third in the world by volume** and **14th by value** among pharmaceutical producers globally[7]. The country accounts for roughly 20% of global generic drug supply, 40% of the generics demand in the US and ~25% of all medicines in the UK. The industry is further estimated to grow to achieve an impressive value of US$450 billion between 2025 and 2047 with continued focus on moving up the value chain[8].

India has also emerged as a global leader in vaccine manufacturing and supply, accounting for nearly **60% of global vaccine output** and supplying about **70% of the vaccines procured by the World Health Organization (WHO)** for its essential immunization programs[9]. Home to some of the world's largest vaccine producers such as the **Serum Institute of India**, **Bharat Biotech** and **Biological E**, the country has built a robust ecosystem spanning research, development, large-scale production and global distribution.

India's response to the COVID-19 pandemic showcased its capacity for innovation and large-scale execution. The development of Covaxin – the nation's first indigenous vaccine created by Bharat Biotech in

[4] https://www.pharmabiz.com/NewsDetails.aspx?aid=181258&sid=1&utm_source=chatgpt.com
[5] https://indiamacroindicators.co.in/resources/blogs/indias-pharma-sector-growth-and-global-reach-fy2026
[6] https://indiaemployerforum.org/world-of-work/pharma-industry-in-india-2025-2030/
[7] https://pharma-dept.gov.in/sites/default/files/Final%20English%202024-25%20AR%20%281%29.pdf
[8] https://www.indiaoppi.com/wp-content/uploads/2023/11/OPPI_report-Reimagining_pharma_and_healthcare_H_FinalForWeb.pdf
[9] https://cgimelbourne.gov.in/public_files/assets/pdf/India%27s_vaccine_development.pdf?utm_source=chatgpt.com

partnership with the Indian Council of Medical Research (ICMR) and the National Institute of Virology (NIV) – exemplifies how collaborative efforts can accelerate scientific progress[10]. The country's immunization campaign became one of the largest in the world, delivering over **2.2 billion doses** across its diverse geography and saving 3.4 million lives[11], underscoring the strength of its health infrastructure and digital platforms such as **CoWIN**. Simultaneously, through the **Vaccine Maitri** initiative, India supplied COVID-19 vaccines to over **100 countries**, reaffirming its position as a dependable partner in global health security[12].

Export market

Indian pharma exports play a pivotal role in the country's economic growth, accounting for ~6% of India's total merchandise exports by value[13]. The value of pharma exports rose from US$15.07 billion in 2013-14 to US$27.85 billion in FY 2023-24, reflecting a CAGR of ~7%[14]. Exports are expected to surpass US$30 billion by the end of this year[15]. Formulations and biologicals constitute over 75% of the total exports, followed by bulk drugs and drug intermediates[16,17].

This growth is largely driven by exports of generics drugs to over 200 countries, covering both developed and developing markets. India is the source of 60,000 generic brands in over 60 therapeutic categories[18].

Domestic market

The moving annual turnover (MAT) for the Indian pharma market between Aug'24 and Jul'25 increased by 7.4%[19], achieving a total turnover of over US$26 billion. Cardiac, gastro-intestinal, anti-infectives and diabetic segments were the major growth contributors[20].

From "pharmacy of the world" to 'value-led transformative innovation'

Historically, India's strength has been in process chemistry, generics and cost-effective scale. Today, the narrative has started to shift. A growing set of Indian firms and an evolving biotech start-up ecosystem are investing in discovery and innovation. India's strength during COVID in developing new vaccines and its recent CAR-T successes demonstrate the will and capability to enable this shift. Advances in this innovation space are discussed in more detail in the second chapter.

Rise of CRDMOs as a sunrise sector

The global CRDMO industry, comprising Contract Research Organizations (CROs) and CDMOs, is forecast to reach US$303 billion by 2028, growing at a CAGR of 9.0% from 2023 to 2028[21]. This momentum is driven by pharmaceutical companies' strategic pivot towards an asset-light model to focus the objective of concentrating on their key competencies – innovation and commercialization. An estimated over 50% pharma R&D budgets are outsourced to CRDMOs globally. Additionally, the emergence of smaller biotech firms lacking extensive infrastructure, and the impending patent expiries of numerous biologics are other significant growth opportunities for the CRDMO sector.

North America and Europe continue to lead the CRDMO market, however Asia-Pacific is projected to grow at 12% CAGR (2023–28) becoming the fastest among all regions, outpacing Europe (10%) and North America (5%). Within APAC, China is the largest player, followed by India and other Asian countries.

[10] https://www.bharatbiotech.com/images/press/Indias-1st-COVID-19-Vaccine-COVAXIN-Developed-by-Bharat-Biotech-gets-DCGI-approval-for-Phase-I-and-II-Human-Clinical-Trials.pdf
[11] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1904282
[12] https://www.indiatoday.in/health/story/india-leads-global-vaccine-supply-who-70-percent-generic-medicines-affordable-healthcare-2741579-2025-06-16?utm_source=chatgpt.com
[13] https://indiantradeportal.in/vs.jsp?lang=2&id=0,31,24100,24114
[14] https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=152038&ModuleId=3
[15] https://www.pib.gov.in/PressReleasePage.aspx?PRID=2173149
[16] https://www.thehindu.com/business/Industry/fy25-india-pharma-exports-cross-30-billion-surge-31-in-march/article69465333.ece
[17] https://ibef.org/exports/pharmaceutical-exports-from-india
[18] https://ibef.org/blogs/domestic-medicine-manufacturing-contributing-to-the-growth-of-the-indian-pharmaceutical-industry
[19] https://www.ibef.org/news/indian-pharmaceutical-market-grows-7-9-in-july-led-by-chronic-therapies
[20] https://ibef.org/news/indian-pharmaceutical-market-grows-7-9-in-july-led-by-chronic-therapies
[21] https://www.sailife.com/wp-content/uploads/2025/08/Investor-Presentation-30.06.2025.pdf

India's advancing CRDMO industry

CRDMOs/CDMOs represent the next frontier in India's pharmaceutical growth story—marking a decisive shift from volume-based manufacturing to value-driven innovation partnerships. With a projected CAGR of around 14% between 2023 and 2028, India's CRDMO industry is set to be among the fastest-growing globally and reach a total value of US$14 billion—effectively doubling its 2023 size of US$7 billion. CDMOs are expected to account for nearly 75% of the US$14 billion CRDMO market, reaching about US$11 billion[22].

Over the past decade, India's CRDMO ecosystem has undergone a rapid transformation — fuelled by rising global outsourcing demand from multinational pharma companies and virtual biotechs, and supported by India's strengths in speed, efficiency, cost competitiveness and scientific talent. The momentum is also being shaped by global policy shifts and geo-political compulsions, that has accelerated a structural **realignment of global supply chains**, opening a window for India to emerge as a credible and secure **alternative partner** for R&D and manufacturing.

A key shift underway is the move from transactional outsourcing to integrated, value-based partnerships — where Indian CRDMOs provide end-to-end solutions and share strategic responsibilities with clients. This marks an evolution of the outsourcing model itself: from a "we send you a task" approach to a "we partner with you in co-innovation and virtual discovery" model, reflecting a broader trend towards externalised discovery functions and **deeper collaboration** across the pharmaceutical value chain[23].

The Indian CDMO/CRDMO firms are increasingly building **specialized platforms** (e.g., ADCs, bioconjugates, peptides) and **capabilities** to win global pharma business. The deals show a **shift from simple manufacturing outsourcing** (generic APIs, intermediates) to **higher-value partnerships** (ADC development/manufacture, advanced intermediates, earlier-stage NCE work). The investment in capacity expansion (e.g., Divi's INR650–700 cr) is a strong signal of commitment and expected revenue lift from the partnership.

Across Indian CRDMOs/CDMOs, **deal flow is tilting toward advanced modalities, including biologics and mAbs** manufacturing, **antibody–drug conjugates** (ADCs), **GLP-1 fill–finish** and **cell/gene-adjacent discovery** partnerships. Several agreements have been framed as **multi-year/strategic partnerships** with **capacity investments** to expand capacity and build new capabilities, underscoring a shift from transactional supply to **trusted, capability-led partnerships** that prize quality, scale and tech differentiation.

[22] https://www.sailife.com/wp-content/uploads/2025/08/Investor-Presentation-30.06.2025.pdf
[23] https://www.cphi.com/content/dam/esa/hn/cphi/en/brochures/CPHI-trend-report-outsourcing-trends-and-strategies.pdf

India CRDMO/CDMO landscape: Recent partnerships *(not exhaustive)*		
	Platform/product	**Investment**
Aurobindo	Biologics manufacturing contract with Merck Sharp & Dhome for domestic and international markets (Mar'24)	Aurobindo invested INR1,000 crore to set up a biologics manufacturing facility
Gland Pharma	GLP-1 portfolio manufacturing contracts	INR200 crore to expand capacity from 40 million to 140 million units
Aurigene	Discovery services to Edity Therapeutics in cell therapy (Jyl'24)	-
Divi's Labs	Long-term contract with global company for manufacturing of advanced intermediates (Apr'25)	INR650-750 crore in manufacturing capacity expansion

Sources: EY analysis, Aurbindo-MSD; Gland Pharma; Aurigene - Edity; Divi's Labs

As India continues to strengthen its regulatory frameworks, scientific capabilities and infrastructure, its CRDMO sector is well positioned to capture a significantly larger share of the global outsourcing market. The subsequent chapters will examine in greater detail the sector's advancements, opportunities and the imperatives needed to sustain this ascent.

