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THE INDIAN CRO/CDMO OUTSOURCING GUIDE

A STRATEGIC ROADMAP FOR GLOABL COMPANIES

Summary

In this guide, we provide a concise overview of India's CRO and CDMO landscape for foreign pharmaceutical and biotech companies seeking reliable outsourcing partners. The guide explains the roles of CROs, CDMOs, and integrated CRDMOs, highlights why India has become an important global outsourcing destination, and outlines the key factors companies should evaluate before entering partnerships.

It also covers the regulatory, legal, and commercial considerations that influence successful outsourcing in India, including compliance expectations, intellectual property protection, foreign investment context, and partner qualification. Overall, the guide is intended to help readers make informed decisions when selecting Indian partners for research, development, and manufacturing activities.

Why India? Service Offerings from CRO, CDMO to Integrated CRDMO

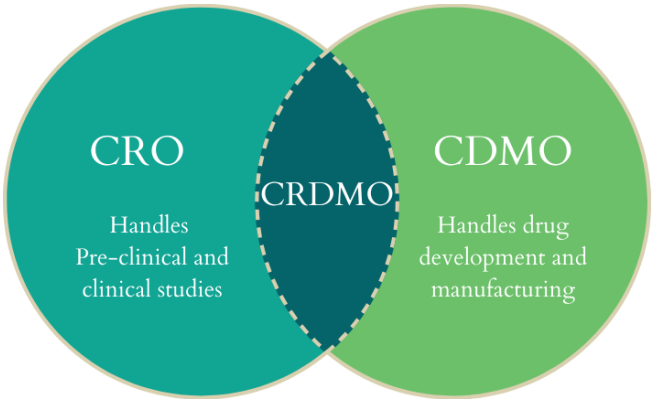


Figure 1: CRO, CDMO and integrated CRDMO

A **CRO** - Contract Research Organisation - is an important component of the drug development ecosystem, providing a range of services from the discovery of a molecule to its post-marketing surveillance.

- **Drug Discovery** – CROs provide services such as target identification and validation.
- **Pre-clinical Research** – Studies in accordance with GLP required for Investigational New Drug (IND)/Clinical Trial Application (CTA) filing with different regulatory agencies.
- **Clinical Trial Planning and Management** – During all three phases of clinical trials, the organisation is responsible for site selection, patient recruitment, monitoring and retention.
- **Data Management** – The pre-clinical and clinical data entry and validation, database designing and data analysis also fall under the responsibility of CRO.
- **Post- marketing surveillance** – Pharmacovigilance and risk management of drug post–marketing.
- **Administrative Services** – Throughout the process, various administrative services such as strategic consulting and protocol development, project management, statistical analysis, safety and efficacy summaries, etc., are also provided by CROs. [1]

A **CDMO** – Contract Development and Manufacturing Organisation- combines two critical functions of drug development and manufacturing.

- **Drug Formulation and Development** – Formulation of a dosage form to ensure its stability, efficacy and scalability.
- **Analytical Method Development** – Establishment of protocols for quality control of the formulation.

- **Technology Transfer** – CDMOs ensure the scaling of the project from lab to commercial.
- **Manufacturing** – Manufacturing of API or formulation in sufficient quantities, ranging from small amounts for clinical trials to commercial success scales- GMP compliant. [2]

India is shifting towards a more integrated approach: a CRDMO – Contract Research, Development and Manufacturing Organisation Model - an end-to-end innovation model that will ensure an efficient path to market. These organisations combine the services of a CRO and CDMO to provide a holistic approach from discovery to market. [3]

Benefits of a CRO/CDMO/CRDMO

- Reduce infrastructure costs
- Access additional and specialised experts
- Faster timelines
- Meet production deadlines and increased demands
- Reduce technology transfer risks. [2,4]

Technical Capabilities of the Indian CRDMO Market

Indian CRO/CDMOs provide services ranging from traditional small molecules to complex novel modalities, including, but not limited to, biosimilars, monoclonal antibodies, antibody-drug conjugates, Cell and gene therapy, and precision medicine [5]. Currently, India has 600+ FDA-approved sites all over India providing a variety of services.

