Independent Market Assessment of the Global and Indian CRDMO Market

08- 07-2024

FROST & SULLIVAN

Contents

1 GLOBAL PHARMACEUTICAL INDUSTRY OVERVIEW

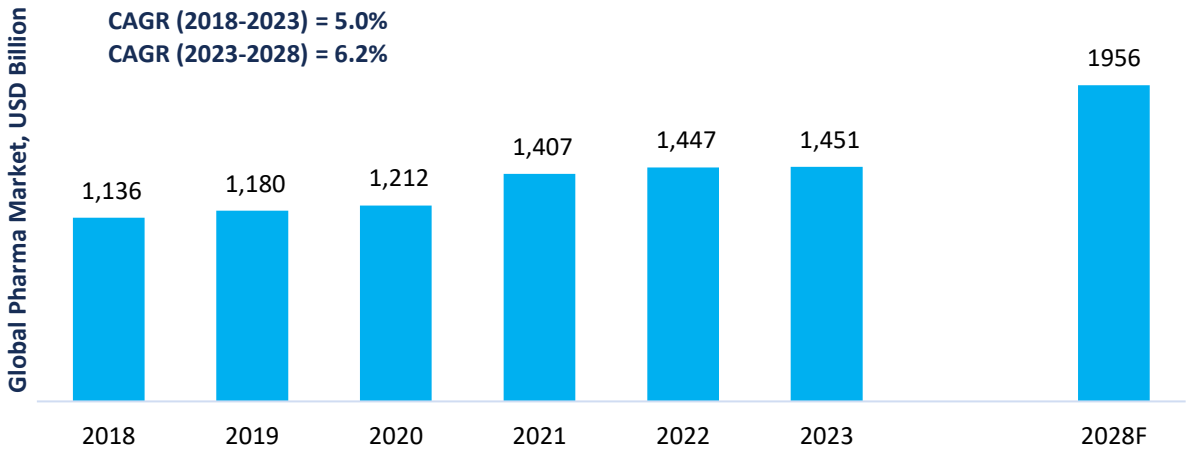
1.1 Market Size and Growth Potential

Resilient and sustainable long-term growth has been evident in the Global Pharmaceutical industry, particularly driven by an increase in chronic diseases, sedentary lifestyles, growth of the geriatric population and increasing health consciousness. The global pharmaceutical industry is undergoing a transformation across its entire value chain led by increasing focus on product innovation and operational optimization

The global pharmaceutical market was valued at USD 1,451 billion in 2023 and is projected to reach USD 1,956 billion by 2028, growing at a CAGR of 6.2% from 2023 to 2028. This growth is primarily attributable to factors like increasing incidence of chronic diseases, sedentary lifestyles leading to diseases and increased health consciousness amongst people. The aging population is also an amplifying factor driving demand- according to WHO, from 2015 to 2050, the percentage of the global population over 60 years will nearly double from 12% to 22% and is anticipated to reach approximately 2.1 billion by the year 2050.

The global pharmaceutical sector is undergoing a profound transformation across its entire value chain, driven by a strong emphasis on product innovation, healthcare equity (healthcare for all), technological advancements, operational efficiency, enhanced engagement with healthcare providers and patients and favourable policies. Despite facing inherent challenges within this transformative landscape, the pharmaceutical industry has demonstrated remarkable agility and delivered ground-breaking innovations, particularly highlighted during the COVID-19 pandemic, enjoying resilient growth.

Exhibit 1.1: Global Pharmaceutical Market, 2018 - 2028F



Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan

1.1.1 Global Pharmaceutical (Pharma) Market by Modalities[1]

The global pharma market comprises primarily of 2 key types of drugs by modality: small and large molecule drugs.

Small molecule drugs have been the mainstay of the pharmaceutical industry for over a century. Defined as any organic compound with low molecular weight, small molecule drugs are known for their affordability, ease of administration (largely orally), and broad therapeutic coverage. Small molecule drug substances are typically manufactured using synthetic chemistry processes.