Next-gen Global Capability Centers (GCCs): Driving digital and analytical innovation as strategic partners

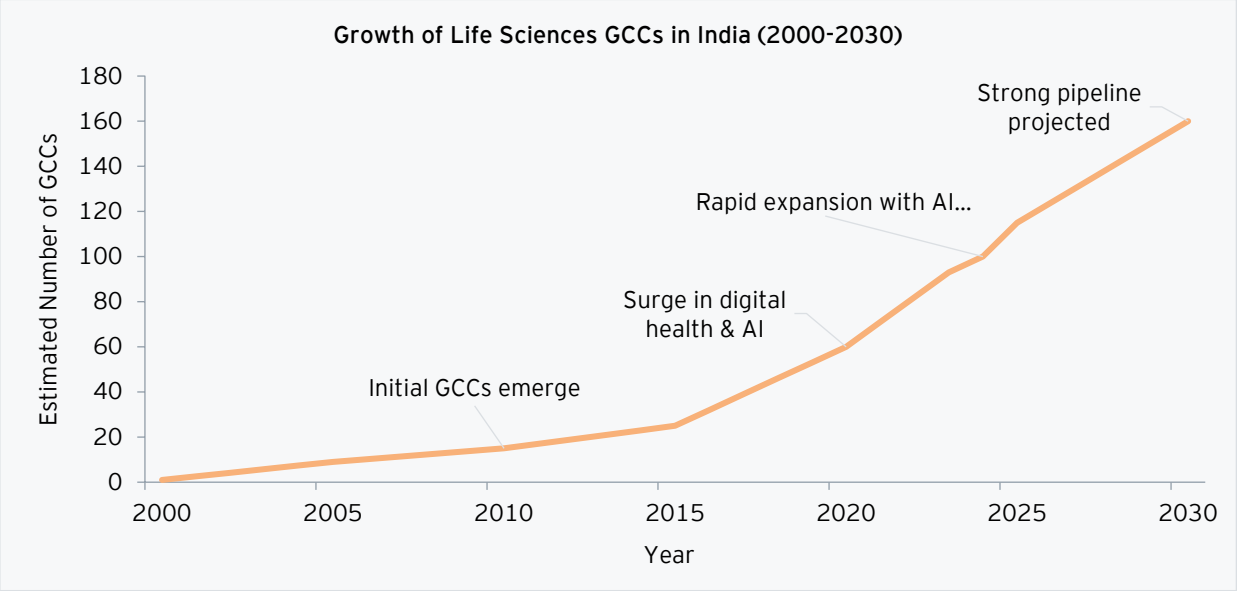
India's GCC ecosystem

The ecosystem has evolved from cost-centric offshore units to strategic hubs driving global innovation and digital transformation. Driven by strong talent depth and digital capabilities, India's network of over 1,800 GCCs, employing about 1.9 million professionals, is poised to grow from US$64.6 billion in 2024 to US$110 billion by 2030[24].

India's advancing life sciences GCC network

Of the top 50 life sciences organizations globally, 23 have their GCCs in India[25]. Notably, over 50% of these organizations have entered the Indian market within the last five years. This trend underscores the pivotal role GCCs play in shaping strategic decisions for executive leaders as they navigate the complexities of the next decade, characterized by geopolitical uncertainty, heightened competition, rapid technology advancement and increasing regulatory scrutiny.

[24] https://community.nasscom.in/communities/global-capability-centers/gcc-industry-brief-feb-2025-inductus
[25] https://www.ey.com/content/dam/ey-unified-site/ey-com/en-in/pdf/2025/ey-reimagining-life-sciences-global-capability-centers.pdf



Sources: EY India report - Reimagining life sciences Global Capability Centers

In a 2023 EY report, ***Reimagining pharma and healthcare for India@100***, it was detailed how the GCCs in India have evolved from backend functions to becoming strategic partners to global firms. Novartis, among the first pharma companies to establish a 20-member team in India in 2001, now operates one of the largest pharma GCCs in the country with more than 8,500 employees driving global functions in data science, development, clinical trials and regulatory operations[26]. Other large companies including GSK, AstraZeneca, BMS and Takeda have also established GCCs focused on embedding AI, digital twins and immersive technologies across the drug discovery-to-commercialization value chain. Collectively, these GCCs reflect how global pharma is leveraging India's scientific talent and technology ecosystem to transition from shared services to high-value innovation hubs.

The GCC landscape continues to advance and expand rapidly, driven by continued investments by its global MNCs in digital, R&D and advanced capabilities. Eli Lilly is setting up second GCC in Hyderabad equipped with artificial intelligence (AI), automation, cloud computing and software product engineering to support accelerated innovations, creating around 1,500 new jobs[27]. Bristol Myers Squibb has opened a US$100 million innovation hub employing 1,500 specialists in global drug development and digital functions[28], while Amgen has launched a US$200 million technology and innovation center focused on AI and data science[29]. Sanofi is investing €400 million to nearly double its Hyderabad GCC headcount to 2,600 by 2026[30], and Novo Nordisk is expanding its Bengaluru hub by 16% to 5,000 employees[31].

Together, these developments highlight the continued confidence of global pharma leaders in India's talent, digital infrastructure and growing strategic role in high-value innovation and global operations.

[26] https://timesofindia.indiatimes.com/city/delhi/pharmacy-of-the-world-over-55-gccs-3-lakh-jobs-how-india-is-preparing-to-move-up-the-value-chain/articleshow/123989076.cms?utm_source=chatgpt.com
[27] https://pharma.economictimes.indiatimes.com/news/pharma-industry/eli-lilly-inaugurates-gcc-in-hyderabad-to-fuel-ai-plans/123092849
[28] https://www.business-standard.com/companies/news/bristol-myers-squibb-opens-innovation-hub-worth-100-million-in-hyderabad-124022600809_1.html?utm
[29] https://timesofindia.indiatimes.com/business/india-business/amgen-opens-new-tech-and-innovation-centre-in-hyderabad-with-starting-investment-of-200m-in-2025/articleshow/118524509.cms?utm
[30] https://scalegcc.com/sanofi-gcc-in-hyderabad-boosts-indias-life-sciences-hub/
[31] https://yourstory.com/enterprise-story/2025/04/novo-nordisks-india-gcc-steadily-moves-value-chain

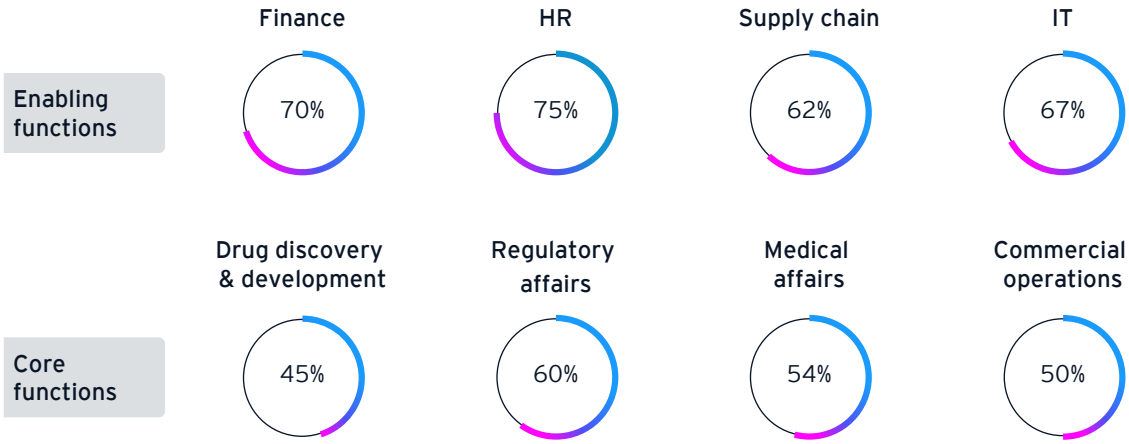
India Life Sciences GCC landscape: Recent investments			
	Investment size	**Key capabilities**	**Hiring plan**
Eli Lilly	Second GCC	▪ Automation, artificial intelligence, software product engineering and cloud computing to deliver advanced technology solutions	▪ ~1,500 people, including technology engineers and data scientists
BMS	US$100 million	▪ Innovation hub to accelerate global drug development and IT/digital capabilities ▪ Focus on critical disease areas including cancer, cardiovascular, immunology and fibrotic diseases	▪ >1,500 people
Amgen	US$200 million	▪ A technology and innovation center with a focus on digital, AI, and data science capabilities to enhance enterprise-wide efficiencies	▪ ~2,000 people
Sanofi	~US$430 million	▪ Technology and digital capabilities to support its expanding operations	▪ More than double headcount from ~1,000 to 2,600 by 2026 ▪ Plan to hire data scientists, software and data engineers, and AI specialists to
Novo Nordisk		▪ Transforming GCC into a global digital and operational hub	▪ 16% expansion in workforce to 5,000 people

Sources: EY analysis, Eli Lilly GCC Hyderabad; Bristol Myers Squibb; Amgen; Sanofi GCC; Novo Nordisk

Modern GCCs in India manage integrated functions across the entire life sciences value chain. They encompass core functions such as drug discovery, clinical trial operations, pharmacovigilance, regulatory affairs, real-world evidence (RWE) analytics, digital therapeutics and supply chain analytics, as well as enabling functions such as finance, human resources, information technology and data analytics– all while driving outcomes through artificial intelligence. This comprehensive approach enhances operational efficiency and supports industry's growth needs in an ever-evolving global and regulatory landscape.

> GCCs in India have evolved alongside the country's growing talent and digital capabilities. What began as process and operational excellence centers has transformed into hubs that now **own global capabilities** — driving strategic transformation across R&D, manufacturing and enterprise operations. India's digitally native and innovation-driven talent base now combines deep functional knowledge with advanced technology expertise, enabling GCCs to lead change rather than just support it. This shift from executing to owning has made India's GCC ecosystem a vital pillar of global pharma innovation.
>
> *CXO, leading global pharma GCC*

The GCC penetration across core functions has also seen a significant uprise over the last five years:



Sources: EY India report - Reimagining life sciences Global Capability Centers

GCCs: Strategic anchors in India's life sciences ecosystem

In addition to contributing to economic growth and generating employment, GCCs are emerging as powerful enablers of innovation within India's pharmaceutical and healthcare landscape, bridging global expertise with local scientific talent and academic excellence. The rise of GCCs is generating positive collateral benefits for the broader Indian pharmaceutical ecosystem. Their deeper integration with global workflows is fostering stronger governance, communication and data flow, helping align Indian operations with international quality and compliance standards.

GCCs are also helping bridge capability gaps in high-end specialties, from novel modalities and digital health to first-in-class discovery programs. As they take on more strategic mandates in discovery and advanced analytics, IP protection, data security and quality compliance are becoming central priorities—prompting Indian suppliers and partners to elevate their own regulatory and quality frameworks. This "reverse pressure" effect is accelerating the ecosystem's alignment with global best practices.

> From an industry perspective, one of the biggest shifts over the last decade has been India's ability to **upscale its knowledge potential,** particularly in the healthcare and life sciences sectors through the rise of GCCs. The key strength of these GCCs lies in how they leverage **India's vast knowledge pool,** bringing global expertise into the country to serve worldwide operations. This model has not only deepened India's integration into global pharma value chains but has also **enhanced domestic talent, technical capability and global problem-solving capacity** across the ecosystem.
>
> *CXO, leading global pharma MNC*

> The GCC talent has evolved – understanding of business at a global scale, innovative medicines, the various processes involved in research and development, operations, manufacturing and so on. This expertise was just beginning to come to India 15 to 20 years back, but today it is in abundance. As GCCs take on higher-value, innovation-led roles, they are strengthening the broader life sciences ecosystem — building digital and scientific capabilities, fostering collaboration with academia and start-ups and raising quality and compliance benchmarks across India's pharma landscape. In addition, by providing growth opportunities, the GCCs are also helping prevent brain drain. Overall, GCCs is a complete win-win-win situation – great for the company, great for the country and great for the community.
>
> *CXO, leading global pharma MNC*

Collaborative partnerships are further driving this transformation. For instance, AstraZeneca's GCC has partnered with academia such as Sastra University[32], while Novo Nordisk's GCC has joined hands with the International Institute of Information Technology (IIIT) Bangalore and Manipal Academy of Higher Education (MAHE)[33] to explore breakthrough innovations and improve efficiency across the pharma value chain and its applications in healthcare, and its recent collaborations with AI start-ups illustrate how GCC-led alliances are nurturing research, talent development and digital innovation across India's life sciences landscape.