Small Molecules

India is known for its small-molecule manufacturing facilities and has a large number of FDA-approved facilities. The established name for the manufacturing facilities comes from strict adherence to global regulatory norms, assurance of supply, an educated workforce and reduced financial burden. [6]

Biologics

With the growing demand for biologics, the Indian CRO/CDMO market is also shifting in the same direction. New facilities from previously established names are opening, along with new names entering the market [7]. Biologic CRDMOs are expected to have higher growth rates than small-molecule CRDMOs [8].

Antibody Drug Conjugates

As the ADC market expands beyond oncology to metabolic diseases, autoimmune diseases, and infectious diseases, India offers discovery-to-production of mAbs, cytotoxic agents, and linkers in a single facility [9].

Cell and Gene Therapy

India encompasses specialised scientists and researchers, and a robust regulatory framework supporting a CDMO hub for CGT manufacturing [10].

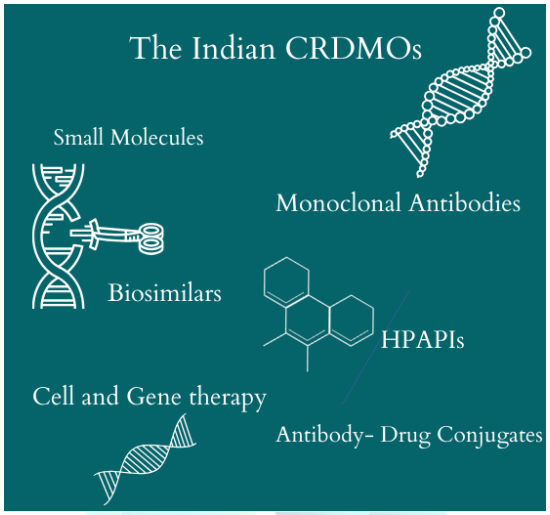


Figure 2: Therapeutic capabilities of Indian CRDMOs

Other Markets

Nutraceuticals & Functional Wellness

The global nutraceutical industry is on the rise, driven by increasing demand for immunity boosters, protein blends, and personalised medicine. A nutraceutical CDMO in India provides formulation development, testing, GMP-certified production, and packaging, all under one roof. The CDMO leverages its expertise to develop safe, effective products that comply with local and global regulations, enabling brands to expand without their own production lines [11].

Cosmetics & Personal Care

The cosmetics and skincare industries have been booming over the past few years and will continue to do so. Skincare and haircare have become an essential part of healthcare. The CRDMO market in India offers a stronger manufacturing base, cost efficiency, and skilled expertise in the cosmetics & topical dermatology sectors. The CRDMOs provide end-to-end services, from formulation development to commercial manufacturing [12].

Medical Devices & Combination Products

The medical devices market in India is currently limited, but with new policies and CDSCO regulations, it is expected to expand by 2030. Indian medical device CRDMOs offer end-to-end services – including design, prototyping, regulatory compliance (CDSCO, FDA), and manufacturing – which reduce costs and accelerate time-to-market [13].

Veterinary & Animal Health

Indian veterinary CRDMOs offer end-to-end services, including formulation development, manufacturing, and regulatory support for livestock and companion animals for the development of veterinary drugs and vaccines [14].

Agrochemicals and Crop Science

Indian agricultural CRDMOs offer research and development, process development, and the cost-efficient manufacturing of agrochemicals in high-tech labs that comply with global standards [15].

Why Global Partners Choose India?