In contrast, large molecule drugs, or biologics, have a large molecular weight and made of proteins that are complex in structure compared to small molecule drugs. Large molecule drugs are costly to manufacture and, at this time, in most cases can only be administered by injection or infusion. Large molecule drug substances are typically manufactured biologically, i.e. extracted from living organisms, but often include certain synthetic chemistry processes. Antibody Drug Conjugates (ADC) are one such example, which combine antibodies made through biological means with small molecule drug substances made through synthetic chemistry processes.

The Global Pharmaceutical market is dominated by small molecules today, accounting for over 65% of the market by revenue in 2023. Over the past decade, advances in technology, synthetic methodology, and new areas of biology have opened up more opportunities for innovative and creative small-molecule drugs. The dominance of small molecules is anticipated to persist, led by ongoing research and development (R&D) efforts in small molecules, such as modulating RNA splicing, stimulating specific types of stem cells, and developing drugs with antibody or peptide conjugates, to name a few. The pharmaceutical industry is also witnessing a rise of large molecules or biologics in recent years. Biologics are known for their efficacy and targeted action. Valued at USD 480.0 billion in 2023, the biologics market is forecasted to reach USD 752.1 billion by 2028, with a compounded annual growth rate (CAGR) of 9.4% from 2023 to 2028. While the biologics market is expected to grow faster than the overall pharmaceutical market over 2023-28F driven by the increasing adoption of innovations such as immunotherapies

Exhibit 1.2A: Global Pharma Market by Modality, 2018 - 2028F

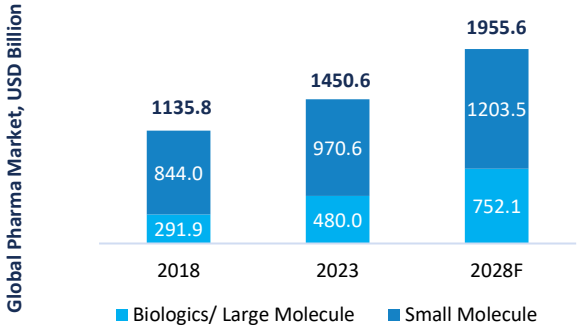
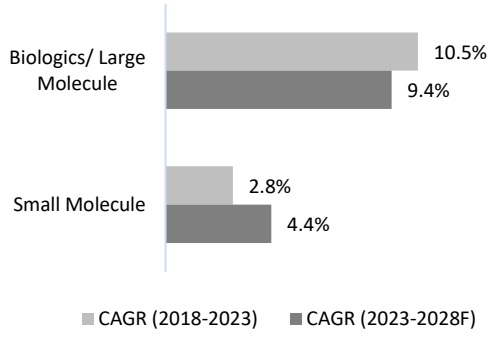


Exhibit 1.2B: Growth Rate of Global Pharma Market by Modality, 2018 - 2028F



Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan

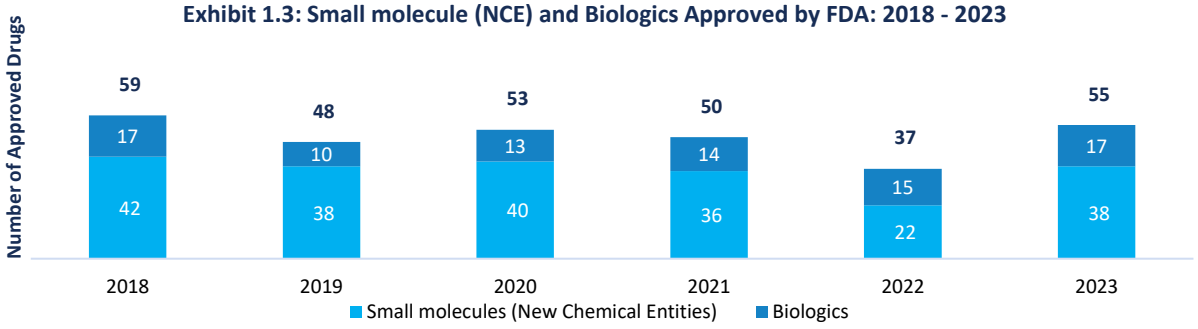
[1] Large molecules or biologics refer to vaccines, antibody therapies, recombinant proteins, vaccines, cell and gene therapies and peptides.