Anchored by world-class generics, cutting-edge CRDMOs and data-driven GCCs — each reinforcing the other — India is poised to redefine global healthcare innovation. The next decade offers an unprecedented opportunity to translate this scale into sustained scientific and economic leadership.

[32] https://www.astrazeneca.in/media/press-releases/2023/AstraZeneca-tieup-with-SASTRA-University.html#
[33] https://www.iiitb.ac.in/media/novo-nordisk-and-iiit-bangalore-sign-mou-to-drive-industryacademia-research-opportunities-and-skill-development

02

Growth potential and current gaps

In Chapter 1, we outlined the macro trends shaping India's pharmaceutical landscape—the scale of its industry, its contribution to global supply and its competitive positioning. In this chapter, we turn our focus to the **next phase of the journey**—identifying the opportunity areas and structural gaps that will determine how India sustains and strengthens its leadership in global pharmaceuticals. Realizing the global leadership potential demands a fundamental shift from **volume-based competitiveness to a balanced "volume + value" model**, underpinned by innovation, quality and differentiated capabilities.

The chapter also explores the **emergence of India's CRDMO/CDMO ecosystem** as a frontier growth engine—highlighting how it can accelerate innovation and global integration—while examining the **headwinds and systemic constraints** that must be addressed to fully unlock this opportunity.

The next growth horizon shifting from 'scaling volume' to 'scaling science'

Partnerships have paved the way but challenges need to be overcome.

The global rise of generics was propelled by two powerful tailwinds: a wave of patent expirations of blockbuster originator drugs—particularly across the United States and Europe—and intensifying cost-containment pressures on healthcare systems, which compelled payers to seek affordable therapeutic alternatives. Indian pharmaceutical companies successfully capitalized on this opportunity, leveraging their cost-efficient manufacturing and chemistry expertise to emerge as the undisputed global leader in generics.

Navigating new headwinds in the changing economics of generics

The generics-led model has served India's pharmaceutical industry remarkably well. Over the past few decades, the country has earned global recognition as the "pharmacy of the world," supplying affordable, high-quality generic medicines and vaccines to both developing economies and highly regulated markets. This export-driven growth strategy delivered scale, deep market penetration and international credibility—firmly establishing India as a cornerstone of global healthcare supply chains. Yet, as the industry matures, experts in our primary research cautioned that this very success has fostered a structural dependence on low-margin, volume-driven growth, which now poses a constraint on India's future growth trajectory. Sustaining momentum will require moving beyond cost advantage toward innovation, differentiation and value creation. Heightened global scrutiny on quality, data integrity and environmental compliance is adding further layers of cost and operational challenge, especially for legacy manufacturers with older facilities.

> "There is still short-term thinking, especially on the innovation side. Many companies remain focused on the next wave of patent expiries rather than what the next 15 years should look like. But the reality is changing — the cost of serving Western markets is rising, and the old model of competing on 'first-to-file' generic strategies and fighting in an overly competitive market with inability to hold price makes it unsustainable. Also, with growing trade barriers and global uncertainty, companies are beginning to realize that it is time to get their act together and it is critical to invest in innovation.
>
> *CXO, leading global biopharma MNC*

Generic drug industry

Tailwinds

- The US and EU markets will see US$180 billion worth of medicines lose patent protection by 2035[1]
- Indian players already possess significant strength and a strong opportunity to **capture global leadership by** expanding their US operations and leveraging their expertise in complex generics[2]

Headwinds

- Increasing pricing pressures
- Diminishing profit margin
- Geopolitical realignments
- Evolving global policy environment
- Rising input and compliance costs
- Heightened global scrutiny of quality, data integrity, and environmental mandates

Sources: EY analysis, Indian generic drug market, 1. Policy Circle, 2. chemindigest

The traditional generics market, though continuing to expand in volume, is increasingly constrained by stringent price controls and shrinking margins. The US generics market has become very volatile with double digit dips in multiple segments [34,35]. These pressures are being amplified by geopolitical realignments, an evolving global policy environment and rising input and compliance costs. Heightened global scrutiny on quality, data integrity and environmental compliance is adding further layers of cost and operational challenge, especially for legacy manufacturers with older facilities.

[34] https://www.businesstoday.in/industry/pharma/story/us-generics-market-to-face-prolonged-price-erosion-in-2024-antique-stock-broking-406847-2023-11-23?utm_source=chatgpt.com
[35] https://www.ndtvprofit.com/markets/pharma-companies-under-pressure-as-us-price-erosion-continues

Strategies adopted by Indian pharma companies to combat generics pricing pressure and margin erosion

Company	Market/segment	Management signal	Shift towards value
Sun Pharma	US generics (base portfolio)	Significant price erosion; selective participation in molecules with high price erosion	▪ Branded-Rx leadership model: focus on specialty products and high-entry-barrier segments ▪ SPARC focuses on innovative therapies, including ADCs
Dr. Reddy's	North America generics	Revenue declined ~11% YoY in Q1 FY26 on price erosion in key molecules	Key goal is to shift from product mix toward higher-barrier products ▪ Medium term: injectables, complex oral solid dosage forms ▪ Long term: biosimilars, drug-device combinations, advanced therapies including GLP-1s ▪ Aurigene focuses on biologics, including oncology drugs
Cipla	US generics	Market stable with moderate price erosion	▪ "Future Fit" strategy: launch innovative products and expand presence in high-margin segments like respiratory and oncology ▪ Investments in complex generics, such as long-acting injectables and peptides; selective biosimilars
Lupin	US oral solids	Price erosion eased to low single digits; growth led by complex launches (e.g., inhalation)	▪ Heavy push on complex generics, inhalers, injectables, transdermal patches, ophthalmic solutions ▪ Completed the carve-out of the trade generics business in India into a wholly owned subsidiary, with a focus on pivoting to complex products ▪ Lupin Biotech CDMO for biologics, Luin Manufacturing Solutions (LMS) for API and small molecules
Aurobindo	US generics	Overall pricing environment modest; double-digit erosion persists in a subset of SKUs; some SKUs see price increases	▪ Advancing its biosimilar pipeline ▪ Scaled manufacturing of complex generics such as injectables and inhalers ▪ CuraTeQ biologics CDMO

Sources: EY analysis, company annual reports

While opportunities persist—particularly as a new wave of blockbuster drugs approaches patent expiry—the generics engine alone is no longer sufficient to sustain long-term growth or profitability. To achieve revenue growth and margin improvement, leading pharmaceutical 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. In parallel, many are extending into the CRDMO/CDMO space, leveraging their scientific expertise and manufacturing infrastructure to serve global innovators and capture value across the pharmaceutical development and production continuum.

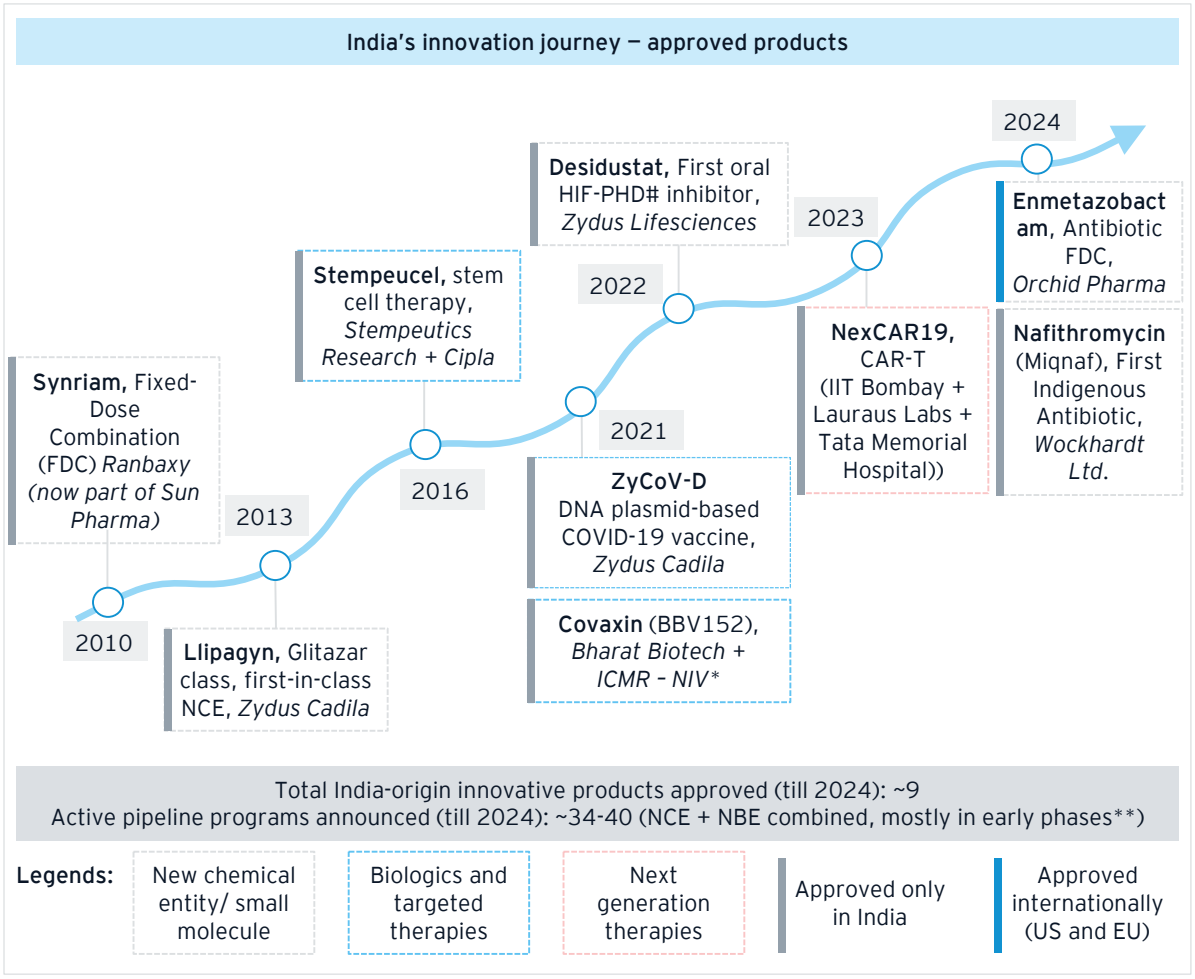
The big opportunity of becoming "value creator" from "volume leader"

Prescription drugs globally are valued at ~US$1.15 trillion and are expected to grow at ~7.4% to US$1.76 trillion by 2030[36]. Within this market, innovative next-generation therapies including biosimilars, biologics, peptides, mRNA, cell and gene therapy and ADCs are projected to represent around 43% of the global pharmaceutical market by value – a significant increase from 34% in 2023[37]. For example, the mRNA therapeutics market alone is estimated at US$34 billion in 2023 and is expected to reach US$41 billion by 2028 (CAGR ~4%)[38]. Likewise, the global ADC market, valued at ~US$10 billion in 2023, is forecasted to grow to ~US$28 billion by 2028 (CAGR ~23%)[39].