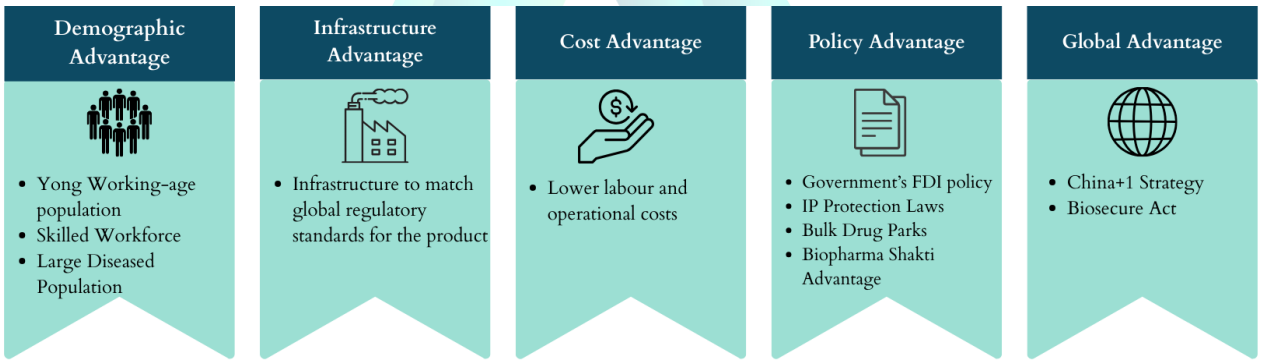


Figure 3: Advantage of India in CRO/CDMO structure

- **Demographic Advantage**
  - **Young working-age population** – India has a relatively young population compared to its competitors, which provides an opportunity for a better workforce pool.
  - **Skilled Workforce** – Apart from the young, the Indian workforce is skilled for science-intensive work, with a high number of STEM graduates, along with good English-speaking skills.
  - **Large Diseased Population** – India provides a large patient pool for various diseases, including lifestyle disorders such as diabetes, hypertension and chronic

diseases such as cancer. India offers a diverse range of patients who haven't been treated earlier, along with a diverse gene pool [16].

- **Infrastructure Advantage**

  The Indian facilities have experience working with global agencies such as the FDA and EMA and are equipped to comply with global regulatory standards. The Indian manufacturing facilities also have a lower percentage of OAI (Official Action Indicated) Flags. [17]

- **Cost Advantage**

  India offers significant cost advantages in both labour and operational expenses, thereby reducing overall costs by 35-40% [18].

Service Category	India	Western Markets
Drug Discovery (per compound)	USD 500K-2M	USD 3-5M
Clinical Trial (Phase III)	USD 2-5M	USD 10-15M
API Manufacturing (per kg)	USD 100-500	USD 500-2000
Formulation Development	USD 50-100K	USD 200-400K
Regulatory Support (per NDA)	USD 100-300K	USD 300-800K

**The costs are subject to change as per therapeutic area, complexity and other project requirements.*

- **Policy Advantage**
  - **Government's FDI Policy** – The Indian government's FDI policy increases the ease of doing business in most sectors, especially the pharma sector [19].
  - **IP Protection Laws** – India has strict laws revolving around product patents and patent infringement, which makes it a supportive hub for research & development [20].
  - **Bulk Drug Parks** – These facilities in India have helped reduce the operational costs [21].
  - **Biopharma Shakti Initiative** – Declared in the Union budget 2026, it aims to make India a global hub for advanced biological therapies in the next 5 years [22].
- **Global Advantage**
  - **China+1 Strategy** – The strategy emphasises exploring different manufacturing locations to strengthen the resilience against global concentration risk. India emerges as a strong location amidst these geopolitical tensions for supply chain diversification [23].
  - **Biosecure Act** – The US has proposed the Biosecure Act, which seeks to block US-based companies from using biotechnology equipment or services from Chinese CDMO services [24].

