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Can India’s CDMOs Lead the Next Biopharma Wave?

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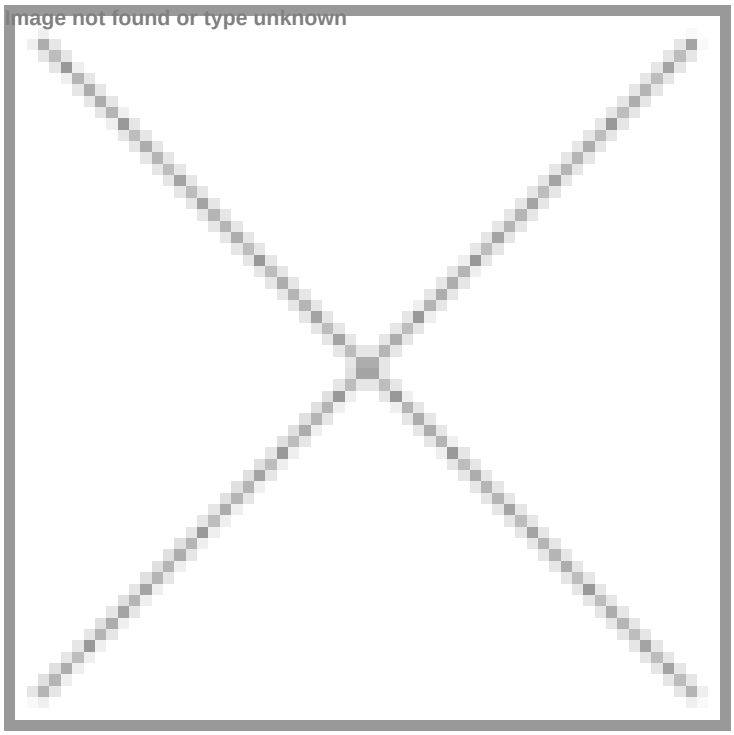
India’s Contract, Development, and Manufacturing Organisation (CDMO) sector is projected to grow from $3–3.5 billion today to $22–25 billion by 2035, noted ??Boston Consulting Group (BCG). While small molecules continue to form the backbone of manufacturing, new opportunities are emerging in biologics, antibody drug conjugates (ADCs), gene therapies, and RNA therapeutics. As India gears up for this next phase of expansion, what challenges stand in the way, and how is the industry preparing to address them? Let’s find out.



India’s CDMO industry accounts for 2–3 per cent of a global market valued at over $140 billion in 2024 noted BCG report. Growth has been supported by established small molecule capabilities, faster project initiation timelines, focus on quality systems, and cost competitiveness. India also has more than 650 US Food and Drug Administration (FDA)-compliant pharmaceutical plants, one of the highest counts outside the United States.

While small molecules represented 68.23 per cent of the India contract manufacturing organisation market in 2024, the demand is gradually shifting. New modalities such as peptides, biologics, and other advanced therapies are gaining share in global pipelines. Biologics contracts, in particular, are accelerating, with a projected CAGR of 15.79 per cent, which could lift their share to well above 30 per cent by the end of the decade according to the Mordor Intelligence report. In response, Indian CDMOs are entering strategic partnerships, technology collaborations, and co-development agreements to expand capabilities and participate in higher-complexity segments.

From Small Molecules to Specialised Therapies

As the industry shifts beyond its traditional small molecule base, efforts are underway to reposition India's CDMO ecosystem for more complex and innovation-driven segments. In 2024, eight Indian CDMOs announced that they had formed a trade group to raise the profile of India's drug services sector and position the country as a destination of choice. In 2025, amid concerns over the lack of a clear and unified industry definition and slow structural progress, leaders came together to form the Innovative Pharmaceutical Services Organisation (IPSO). As a dedicated industry body uniting 11 leading CRDMO companies, IPSO aims to create a strategic blueprint and roadmap to define the CRDMO sector and accelerate India's presence in biopharma innovation.

Companies are also expanding their capabilities in advanced modalities. Aragen has launched a new cell line development and early manufacturing platform, while Bharat Biotech has introduced Nucelion, a next-generation cell and gene therapy CRDMO.

Companies are also opening new facilities both domestically and internationally to expand capacity and strengthen their manufacturing footprint. Eli Lilly has announced over $1 billion in new contract manufacturing investments in India. Jubilant Biosys has opened a new discovery and preclinical facility in Noida, doubling its chemistry capacity for research and scale-up projects. Cohance Lifesciences has injected Rs 23 crore into a cGMP oligonucleotide facility in Hyderabad. Shilpa Medicare has opened a flow chemistry manufacturing centre in Bengaluru, strengthening high-complexity API manufacturing.

Indian CDMOs are also scaling their global presence. Akums has broken ground for its first overseas manufacturing facility in Zambia. Hyderabad-based Novopor Advanced Science has expanded internationally through the acquisition of US-based FAR Chemical, strengthening its position in custom and complex specialty chemical manufacturing. Enzene has announced the opening of a new continuous biomanufacturing facility in the US. Cohance Lifesciences has announced a $10 million investment in a cGMP bioconjugation suite in the US.