Innovation in action: India's pharma and CRDMOs fueling the next wave of value creation

Pharma evolution

Over the past few years, Indian pharmaceutical 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. This transformation is being powered by strategic collaborations, licensing deals and acquisitions, as Indian firms seek to build global relevance in high-science domains.



*ICMR-NIV: Indian Council of Medical Research-National Institute of Virology
#HIF-PHD: Hypoxia-Inducible Factor-Prolyl Hydroxylase Domain
** - indicative number of NBEs/ NCEs basis publicly disclosed information by Indian Pharma companies (information sourced from Zydus Life Sciences, Sun Pharma, Wockhardt, Glenmark, Biocon, Emcure, NATCO Pharma
Sources: EY analysis

[36] https://www.evaluate.com/thought-leadership/2025-world-preview/
[37] Viksit Bharat@2047:Transforming India from pharmacy of the world to pharma powerhouse for the world - https://www.ey.com/content/dam/ey-unified-site/ey-com/en-in/insights/health/documents/ey-oppi-thought-leadership-viksit-bharat-2047.pdf
[38] https://www.globenewswire.com/news-release/2024/10/15/2962942/0/en/mRNA-Therapeutics-Industry-Research-2024-2028-Long-term-Forecast-to-2033-Emerging-Self-Amplifying-mRNA-Platforms-Scalability-and-Flexibility-Expected-to-Revolutionize-Vaccine-Devel.html
[39] https://www.norstella.com/the-adc-market-hot-or-too-hot-to-handle/

A prominent recent milestone is the US FDA "Fast Track" designation (April 2025) for ISB 2001, an investigational trispecific antibody developed by Ichnos Glenmark Innovation (IGI)—a joint venture between US-based Ichnos Sciences and India's Glenmark Pharmaceuticals. The therapy, which targets BCMA, CD38 and CD3 for relapsed or refractory multiple myeloma, is a first-in-class trispecific antibody built on IGI's proprietary BEAT® platform. In mid-2025, IGI further signed an exclusive global licensing and commercialization pact with AbbVie, positioning this as one of India's most significant innovation-linked global deals in recent years[40].

Indian companies are increasingly pursuing strategic acquisitions and licensing agreements to gain access to novel modalities and accelerate their innovation pipelines. Sun Pharma Advanced Research Company (SPARC), the innovation arm of Sun Pharma, entered a licensing agreement with US-based Biomodifying Technologies in 2021 for bispecific antibodies and ADC platforms targeting oncology and autoimmune diseases[41]. In early 2025, SPARC submitted an IND application to the US FDA for SBO-154, a novel ADC candidate for solid tumors[42].

Cipla strengthened its presence in next-generation therapeutics by investing €3 million in 2022 in the German biotech firm Ethris to co-develop mRNA-based therapies, followed by an additional €3 million investment in 2024 to advance this collaboration[43]. Reinforcing its commitment to this domain, Cipla established a new subsidiary in Germany — CiplaRNA GmbH — in May 2025 to accelerate mRNA formulation and drug development activities[44].

India is also beginning to make tangible progress in the cell and gene therapy (C&GT) space. A landmark example is Cellogen Therapeutics, which recently secured patent approval for the world's first indigenously developed bi-specific third-generation CAR-T cells. The company, backed by US$2 million in funding from NATCO Pharma, is partnering with Christian Medical College (CMC), Vellore, to conduct early-phase clinical trials evaluating the therapy's safety and efficacy. The initiative has strong institutional backing from the Council of Scientific & Industrial Research (CSIR), the Regional Centre for Biotechnology and the Institute of Genomics and Integrative Biology—demonstrating India's growing ecosystem approach to breakthrough innovation.[45]

Miltenyi Biotec India and BIRAC have entered a landmark partnership to strengthen India's cell and gene therapy (C&GT) ecosystem through training, translational research, point-of-care CAR-T manufacturing and start-up mentorship. The alliance merges global CGT expertise with India's public innovation framework to build local capabilities, enhance access to advanced therapies and position India as a global hub for next-generation biomedical innovation[46].

Another compelling example of homegrown innovation is Bugworks Research, a C-CAMP-supported start-up advancing cutting-edge R&D in next-generation broad-spectrum antibiotics to combat antimicrobial resistance (AMR) and novel small-molecule therapies for cancer[47, 48]. The company has also entered into a co-development collaboration with the Global Antibiotic Research & Development Partnership (GARDP) to design and advance both intravenous and oral antibiotic formulations, underscoring its commitment to addressing some of the most pressing global health challenges[49,50].

[40] https://www.newindianexpress.com/business/2025/Jul/11/glenmark-abbvie-deal-a-turning-point-in-indian-drug-innovation
[41] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/sparc-enters-licensing-pact-with-biomodifying-for-licensing-of-novel-drug-targets-against-cancer/articleshow/88071208.cms?from=mdr
[42] https://www.expresspharma.in/sparc-announces-submission-of-ind-application-for-sbo-154-to-usfda/
[43] https://www.ethris.com/news/eu3m-cipla-investment/
[44] https://medicaldialogues.in/news/industry/pharma/cipla-eu-uk-incorporates-new-wholly-owned-subsidiary-in-germany-149185#:~:text=%2C%20UK...-,Cipla%20(EU)%2C%20UK%20incorporates%20new%20wholly%20owned%20subsidiary%20in,%2Dinfective%2C%20and%20CNS%20segments.
[45] https://www.expresspharma.in/indian-biotech-firm-develops-first-indigenous-bi-specific-3rd-generation-car-t-cells-for-cancer-treatment/
[46] https://www.thehindu.com/news/cities/Hyderabad/miltenyi-biotec-birac-partner-to-boost-cell-and-gene-therapy-capabilities/article69709969.ece
[47] https://www.ccamp.res.in/c-camp-innovation-insights-1
[48] https://bugworksresearch.com/project-portfolio/#onco-anchor
[49] https://www.amr-insights.eu/novel-broad-spectrum-antibiotic-compound-prioritized-for-development-in-fight-against-amr/
[50] https://bugworksresearch.com/wp-content/uploads/2025/07/20250721_PR_GARDP-BW_BWC0977-Oral.pdf

Evolution of pharma industry: small molecules to next-generation therapeutics

	Small molecules (1950s)	Biologics and targeted therapies (1980s)	Next-gen therapeutics (new modalities)* (2000s)	(2015+)	(2020+)			
			Cell and gene therapies (CGTs)	Antibody-drug conjugates (ADCs)	DNA & RNA based therapies (mRNA, RNA)	Proteolysis targeting chimera (PROTAC)	Bispecifics / tri-specifics	Radioligand Therapy (RLT)
Global landscape	Constitute ~50% of global pharma sales High competition and pricing challenges could limit potential value growth	Constitute only a small percentage of total prescriptions in the US; However, they account for ~46% of total drug spend in the country	>22 FDA approved therapies on the market in 2025 ~200 approvals expected by 2030	Market to reach US$28 billion by 2028 at a CAGR of ~23% 15 ADCs launched globally (as of Nov 2024)	By 2024, the US had ~21 FDA approved RNA-based therapies >130 RNA programs in trials	PROTACs oncology market to reach US$3.7 billion by 2030 First PROTAC drug is expected to enter the market by 2027	~17 bispecific Ab approved; market projected to reach US$50 billion by 2030 (US$12 billion in 2024) No approved Trispecific Ab; ~50 in pipeline	~Three to five next-gen RLT approved ~70-80 assets in pipeline
India landscape	Journey started with the first indigenous approval in 2013 Four NCEs to date: ▪ Llipagyn ▪ Desidustat ▪ Enmeta-zobactam (inter-nationally approved) ▪ Nafithromy	135 biosimilar approved; only nine approved inter-nationally NBEs in pipeline	First CGT approved in 2016 Two CAR-Ts (NexCAR-19 and Qartemi) approved Multiple assets in pipeline (early stages)	Ongoing research with various assets in pipeline	Gennova's GEMCOVAC established India's first mRNA vaccine Research ongoing	Ongoing research with various assets in pipeline	Assets under clinical develop-ment; Trispecific Ab - ISB 2001 (AbbVie and Ichnos Glenmark Innovations) in phase I	Limited or no research and development initiatives in this field

*primarily focussed on monoclonal antibodies

Sources: DCAT value chain insights; IQVIA; Pharmacy Times; BioMed Central; Business Wire - BsAb, BusinessWire – TriAb; Clearview HCP - RLT

Innovation journey: Next-generation therapeutics pipeline

Antibody-drug conjugates (ADCs)

Industry

- **Sun Pharma (SPARC)**
  - **SBO-154:** Novel ADC asset; submitted IND application to USFDA in Q1 2025
- **Zydus**
  - Biosimilar for Roche's first ADC blockbuster Kadcyla

Academia

- **Institute of Science Education and Research (IISER), Bhopal**
  - BHoPAL: technology for attaching chemical tags to proteins without compromising its function

Tri-specific antibodies

Industry

- **Ichnos Glenmark Innovation (IGI)**
  - Global licensing deal with AbbVie for ISB 2001, a first-in-class trispecific antibody (BCMA × CD38 × CD3) in Phase 1 trials for relapsed/refractory multiple myeloma

mRNA/ RNA therapies

Industry

- **Gennova** developed India's first mRNA vaccine, **Gemcovac**, and introduced thermo-stable mRNA technology – a platform that can be used beyond COVID (2023)
- **TechInvention** signed an MoU with **Belgium's Quantoom Biosciences (2025)**
  - To boost local manufacturing of mRNA and self-amplifying RNA (saRNA) vaccines in India

Academia

- **Gennova Biopharmaceuticals** partnered with **CEPI (Coalition for Epidemic Preparedness Innovations) (2025)**
  - To develop AI-enhanced self-amplifying mRNA vaccines against major infectious disease threats