The Hurdles

Supply Chain Dependency

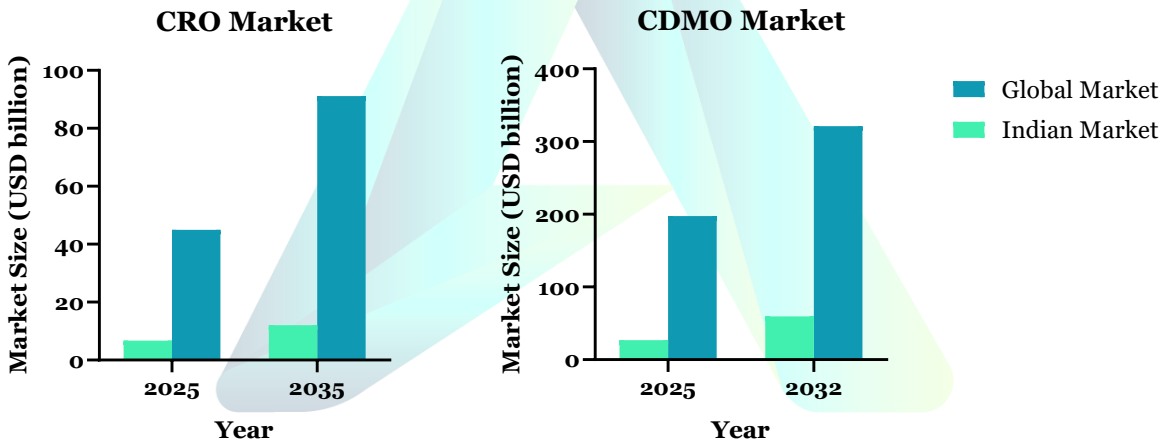
For raw material Indian CRDMOs are dependent on imports from other countries. [25]

Price Competitiveness

As the sector grows, competition amongst domestic service providers also increases, which can lead to overpromises and underperformance.

Market Landscape

The global pharmaceutical CRO and CDMO market was valued at USD 44.95 and 197.40 billion in 2025 [26,27]. The global markets are expected to grow at 7.33% and 7.12% annually for the CRO and CDMO sectors, respectively. The Indian CRO and CDMO market held its value at USD 6.74 and 26.75 billion in 2025 and is expected to grow at 6.00% and 12.06% annually. The Indian CRO is expected to reach USD 12 billion by 2035, while the CDMO market is expected to reach 59.35 billion by 2032 [28,29].



Graph 1: Global and Indian CRO and CDMO Market

Currently, clinical trials dominate the Indian CRO market, and the manufacturing of generic drugs at a commercial scale accounts for a major share of the CDMO market. The Indian CRO and CDMO market is currently shifting towards regulatory affairs, biostatistics, biologics, and other high-end modalities. The market is transforming the adoption of digital and AI methodologies across all sectors. Oncology is the therapeutic area dominating the market and will continue to do so, but the shift from oncology small molecules to oncology biologics is under observation [28,30].

Selecting the Right CRO/CDMO Partner

- **Therapeutic Expertise**: Match the CRO/CDMO capabilities with your product profile.
- **Regulatory Track Record**: Verify FDA approval history, successful NDA submissions, inspection records, and audit reports.
- **Technical Capabilities**: Assess analytical infrastructure, manufacturing scale, and specialised equipment available with CDMO.
- **Quality Systems**: Review GMP/GCP/GLP compliance, audit reports, certifications (ISO, ICH adherence).
- **Project Management**: Evaluate project tracking systems, communication protocols, and milestone achievement.
- **Financial Stability**: Assess company size, ownership structure, and investment in infrastructure.
- **Cultural Fit**: Evaluate communication style, working methodologies, and alignment with your business model.
- **References**: Obtain and contact current clients for objective feedback on collaboration experience.
- **Scalability**: Confirm capacity to grow with your program from development through commercialisation.
- **Data Security**: Verify cybersecurity measures, data backup systems, and regulatory audit trail maintenance.

Where Aventiq Bio Comes

With our AI-vetted checklist of 50+ parameters across 150+ vendors, ranked independently, we help you select the right CRO/CDMO partner with vendor neutrality and on-the-ground accountability.

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