,

antibody-drug conjugates, and gene and cell therapies, small molecules are expected to continue comprising 62% of the overall pharma market in 2028F.

Furthermore, the dominance of small molecules in new drug approvals underscores their prominence. Over the period from 2018-2023, an aggregate of 302 drugs were approved by the US FDA, of which 72% were small molecule NCEs.

Exhibit 1.3: Small molecule (NCE) and Biologics Approved by FDA: 2018 - 2023



Source: USFDA, Frost & Sullivan

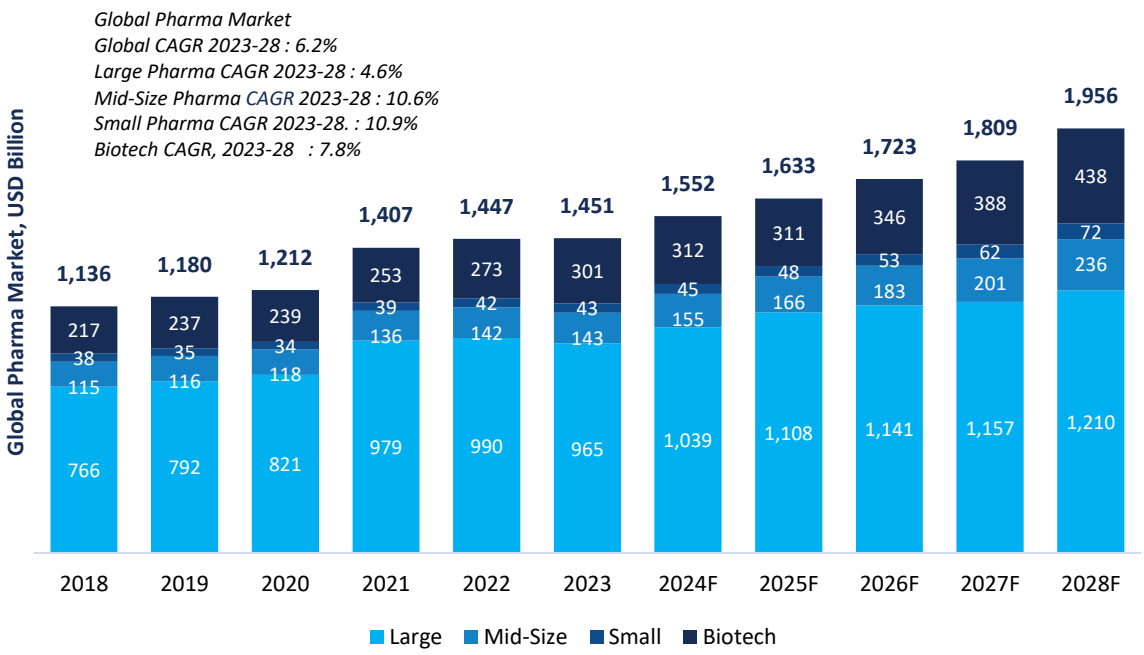
1.1.2 Global Pharmaceutical Market by Company Type

Currently, the global pharmaceutical market is dominated by large global pharmaceutical companies (Pharma companies with revenues > USD 10 billion). Mid-size pharmaceutical companies comprise companies with revenues in range of USD 500 million to USD 10 billion. Small pharmaceutical companies with annual revenue lower than USD 500 million and biotechnology companies ("**biotechs**"), are growing rapidly as compared to large pharmaceutical companies. This growth has been fueled by capital investment, including venture capital investment, in these companies.