CAR-T landscape

Industry

Approved therapies

- NexCAR19 (ImmunoAct) first indigenously developed CAR-T in India (Oct'23)
- Qartemi (Immuneel Therapeutics, Jan'25)

Pipeline and regulatory approvals

- **Cellogen Therapeutics:** secured patent for world's first indigenously developed bi-specific third generation Chimeric Antigen Receptor T (CAR-T) cells (2025)
- **Dr. Reddy's Laboratories: Two** CAR-Ts in development
- **Immuneel:** Three in pre-clinical and two in discovery phase
- **Intas Pharma:** Five autologous cell therapies
- **ImmunoACT:** Four in pipeline (discovery – clinical)

Academia

- **Gujarat Biotechnology University (GBU)** partnered with **Celliimune Biotech**
  - To develop an indigenous CAR-T cell therapy for blood cancer patients in India (2025)

Non-exhaustive
Sources: Tri-specific, TechInvention, mRNA vaccine – India, Gennova Biopharmaceuticals, Cellogen Therapeutics, Gujarat Biotechnology University, Immuneel; company website (ImmunoACT, Intas Pharma, DRL) accessed on 5 October 2025

CRDMO/CDMO evolution

Over the years, India's CRDMO/CDMO industry has steadily evolved from a cost-efficient outsourcing destination to a critical node in the global innovation network. Strategic partnerships such as Syngene's long-term collaborations with Amgen and Bristol Myers Squibb (BMS) exemplify this transformation. The dedicated Syngene Amgen Research & Development Center (SARC)[51] and the Biocon-Bristol Myers Squibb Research and Development Center (BBRC) in Bengaluru[52] provide end-to-end support across discovery, development and manufacturing – spanning chemistry, biology, analytics and process research – reflecting deep scientific integration and long-term trust.

Today, the industry stands at an inflection point – entering a phase of accelerated collaboration, technological expansion and scientific depth. Indian CRDMOs are rapidly extending their capabilities beyond traditional chemistry services into high-value segments such as biologics, antibody–drug conjugates (ADCs), oligonucleotides and radiopharmaceuticals, marking a shift from volume-based to value-driven, technology-intensive partnerships.

Over the past 12 to18 months, firms such as Syngene, Piramal Pharma Solutions, Divi's, Laurus Labs, Gland Pharma, Aurigene, Sai Life Sciences and Enzene have forged alliances with global innovators in areas like antibody–drug conjugates (ADCs), GLP-1 injectables, biologics, DNA-encoded libraries and cell therapy discovery.

These collaborations—often paired with capacity investments and acquisitions—underscore a clear intent: to move up the pharmaceutical value chain and integrate advanced R&D with large-scale GMP manufacturing.

Indian CRDMOs are also forming strategic partnerships to deepen scientific capabilities and offer truly integrated end-to-end services. Collaborations such as Aurigene with Vipergen (for DNA-encoded library screening)[53,54], Syngene with ExcellGene (for cell-line and protein-expression platforms)[55] and Sai Life Sciences with Agility and Centrix (for integrated CMC solutions)[56] exemplify how Indian firms are combining discovery, development and manufacturing strengths to become full-spectrum global partners for biotech and pharma innovators.

These organizations are increasingly establishing an international manufacturing footprint—either through greenfield facilities or strategic acquisitions—to be closer to key clients, meet regulatory expectations and strengthen their global delivery model. Examples include Syngene's acquisition of Emergent BioSolutions' biologics site in the US[57] and Enzene's new continuous manufacturing facility in New Jersey[58]. These moves reflect a deliberate strategy to enhance client proximity, diversify risk and position India's firms as globally integrated, trusted partners capable of end-to-end execution for complex and emerging therapies.

> A decade ago, the Indian CRDMO industry was valued at under US$1 billion; today it stands at US$3 billion to US$3.5 billion. Although still about one-tenth the size of China's US$30 billion to US$35 billion market, India has clearly established itself as a credible global destination, with international pharma and biotech companies increasingly considering Indian CRDMOs for partnership opportunities.
>
> *CXO, leading Indian CRDMO company*

[51] https://www.biopharminternational.com/view/syngene-international-establishes-rd-center-amgen
[52] https://www.bms.com/about-us/our-company/worldwide-facilities/our-research-facilities/bangalore-india.html
[53] https://www.bms.com/about-us/our-company/worldwide-facilities/our-research-facilities/bangalore-india.html
[54] https://www.contractpharma.com/breaking-news/aurigene-vipergen-partner-to-co-market-offer-del-screening-technologies-to-customers/
[55] Syngene with ExcellGene (for cell-line and protein-expression platforms),
[56] https://www.expresspharma.in/sai-life-sciences-agility-life-sciences-and-centrix-pharma-solutions-launch-integrated-cmc-partnership/
[57] https://www.reuters.com/business/healthcare-pharmaceuticals/indias-syngene-international-acquires-first-us-biologics-facility-50-mln-2025-03-10/
[58] https://www.contractpharma.com/breaking-news/enzene-opens-new-biomanufacturing-facility-in-hopewell-nj/

CRDMOs/CDMOs investing in advancing capability and expanding capacity
Focused on advanced and novel modalities (non exhaustive)

	Manufacturing footprint expansion		Partnerships
	India	International	
Laurus Labs	▪ >400 KL commercial microbial fermentation facility ▪ Gene-therapy GMP facility – INR120-130 crore		
Syngene	▪ Expanded research facility at Hyderabad site ("Genome Valley"), including PROTAC laboratory offering end-to-end PROTAC solutions	▪ Acquired its **first US biologics drug-substance** facility from Emergent) fitted with multiple monoclonal antibody (mAbs) manufacturing lines	▪ Launched advanced protein production platform in collaboration with ExcellGene (2024)
Sai Life Sciences	▪ Novel biologics manufacturing ▪ **Dedicated Peptide Research Center** equipped for complex peptide synthesis, discovery and conjugates		▪ 'Integrated CMC* Partnership' partnership with Agility Life Sciences and Centrix Pharma Solutions to accelerate drug development for innovators ▪ - collaboration combines CMC expertise of Sai in API development, Agility in formulation development, and Centrix in drug product development and clinical manufacturing
Cohance	Announced INR98 crore site capacity expansion across India and US ▪ INR23 crore: new cGMP compliant oligonucleotide facility ▪ ~INR85 crore; cGMP bioconjugation capabilities expansion at NJ Bio site		▪ NJ Bio (Princeton, NJ) acquisition, adding end-to-end **ADC/XDC capabilities (payload-linker chemistry, bioconjugation, analytical) in** 2024 ▪ Acquired controlling stake in Sapala Organics **specializing in oligonucleotide drugs** and nucleic acid building blocks (2024)
Piramal Pharma Solutions		▪ US$90 million to expand US facilities for sterile injectables and ADCs (2025) ▪ ADC Manufacturing Facility in the UK (2023)	▪ Partnership with IntoCell, expanding its Payload-Linker Platform and Bioconjugate Capabilities (2025)

*CMC: Chemistry, Manufacturing and Controls

Sources: Laurus Labs 1, Laurus Labs 2, Syngene 1, Syngene 2, Syngene 3, Sai Life Sciences, Cohance 1, Cohance 2, Cohance 3, Piramal Pharma Solutions; Jubilant Pharmanova, Syngene 4, Syngene PROTAC; Enzene; Sai Life Sciences – CMC partnership; Piramal – IntoCell; Aurigene – manufacturing; Aurigene - partnership

CRDMOs/CDMOs investing in advancing capability and expanding capacity
Focused on advanced and novel modalities (non exhaustive)

	Manufacturing footprint expansion		Partnerships
	India	International	
Jubilant Pharmova		▪ US$50 million investment to expand PET **radiopharmaceutical manufacturing capacity,** positioning itself among top two radio pharma providers in the US	
Enzene Biosciences		▪ First manufacturing base in the US	
Aurigene	▪ Inaugurated its biologics facility spread across 70,000 sq.ft. in Genome Valley, a bio cluster located in Hyderabad, India		▪ Strategic partnership with Vipergen for offering DNA encoded library (DEL) screening and integrated drug discovery services to accelerate success

*CMC: Chemistry, Manufacturing and Controls
Sources: Laurus Labs 1, Laurus Labs 2, Syngene 1, Syngene 2, Syngene 3, Sai Life Sciences, Cohance 1, Cohance 2, Cohance 3, Piramal Pharma Solutions; Jubilant Pharmanova, Syngene 4, Syngene PROTAC; Enzene; Sai Life Sciences – CMC partnership; Piramal – IntoCell; Aurigene – manufacturing; Aurigene - partnership

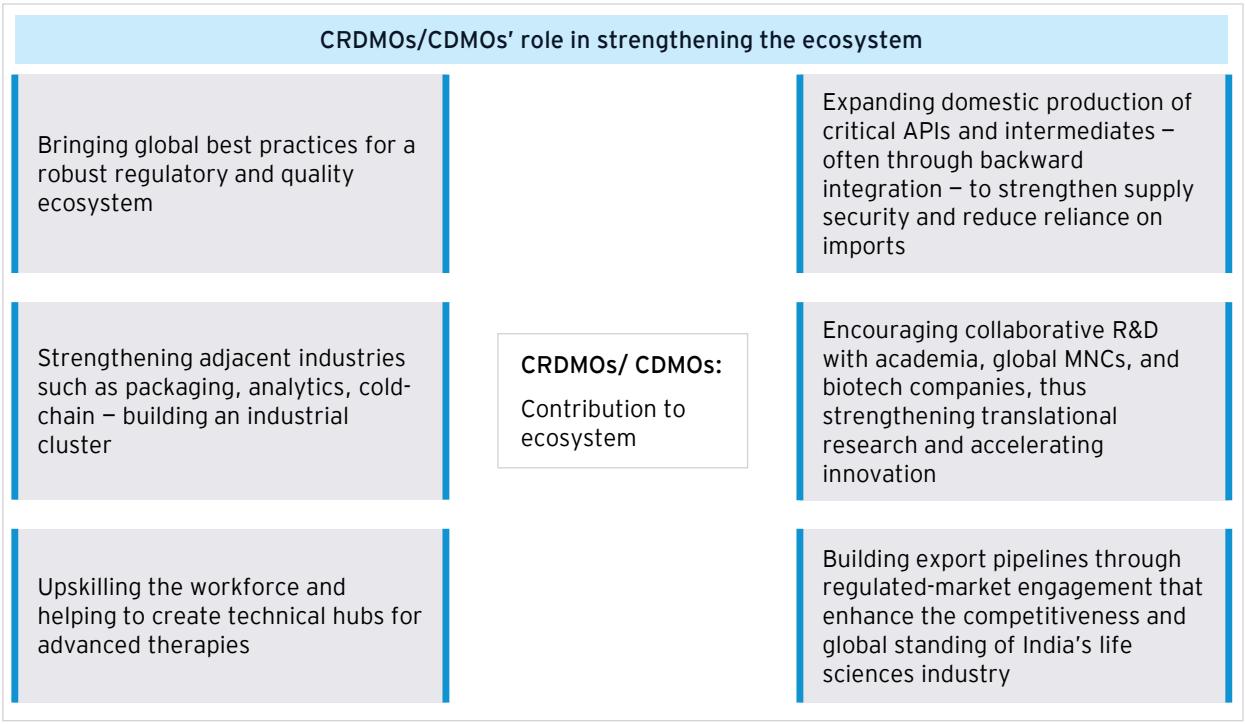
Continuing the momentum

To accelerate India's dominance in biopharma innovation, 11 leading CRDMO companies—Syngene International, Aragen Life Sciences, Laxai Life Sciences, Sai Life Sciences, Aurigene, Anthem Biosciences, Jubilant Biosys, Piramal Pharma Solutions, TCG Lifesciences, Neuland Laboratories and o2h Discovery—have launched the Innovative Pharmaceutical Services Organization (IPSO), a dedicated industry platform aimed at advancing India's CRDMO sector. IPSO's charter focuses on fostering industry collaborations, developing specialized talent, advocating policy measures such as streamlined clearances and regulatory approvals, setting up innovation parks, and strengthening supplier ecosystem by incentivizing local manufacturers[59].