Strategic development and CDMO partnerships are also accelerating such as Sai Life Sciences, Agility Life Sciences, and Centrix Pharma Solutions have launched an Integrated CMC partnership to provide end-to-end Chemistry, Manufacturing and Controls services to innovator biopharma companies.

This expansion into advanced and high-value segments also introduces a new set of challenges for the sector.

Challenges

While India's CDMO sector continues to expand, industry leaders agree that the challenges confronting the sector can broadly be categorised into four themes: rising complexity of therapies, escalating regulatory and compliance demands, supply chain and geographic risks, and persistent margin pressures amid demand volatility.

Complexity of Therapies and Technology Upgradation

"One of the biggest challenges currently facing CDMOs is that even simple 'small' molecules have become complex. Customer pipelines are no longer dominated by conventional small molecules; instead, there is rising demand for capabilities in peptides, oligonucleotides, antibody–drug conjugates and other advanced modalities. As a consequence of this shift CDMOs have had to advance and invest in deeper process expertise, advanced technologies, and more sophisticated analytical and quality frameworks," said **Saharsh Davuluri, Vice Chairman and Managing Director, Neuland Laboratories.**

Neuland Laboratories Limited has announced a major investment in a new commercial-scale peptide manufacturing facility at its Bonthapally site. Construction of phases one and two, out of four planned phases, began last year, with the first modules expected to become operational by Q2 FY 2027. The facility is being developed to support both development and commercial programmes, including GLP-1s, amylin analogues, and other peptide-based therapies.

"While the Indian CDMO sector has seen substantial growth, it still faces challenges in advanced capabilities like biologics, a high?value segment where many global players have more advanced infrastructure," agrees **Manish Jain, Director, Naprod Life Sciences.**

Regulatory Pressure and Compliance Cost Escalation

“CDMOs face several challenges globally, which are also prevalent in the Indian pharmaceutical industry. A significant issue is navigating complex and constantly evolving regulatory requirements from major health authorities, as well as regulators in India. Indian CDMOs, in particular, must manage the added complexity of aligning with both global standards and domestic regulations. This often involves high costs related to maintaining compliance, ensuring bio?equivalence, and meeting quality standards. Supply chain vulnerabilities are another critical challenge, as CDMOs rely on key raw materials and often face logistical hurdles in importing and distributing these materials. Rising client expectations for more integrated and higher?complexity services, such as biologics and specialised injectables, have put further pressure on these organisations to upskill and optimise their processes,” said Jain.

Pricing and compliance pressures continue to weigh heavily on the companies. “For formulations under price control, conversion charges and packing charges referenced by the Drug Price Control Orders (DPCO) guidelines have not kept pace with real inflation. Since those benchmarks were set, costs of labour, utilities, transport, compliance, and quality systems have risen sharply. However, National Pharmaceutical Pricing Authority (NPPA)-imposed price ceilings restrict the ability to pass on these increases, creating sustained margin pressure for CDMOs,” said **Saurabh Agarwal, Director, HAB Pharma.**

Regulatory upgrades are adding to the cost burden in the domestic market. “The updated Schedule M norms require stronger quality systems, improved facility design, enhanced documentation, and additional trained manpower. While these upgrades are essential for patient safety and global alignment, they significantly increase capital and operating expenditure for manufacturers serving price-sensitive domestic markets,” said Agarwal**.**

International business brings its own set of regulatory pressures. “Many international markets now expect manufacturing standards approaching US FDA or EU Good Manufacturing Practice (GMP) levels. This means heavy investment in infrastructure, data integrity systems, validation, and regulatory documentation. However, pricing expectations in several emerging and regulated markets do not always reflect the true cost of maintaining such high compliance standards,” said Agarwal**.**

Supply Chain Diversification and Geographic Risk

“A second major challenge for CDMOs is the changing geography of outsourcing. Customers are increasingly adopting China-plus-one strategies, alongside growing interest from Western innovators in more local or diversified manufacturing options. So, geographic risk and continuity of supply are now central to sourcing decisions. Therefore, we have been strengthening local sourcing by qualifying reliable Indian suppliers that meet our requirements for quality, reliability and timely delivery. We have also introduced more robust business continuity frameworks to minimise disruptions arising from logistics challenges and geopolitical uncertainty,” said Davuluri.

Echoing similar sentiments, **Neeraj Sharma, CEO & MD, OneSource Specialty Pharma** said, “The CDMO industry is undergoing significant change, driven by global uncertainty, supply chain fragmentation, and growing demand for complex therapies. While regulatory pressures, costs, and capacity constraints remain challenges, they are also prompting pharmaceutical companies to rethink their manufacturing strategies. Increasingly, customers are looking to simplify supply chains and reduce geographic concentration risk by working with partners who can offer integrated, reliable solutions. As companies continue to diversify supply networks and scale critical therapies such as GLP-1s, the importance of dependable, high-quality partners will only grow.”