These developments signal that India's CRDMO industry is rapidly redefining its global identity—from a volume-driven, cost-competitive manufacturing hub to a capability-led, innovation-focused ecosystem. The trend reflects not just growth, but maturity—an evolution from cost-efficient manufacturing to innovation-led co-development on a global stage.

[59] https://www.aragen.com/news/industry-leaders-drive-crdmo-reform-unite-under-ipso-for-a-transformational-leap/

Catalyzing a robust and resilient ecosystem



Beyond their direct business growth, CRDMOs/CDMOs are acting as ecosystem multipliers, strengthening the broader pharmaceutical and life sciences value chain. By embedding global best practices in quality, safety and regulatory compliance, they are elevating industry standards and improving India's credibility as a trusted global supplier. Their investments are also stimulating adjacent sectors—from high-precision packaging, analytical and validation services and cold-chain logistics to automation, digital manufacturing and data integrity solutions.

Many are advancing backward integration into critical APIs and raw materials, reducing import dependence and fortifying supply resilience. Equally important, these firms are building human capital through workforce upskilling in biologics, process engineering and regulatory science, while fostering industry-academia partnerships to strengthen R&D talent pipelines.

Together, these initiatives are helping create a robust, innovation-ready ecosystem that supports sustainable growth, supply security, and India's transition from a manufacturing hub to a comprehensive, innovation-driven life sciences powerhouse.

> "India's CRDMO sector is still evolving beyond traditional small-molecule manufacturing. A few companies are beginning to invest in advanced modalities such as peptides, oligonucleotides, antibody–drug conjugates and cell and gene therapies. For positioning India as a globally competitive CRDMO hub, three priorities will be critical: modernizing policies to support innovator-led manufacturing for global markets, expanding the talent pipeline through focused scientific training and incentives and strengthening domestic supply chains to reduce dependence on China. Progress in these areas will be key to positioning India as a globally competitive CRDMO hub.
>
> *CXO, leading Indian CRDMO company*

The race for innovation: Build momentum now before the window closes

While the industry has made encouraging strides in advancing India's transition toward innovation-led growth, the overall scale and pace of progress still trail global benchmarks. India continues to lag leading innovation hubs, both in the number of novel drugs discovered and developed indigenously, and in the volume of globally approved innovative therapies introduced in the domestic market.

When compared with advanced markets such as the US, Europe, and increasingly China[60], the number of novel molecules, original biologics and advanced therapy candidates originating from India remains modest. In the global CRDMO space as well, India currently represents only three to four percent of the total industry—roughly one-quarter of China's share[61].

> "There have been a few real 'Aha!' moments for India's pharma innovation story, but they remain few and far between — the real challenge is scale. As a sector, we have not yet crossed the threshold of critical mass needed to make innovation a defining strength.
>
> *CXO, leading Indian pharmaceutical company*

India also trails by a wide margin in terms of novel drug approvals. In 2024, around 50 novel drugs were approved by FDA[62]; around 46 by EMA[63] and ~46 Class 1 innovative drugs by China's NMPA[64], while only **~19** new drugs were approved in India that year[65,66]—roughly two to three times fewer than the US.

Over the last few years, China has witnessed a rapid acceleration in pharmaceutical innovation, creating a virtuous cycle that continues to strengthen its life sciences ecosystem. Between 2019 and 2023, China's National Medical Products Administration (NMPA) approved 256 new drugs—including both imported and domestically developed molecules—surpassing the US FDA's 243 approvals over the same period. This remarkable surge reflects the outcomes of a deliberate and state-backed innovation agenda supported by sweeping regulatory reforms. These reforms have spanned faster chemical and biologic drug approvals, the introduction of "first-in-class" designations (with 46 such innovations recorded recently), streamlined clinical trial pathways, and targeted incentives to accelerate translational research.

The results are visible in the form of a vibrant innovation ecosystem—marked by increased R&D investment, rising venture capital inflows and the emergence of a new generation of home-grown biotechs. This momentum has fueled cross-border collaborations, global partnerships and talent retention, positioning China as a leading hub for next-generation therapies and a model for how policy, capital and science can align to drive innovation-led growth.

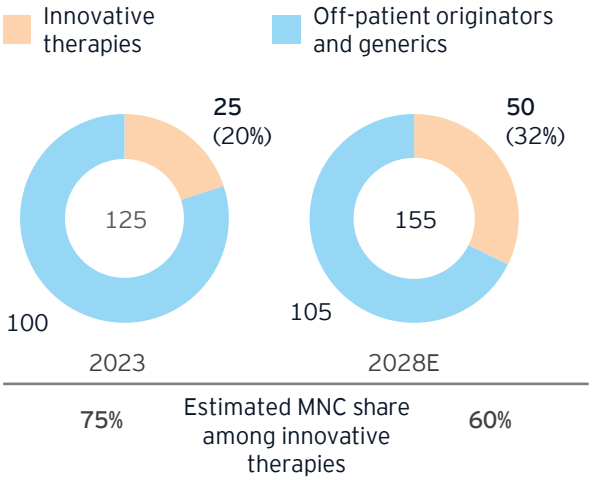
[60] https://www.norstella.com/spotlight-south-korea/?utm_source=chatgpt.com
[61] https://www.jmfinancialservices.in/blogs-and-articles/indias-crdmo-sector-growth-potential-global-impact-and-investment-insights
[62] https://www.fda.gov/files/drugs/published/new-drug-therapy-2025-annual-report.pdf?utm_source=chatgpt.com
[63] https://www.ema.europa.eu/en/news/human-medicines-2024?utm_source=chatgpt.com
[64] https://www.sciencedirect.com/science/article/abs/pii/S0223523425004088
[65] , https://www.fortuneindia.com/amp/story/macro/outlook-2025-indias-cdsco-gives-nod-to-sell-19-new-drugs-in-2024/119658?utm_source=chatgpt.com
[66] https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadApprovalNewDrugs/List%20of%20New%20Drugs%20approved%20in%20the%20year%202024nov.pdf

China's pharmaceutical market has become important both as an end market and as a source of innovation

China market represents attractive commercial opportunities...

Size of China's innovative therapy market expected to be among top 3 globally

China Rx Drugs Market (*Billions USD*)



Data may not be exhaustive

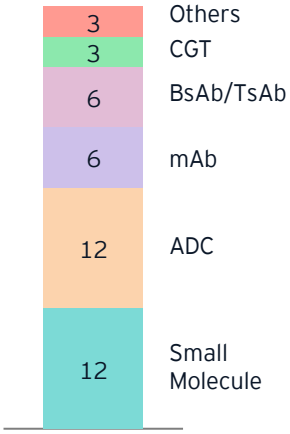
...and made more attractive by access to high quality assets

Most of global MNCs have licensed-in multiple assets originated in China with diverse modalities

# of licensing deals from Top 10 MNCs, 2019-2024 (1)

Pfizer	1
J&J	2
Abbvie	4
MSD	7
Roche	4
Sanofi	3
AstraZeneca	9
Novartis	5
BMS	2
GSK	5
Total	**42**

Licensing deals by modality, 2019-2024



Note: (1) Ranked by 2023 revenue

Source: Tigermed 2023 Annual Results, Tigermed - Leading Contract Research Organization (CRO) for Clinical Trials, Medical Device Trials, IVD CRO Services, and Regulatory Affairs; Biotochina

China's innovative drug market has grown exponentially in the last few years

Early stages: 2010-2017	Entry into value-led innovation:2017- 2021	Global Recognition 2021 onwards
▪ Primarily "me-too" or "me-better" drugs pipeline ▪ Limited clinical development strategy ▪ Fragmented market ▪ Drug lag	▪ Shift towards innovation-led strategy with speed and profile differentiation ▪ Pipeline diversified to include more complex modalities ▪ Return of talent attracted by mix of opportunities	▪ Wave of out-licencing transactions to global MNCs: e.g., 40% of global ADC out-licensing deals since 2021 till 2024 ▪ Co-developments with global leaders ▪ Started to develop assets with global first-wave potential: 15% of first-in-class MoAs are currently developed by Chinese companies

Regulatory reforms and global alignment

2015 reform initiatives	Aligned its regulatory framework with International Council for Harmonisation (ICH) guidelines (2017)	Marketing Authorization Holder (MAH) implementation (2019)	Implemented priority review and special approval pathways	Accelerated clinical trial approvals
streamlined drug approval process, reduce backlogs, and encourage innovation		*encouraged innovation, attracted foreign investment*		*introduced a 30-working-day fast-track review mechanism; down from 60 days*

Current state

46	~80	US$51.5 billion	67
A record-high number of Class-1 innovative drug approvals in 2024	Out-licensing transactions in 2024 (valued in billions)	Total potential out-licensing deal size *(Out-licensing **payment emerging as a new R&D funding source**)*	ICH guidelines fully implemented in China

Source: Tigermed 2023 Annual Results, Tigermed - Leading Contract Research Organization (CRO) for Clinical Trials, Medical Device Trials, IVD CRO Services, and Regulatory Affairs; Biotochina

India's pharmaceutical industry is at an inflection point. The country's growing momentum in next-generation advanced therapies and evolving CRDMO capabilities reflects its steady evolution from a cost-driven manufacturing hub to an emerging innovation and value-creation powerhouse. Yet, the scale and pace of this transformation must accelerate if India is to match the innovation ecosystems of global leaders and secure a larger share of next-generation opportunities. Strong ecosystem partnerships, robust research infrastructure, regulatory agility, funding depth and talent pipelines will be essential to convert early progress into sustainable leadership. The next chapter explores these critical enablers and strategic imperatives that India must prioritize to achieve its future ambition of becoming a true global hub for pharmaceutical innovation and advanced manufacturing.