OneSource, is investing approximately $100 million across drug–device combination products, fill-finish, and assembly, supported by a strong focus on quality, compliance, and consistent execution. “Frequent fluctuations in API, excipient, and packaging material prices make cost planning difficult, especially when finished product prices are regulated,” said Agarwal

The volatility is closely linked to global sourcing dynamics. “API pricing and availability are heavily influenced by global supply chains, particularly India–China trade dynamics. Any disruption quickly impacts cost structures and timelines,” said Agarwal

Packaging inputs add another layer of challenge. “Packaging material volatility - Key packaging inputs such as aluminium and PVC, which are critical for blister and strip formats, have seen sharp and unpredictable price swings. This adds further uncertainty to long-term contract manufacturing agreements,” said Agarwal.

Navigating Market Volatility

While the Indian CDMO sector has seen substantial growth, it still faces volatility and uncertainty. “Indian companies must also manage the risk of fluctuating demand for their services. Companies are investing in infrastructure, but sometimes face challenges in balancing long?term capital expenditures with current demand. The overall global biopharma market slowdown

and regional challenges further add to the volatility and uncertainties faced by CDMOs," said Jain.

Filling the gaps

To tackle these challenges, CDMOs have taken several strategic and operational measures to strengthen their competitiveness and resilience. "CDMOs are responding through a mix of operational discipline and strategic realignment: Stronger cost engineering and efficiency programmes to offset margin pressures without compromising GMP standards; Early client engagement and transparent costing models to align expectations on compliance-driven investments; Diversified vendor bases and strategic sourcing to reduce raw material and packaging volatility risks; Digital quality and documentation systems to improve compliance efficiency under stricter regulatory frameworks; Long-term partnerships instead of transactional contracts, enabling better demand visibility and shared risk planning," said Agarwal.

In terms of growth strategies, CDMOs are increasingly moving toward offering 'end?to?end' services. "This means combining drug formulation, analytical support, and regulatory assistance along with manufacturing, allowing them to reduce development timelines and strengthen client relationships. Indian CDMOs are also focusing on advanced technologies like biocatalysis, continuous manufacturing, and biologics production to keep up with global demand for high?complexity drugs. To address talent gaps, companies are investing in talent development programmes, cross?department collaboration, and forming partnerships with academic and research institutions. These solutions are helping Indian CDMOs stay competitive, increase operational efficiency, and better meet the evolving demands of the global pharmaceutical industry," said Jain.

To tackle regulatory and compliance complexities, CDMOs are enhancing their quality management systems and adopting automated tools to streamline processes, documentation, and ensure faster alignment with regulations. "Many companies are also engaging with industry bodies and government officials to advocate for smoother approval processes and infrastructure support, which will help reduce delays and costs. On the supply chain front, CDMOs are diversifying their sources for raw materials and implementing predictive tools to better anticipate supply disruptions and manage inventories more efficiently," said Jain.

Companies are also taking steps to strengthen and reduce operational risk. "Therefore, we have been strengthening local sourcing by qualifying reliable Indian suppliers that meet our requirements for quality, reliability and timely delivery. We have also introduced more robust business continuity frameworks to minimise disruptions arising from logistics challenges and geopolitical uncertainty," said Davuluri.

An EY report outlines a three-pronged strategy to unlock India's projected $450 billion pharmaceutical potential. First, it calls for greater regulatory agility and policy leadership by aligning Indian GMP standards with global benchmarks, strengthening participation in international regulatory forums, and creating a CRDMO-specific regulatory pathway supported by Regulatory Data Protection to enable early-phase trials and co-development. Second, the report emphasizes the need for stronger R&D investment and innovation financing, including public–private funds to support high-risk research in biologics, cell, and gene therapies. It also urges pharmaceutical companies to raise R&D spending beyond 10 per cent of revenues and establish co-innovation laboratories with academia and startups to bridge the gap between discovery and commercialisation.

Third, it highlights talent and capability development as critical, recommending modernisation of academic curricula to include AI, machine learning, bioinformatics, and regulatory science, along with structured collaboration between industry, CRDMOs, and global capability centers to create job-ready programmes and link research grants to measurable outcomes such as IND filings.

India is laying the groundwork to be ready for the next wave of manufacturing at scale, as a primary supplier of some of the most innovative commercial therapies. The challenges span regulatory complexity to supply chain disruptions and rising expectations in advanced modalities. How the industry continues to address these pressures will shape its transition from a cost-driven outsourcing base to a globally trusted manufacturing and innovation partner. BCG estimates that the Indian CDMO market is projected to grow from $7 billion to $14 billion by 2028, capturing 4 to 5 per cent of the global market; the coming years will be critical in determining whether scale translates into sustained global leadership.

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