03

The way forward: Building an innovation-driven and partnership-led pharma ecosystem

India has firmly established itself as the global leader in generics, supplying affordable, high-quality medicines to markets across the world. The next phase of the growth journey lies in accelerating the transition from volume to value, where both pharmaceutical manufacturers and CRDMOs advance up the innovation curve to capture higher-margin, science-led opportunities.

> India's ambition should be to develop 100 new drugs by 2047. We have made some encouraging progress, but we need to accelerate — significantly. The goal is to reach a turnover of over US$400 billion, positioning India as the number one producer globally by volume and among the top three markets by value. However, achieving this vision will require far more than scale — we must strengthen our innovation pathways and ecosystem readiness to truly lead on the global stage.
>
> *Secretary General, Indian Pharmaceutical Alliance*

Foundations for a future-ready pharma ecosystem through partnerships, digital and policy synergies

Partnerships to strengthen the ecosystem

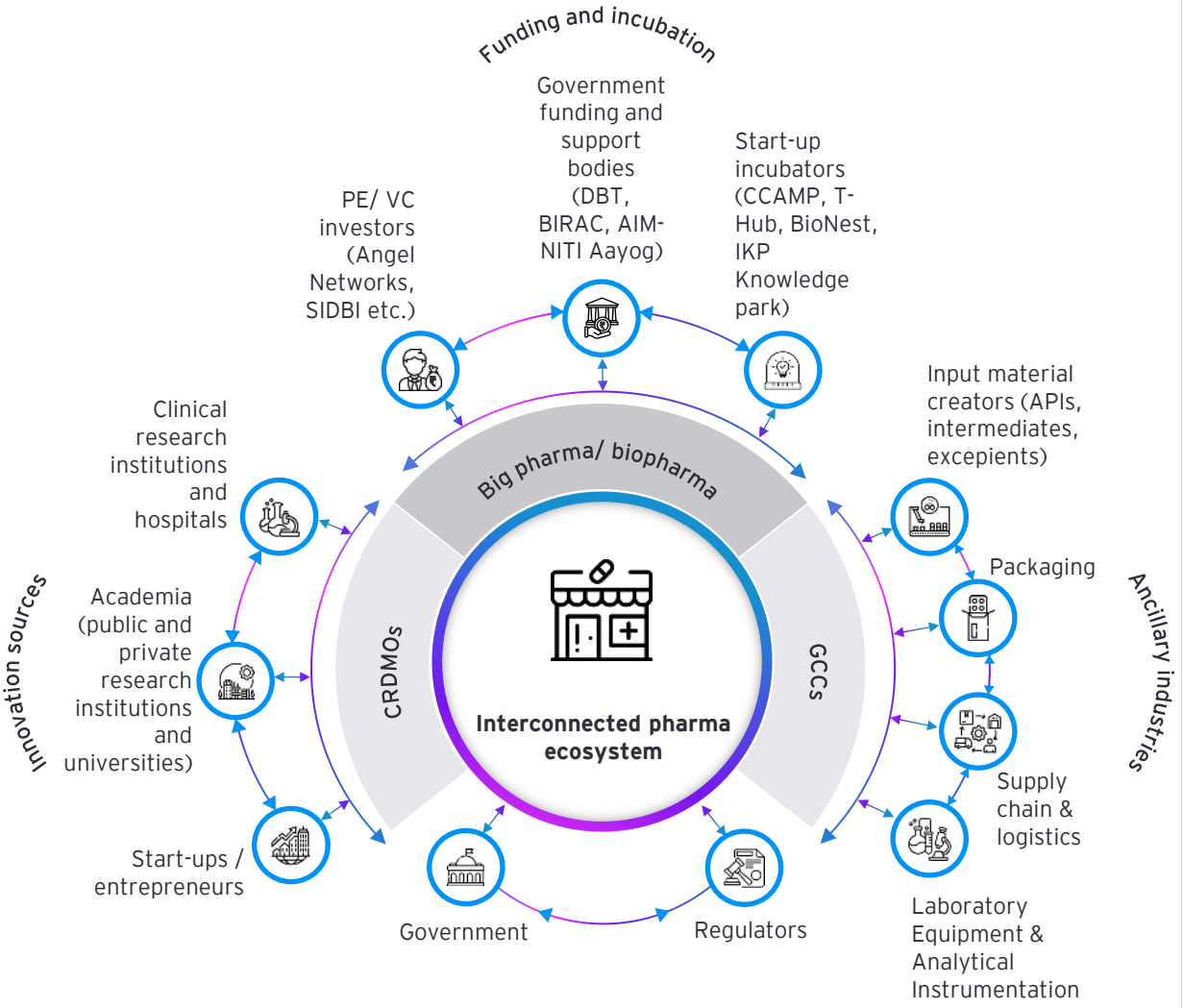
Achieving the value-driven transformation will require more than isolated corporate initiatives; it demands the creation of a robust ecosystem that nurtures research, rewards risk-taking and synergistically connects all elements of the ecosystem.

The ability to realize India's vision of becoming a global pharmaceutical powerhouse hinges on collaborative efforts across all stakeholders in the ecosystem: global and domestic pharmaceutical companies, CRDMOs, GCCs, government, regulators, academia, hospitals, private investors and start-ups. Each segment is evolving to excel in its domain, but now is the time to converge, align priorities and act cohesively to achieve the nation's ambition of emerging as a global leader in pharma and healthcare innovation.

India's pharmaceutical and biotech ecosystem is entering a new phase of purposeful collaboration — one that transcends traditional R&D or licensing models to focus on developing industry-ready talent, strengthening capabilities in advanced and next-generation therapies, empowering start-ups through funding and mentorship and exploring frontier domains such as space biotechnology.

Insights from the CXO interviews conducted for this study reaffirm that a partnership-led innovation ecosystem is one of the most critical success factors for India's next growth leap.

The vision is to establish an interconnected ecosystem where all stakeholders collaborate seamlessly to drive value-led growth and innovation.



Sources: EY analysis

DBT: Department of Biotechnoloy, BIRAC: Biotechnology Industry Research Assistance Council; SIDBI: Small Industries Development Bank of India; AIM: Atal Innovation Mission

Collaborations strengthening the innovation ecosystem

Research and innovation

Partnering companies		Initiatives
Roche	Department for Promotion of Industry and Internal Trade (DPIIT)	▪ Support DPIIT-recognized start-ups focused on critical therapeutic areas including oncology, neurology, etc. ▪ Help start-ups transition from prototype → validation → scale, especially in regulated health-tech domains
Novo Nordisk	IIM Ahmedabad MoU	▪ Multi-dimensional focus on non-communicable diseases (NCDs), particularly obesity ▪ Co-develop and implement programs across three pillars: health system capacity building, policy advocacy, and health economics ▪ Foster collaborative research, regulatory support ▪ Enable data-driven policy formulation
Miltenyi Biotech Next-gen therapeutics capabilities	BIRAC	▪ Alliance to strengthen India's CGT capabilities, ranging from workforce training and translational research ▪ Establish point-of-care CAR-T centers across India using Miltenyi Biotec's CliniMACS Prodigy platform ▪ Support Indian cell-therapy start-ups with funding and mentoring
C-CAMP	France's PariSanté Campus	▪ Launched Indo-French Life Sciences Sister Innovation Hub ▪ Centered on One Health and digital health technologies, fostering connections between research institutions, academia, and industry
C-CAMP	Indegene	▪ Aim is to support early-stage LS start-ups accelerate tech innovation, product development, and go-to-market ▪ Indegene will bring in financial assistance, mentorship, and a digital service suite
DBT	Govt. of Assam	▪ Center and state partnerships to facilitate bio manufacturing activities by leveraging Assam's rich biodiversity and agricultural strength
ISRO	DBT	▪ Inter-ministerial partnership to conduct biotechnology experiments in space station ▪ Innovations in human health research, novel pharmaceuticals, bio therapeutics, regenerative medicine ▪ Opportunities for start-ups in the space and biotechnology sectors to innovate and develop solutions in space biotechnology

Sources: Roche + DPIIT, Novo Nordisk + IIMA, Miltenyi-BIRAC; Miltenyi2; C-CAMP-France; C-CAMP-Indegene; DBT-Assam; ISRO +DBT; ISRO1; ISRO2 (Non-exhaustive)
C-CAMP: Centre for Cellular and Molecular Platforms

Collaborations strengthening the innovation ecosystem		
Skill and talent development		
Partnering companies		**Initiatives**
Pfizer	Gandhi Institute of Technology and Management (GITAM) University	▪ One-of-its kind women-only program to develop a multi-skilled workforce ▪ Offers Bachelors of Chemistry and three-year experience across pharma manufacturing while pursuing bachelor's degree
Enzene Upskilling in advanced manufacturing	Virtuosi	▪ Virtuosi 2.0 is world's first IACET-accredited interactive training platform for the pharma manufacturing ▪ Enzene has integrated Virtuosi into its workforce development programs
IPA+13 Indian and global pharma majors	Pharma Academy for Global Excellence (PAGE)	▪ Industry-academia partnership to launch India's first industry-led training platform for building job-ready professionals in QA, QC, and manufacturing aligned with global quality and regulatory standards ▪ Eligibility: Final-year B.Pharm and M.Pharm students, recent graduates, current pharma professionals
Takeda	BIRAC	▪ Takeda to extend advisory and mentoring support to innovators and entrepreneurs while assisting them from ideation to market deployment of new-age healthcare solutions
Digital-led initiatives		
Early screening and diagnosis		
Astra-Zeneca	Government of Karnataka	▪ Deploy AI-based lung cancer screening technology developed by a start-up named Qure.ai ▪ The tech screens for 29 lung diseases via a single chest X-Ray ▪ Deployed in ~19 to 21 district hospitals in Karnataka (as of 2023)
Digital-led healthcare solutions		
TCS	IIT Kharagpur	▪ Launch advanced research center in digital health and robotics ▪ Aim to drive transformative innovations using AI, embedded systems, and advanced computing tech that can enhance quality of life, improve healthcare delivery, and contribute to the growing field of intelligent systems ▪ Create opportunities for interdisciplinary collaborations, empowering the next generation of technologists and researchers
Drug discovery		
Excelra (global bio-infor-matics Company)	IIT Kharagpur	▪ Multi-year strategic partnership to advance drug repurposing using NLP and ML approaches ▪ Excelra's proprietary Global Repurposing Integrated platform (GRIP) is driven by a rich proprietary database combining over 40 public data sources ▪ Scientists from Excelra and IIT-Kharagpur will use publicly available ontologies and Excelra databases with Drug-Disease-Target relationships for training NLP and ML algorithms

Sources: Pfizer + GITAM; Enzene-Virtuosi; IPA-PAGE; Takeda-BIRAC; AZ + Government of Karnataka; TCS – IIT; Excelra+IIT Kharagpur (Non-exhaustive)

> We need to build a truly world-class R&D ecosystem — without it, we will not be able to go far or realize our full potential as a global pharma leader.
>
> *CXO, leading Indian pharmaceutical company*

> The real power of progress lies in partnerships. Too often, the pharmaceutical industry expects the government to do everything, while the government expects the industry to take the lead — and when that happens, collaboration breaks down. Whether it is innovation, access or delivery, we need to stop assigning responsibility and start sharing it. The solution is simple: bring every stakeholder — government, industry, doctors, patients and funding agencies — to the same table, put the problem at the center and work collectively on practical solutions. That is the only way to drive meaningful change, be it in improving access or accelerating innovation.
>
> *CXO, leading global biopharma MNC*

Innovation ecosystems in Boston and San Francisco demonstrate the power of sustained investment in fostering collaboration across industry, government, academia and healthcare institutions. Partnerships within a robust ecosystem not only contribute to significant healthcare and economic impact for the country but also result in the synergistic growth of each stakeholder within the ecosystem, multiplying success several times.

> In the US, innovation thrives in strong clusters such as Boston and San Francisco. India needs to build and strengthen similar ecosystems in Bengaluru, Hyderabad, Ahmedabad and Mumbai — places where research institutions, medical colleges, world-class hospitals and skilled talent coexist. Fostering such innovation clusters will be key to driving the next wave of pharmaceutical breakthroughs.
>
> *Secretary General, Indian Pharmaceutical Alliance*

Digital-driven acceleration

Another critical enabler for accelerating drug discovery and research is digitalization — powered by strong ecosystem partnerships. Industry experts highlight a growing momentum to deploy digital tools, advanced analytics, real-world evidence (RWE) and AI/ML applications across the pharmaceutical value chain — from early discovery and clinical development to manufacturing functions. These technologies are transforming how molecules are designed, trials are optimized and data are validated, leading to faster timelines, lower costs and higher regulatory confidence. For Indian pharma companies, building digital and technological capabilities through partnerships — with global tech firms, data science start-ups, academia and healthcare innovators — is key to staying competitive. **Experts during interviews unanimously highlighted that with India's inherent strength in digital talent, data sciences and technology infrastructure, strategic digital integration can serve as a powerful differentiator — amplifying the country's innovation capacity and acting as a true multiplier for R&D productivity and global competitiveness.**

CXO survey: Digital Intelligence is India's catalyst and fighting chance for pharma breakthroughs

R&D and clinical development

Digital technologies are reshaping discovery and development – from AI-driven molecule design to predictive clinical trials that cut cost and time:

- AI/ML-driven molecule discovery and pathway prediction
- Predictive analytics in trial design, recruitment, and site performance
- Cloud-based collaboration platforms for real-time data exchange

> Digital transformation is India's strength. Many Indian companies are rapidly adopting not just AI but also intelligent automation, embedding these tools into their operations to enhance R&D productivity, drive efficiency, and strengthen supply chain resilience.
>
> Digital tools are being leveraged extensively in early-stage drug development, enabling faster molecule screening, smarter target identification, and accelerated clinical trials through improved site selection, patient enrolment, and data analytics.
>
> AI allows us to test thousands of dormant molecules across new pathways, cutting months off development cycles — this is where India can lead.
>
> *CXO, leading Indian pharmaceutical company*

Diagnostics and screening

AI, data analytics, and connected devices are expanding access to early diagnosis and population-level screening, making preventive healthcare a reality:

- AI-enabled imaging and early-detection algorithms
- Population-scale digital screening networks and referral systems
- Predictive health surveillance using epidemiological data

> Digital tools are transforming diagnostics — AI imaging, predictive scans, and mass-screening platforms are enabling earlier detection and better patient reach.
>
> We are seeing a new generation of firms using digital diagnostics to bridge patients, providers, and public-health programs — it is innovation at scale.
>
> *CXO, leading global biopharma MNC*

Therapeutics and care delivery

A unified digital health backbone – built on interoperable EMRs and connected care – is critical to improve treatment access and outcomes.

- Interoperable EMR systems for data portability
- Digital prescribing, e-clinics, and telemedicine platforms
- Patient-facing apps for treatment adherence and outcome tracking

> For India to truly adopt digital health, we need connected EMRs and a culture of data mobility — doctors, hospitals, and patients must all be part of this shift.
>
> Data is power; hospitals must see shared data as a national asset, not a private one. That is when digital healthcare will truly take off.
>
> *Secretary General*

CXO survey: Digital Intelligence is India's catalyst and fighting chance for pharma breakthroughs

Manufacturing and supply chain

AI, machine learning and automation are enabling predictive, efficient, and transparent manufacturing – ensuring quality and affordability at global scale:

- Intelligent automation, digital twins, and predictive maintenance
- AI-enabled process optimization and quality control
- Blockchain for traceability and regulatory compliance

> AI may help us achieve what we have not in decades — the best quality at the best price. It will redefine how we scale affordable excellence.
>
> Digitalization is driving a new era of intelligent manufacturing — real-time analytics, process automation, and predictive maintenance are setting new standards.
>
> *CXO, leading Indian pharmaceutical company*

Ecosystem and policy enablement

Creating an integrated, secure, and data-rich ecosystem through interoperability, digital infrastructure, and innovation partnerships will multiply India's innovation potential:

- National health-data framework and RWE standards
- Incentives for digital adoption and EMR interoperability
- Public-private partnerships for digital infrastructure and skills

> India's digital advantage lies in its talent and data depth. With interoperable EMRs and real-world evidence frameworks, we can lead the world in data-driven innovation.
>
> Life sciences is where the financial sector was 15 years ago — on the verge of a digital revolution. With our tech strength, India can make that leap faster.
>
> *CXO, leading Indian pharmaceutical company*

Enablers and actions for India's next growth leap: Voice of the industry

According to interviewed industry **leaders, India's next leap toward becoming a global biotech innovation hub hinges on addressing three high-impact priority areas through collaborative, ecosystem-wide action.**

Regulatory agility and policy leadership

India has made important strides in modernizing its regulatory environment, but it now has an opportunity to become a global benchmark for speed, transparency and predictability. A progressive, science-based regulatory framework – supported by robust intellectual property (IP) protection and regulatory data protection (RDP) – will strengthen investor confidence, attract early-phase research and

position India as a preferred destination for global innovation partnerships.

Key actions for the government and regulators:

- **Advance global harmonization:** Align India's Good Manufacturing Practices (GMP) with the Pharmaceutical Inspection Co-operation Scheme (PIC/S), strengthen participation in international platforms such as the International Council for Harmonisation (ICH), and align standards with leading global pharmacopeias
- **Strengthen regulatory and IP frameworks:** Establish Regulatory Data Protection (RDP) and modern intellectual property practices to promote early-phase clinical trials and global co-development programs
- **Develop a CRDMO-specific regulatory pathway:** Introduce integrated approvals covering research, development and manufacturing services, with clear guidelines on innovation ownership, data transfer and export compliance
- **Enable pathways for novel and rare disease drugs:** Formulate transparent regulatory and approval frameworks for new drug development targeting rare diseases

> Partnerships follow predictability—when data and IP are protected, early-phase innovation will flow naturally into India.
>
> *CXO, leading global biopharma MNC*

> Regulatory harmonization and alignment with international standards are not just a compliance exercise — they are a catalyst for efficiency, credibility and public trust. When India strengthens its alignment with global frameworks like ICH and PIC/S, the benefits are shared across the ecosystem:
>
> - **For government:** Greater regulatory efficiency through mutual recognition, reduced duplication of inspections and enhanced global credibility of Indian authorities
> - **For patients:** Assurance of safe, effective and high-quality medicines that meet the same rigorous standards trusted worldwide
> - **For industry**: Stronger global acceptability of Indian-manufactured products, faster market access and lower compliance costs through consistent quality standards" –
>
> *Policy and advocacy expert, regional pharmaceutical industry trade body*

R&D investment and innovation financing

Indian pharma's R&D momentum is building rapidly. With supportive financing and collaborative risk-sharing models, India can **scale from incremental innovation to breakthrough discovery**. The next leap lies in channeling capital and incentives toward deep-tech research, biologics and advanced therapies.

Key actions: Government organizations, industry, investors and academia

- Create public–private innovation funds for risk innovation fund with venture-style risk-sharing and milestone-based grants
- Introduce minimum market-assurance mechanisms to protect high-investment manufacturers from predatory pricing
- Build co-innovation labs, joint ventures, incubators with academia, government organizations and start-ups
- **Industry** to increase R&D spending beyond 10% of revenues and focus on biologics, ADCs, mRNA, CGTs and other next-generation therapies

> Innovation thrives when bold ideas meet flexible capital — larger, risk-tolerant funding is the bridge to breakthrough science.
>
> *CXO, leading Indian biopharma company*

> Strategic, enduring partnerships—where both sides invest and grow together—are the engines of sustainable innovation.
>
> *CXO, leading global biopharma MNC*

Talent and capability development

India's greatest strength lies in its people. By combining scientific excellence with digital fluency and global exposure, India can nurture a world-class talent base that fuels continuous innovation.

Key actions: Government institutions, academia, pharma majors, CRDMOs and GCCs

- **Government institutions:** Modernize curricula to embed AI/ML, bioinformatics, regulatory science and advanced manufacturing
- **Academia:** Link research grants to translational outcomes such as IND filings and commercialization partnerships; Embed faculty and researchers within industry projects, promoting applied, problem-led innovation
- **Industry, CRDMOs and GCCs:** Co-develop curricula to build job-ready professionals and create joint platforms for developing next-gen capabilities and capacities at scale

> India's edge will come from its people—combining science, technology and creativity into one innovation engine.
>
> *CXO, leading global biopharma MNC*

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Director, Regulatory Drug development & manufacturing, EFPIA

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National President, FOPE and Director, Embiotic Laboratories (P) Ltd

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President OPPI and Vice President & Managing Director, GlaxoSmithKline Pharmaceuticals Ltd

Amitabh Dube
President Elect OPPI and Managing Director, Novartis Healthcare Private Limited

Shubhini Saraf
Director, NIPER Raebareli

Pratima Reddy
Managing Director,
Merck Specialities Private Limited and Country Speaker Merck India

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Head of GCC India,
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Market access and policy lead, India, Organon

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HR Lead India and AP Subcluster), Organon

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