Global Pharma Market is witnessing an increasing rise of Biotechnology companies comprising c.20.8% of the overall market in 2023. Biotechs are the fastest growing segment within the global pharma market, registering CAGR of 6.8% over 2018-2023F and expected to grow at a CAGR of 7.8% over 2023-28F. In this context, biotechnology companies, often referred to as biotech companies, are largely startups in the pharmaceutical sector which typically focus on developing innovative drugs and drug development technologies to address unmet medical needs.

Source: Frost & Sullivan

Exhibit 1.4: Global Pharma Market by Company Size, 2018-2028F



Source: Evaluate Pharma, Frost & Sullivan

1.1.3 Global Pharmaceutical Market by Drug Type

Innovator drugs will keep gaining market share with breakthrough science and expanded utilization to new therapy areas.

Innovator drugs refer to first drugs created containing specific active ingredients and undergo approval or patent process for use. Generic drugs, on the other hand, refer to pharmaceutical drugs that have the same chemical composition as the original innovator drug and can be sold by companies after the patent on the original drug expires .

Exhibit 1.5A: Global Pharma Market by Product Type, 2018 - 2028F

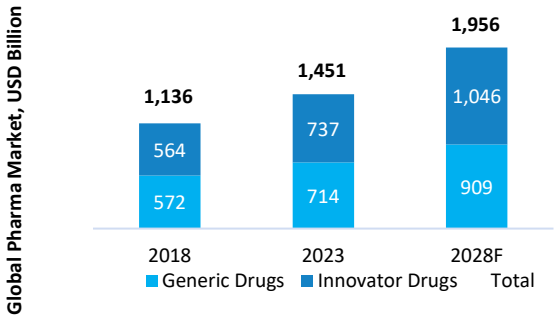
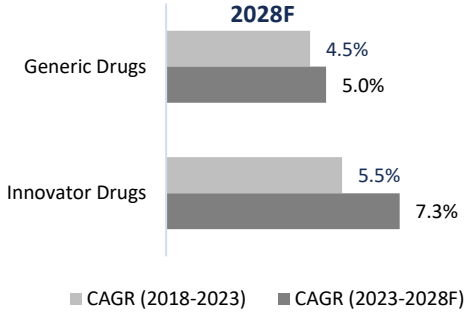


Exhibit 1.5B: Growth Rate of Global Pharma Market by Product Type, 2018 - 2028F



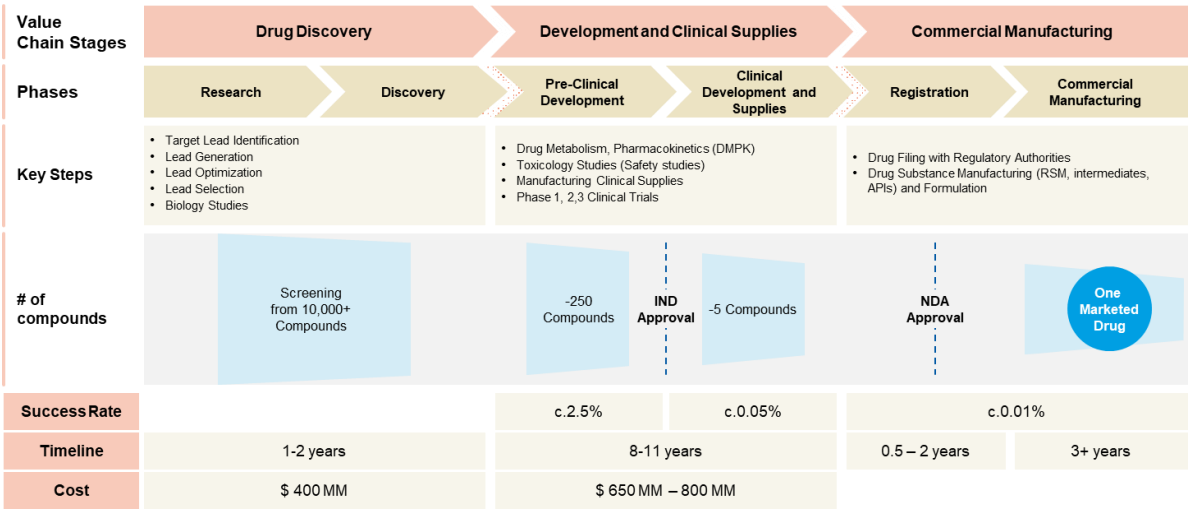
Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan

With more global pharmaceutical and emerging biotech companies investing heavily on innovative drug R&D and with the increasing trend of personalized medicine, the size of the global innovator drugs market increased from US$564 billion in 2018 to US$737 billion in 2023. The innovator drug market is set to grow at CAGR of 7.3% over 2023-2028F to USD 1046 billion by 2028, faster than the overall pharmaceutical market growth. Strong and increasing focus on R&D by pharmaceutical companies is a key driver for the growth of innovator drug market. Biotechnology and pharmaceutical research advancements have led to the discovery of novel drugs that offer improved efficacy, safety, and convenience compared to existing treatments. Growing healthcare spending has provided new opportunities for drug manufacturers to introduce innovative therapies and providing treatment for unmet medical needs. Precision medicine and personalized therapies have become more prevalent, driven by advancements in genomics and molecular diagnostics, enabling the development of targeted treatments tailored to individual patients.

The generic drugs market is also expected to witness a CAGR of 5.0% between 2023 and 2028. Rising competition in the generic drug industry has put a strong pressure on generics pricing in recent years especially in the US. While generics drugs are expected to experience a higher volume growth, pricing pressure will partially offset the value growth.

1.2 Global Pharmaceutical Innovator R&D

1.2.1 Pharmaceutical R&D Value Chain



Source: Frost & Sullivan

In the pharmaceutical industry, a new drug needs to go through extensive testing and regulatory review to examine and verify its safety and efficacy before it is allowed to be released to the market. On average, the process typically takes more than 10 years and requires over US$1 billion in R&D costs from early-stage drug discovery to commercialization. The success rate for developing a new drug from drug discovery to approval is extremely low, and can be lower than 0.01%.

Drug Discovery Phase:

Drug Discovery phase constitutes the processes from target identification to target validation to lead generation and lead optimisation. During this stage thousands of compounds are narrowed down to a few hundred with promising potential. Basic research on the physiological target and development of hypothetical mechanisms of action which could potentially bring about the desired outcome is undertaken. Researchers then look for a lead compound—a promising molecule that could influence the target in line with the projected hypotheses and potentially become a medicine.

Development and Clinical Supplies Phase:

Preclinical Development: Exhaustive laboratory and animal experimentation of the preclinical drug candidates for safety and therapeutic effect to determine whether a compound is suitable for human testing. The process may take several years, and the data generated during this stage is a critical part of the dossier to regulatory bodies to receive approvals for conducting clinical trials.

Clinical Trials: Promising drug candidates are presented to regulatory authorities for permission to conduct human clinical trials via “Investigational New Drug Applications”. Once approved, these drug candidates are referred to as

an Investigational New Drugs ("IND"). INDs proceed to clinical trials which are studies in humans to determine the safety, efficacy, and suitable drug dosage of potential drug candidates.

Drug Substance Development: Covers early stage and late-stage process development and optimisation. Small quantities of drug substance are manufactured under non-GMP conditions for toxicology evaluation and under GMP conditions for initial clinical studies. Depending on the outcome of these studies, larger quantities of drug substance are manufactured for late-stage clinical programs. In this stage, there is increasing emphasis on developing a robust, scalable, safe, and efficient manufacturing process which can be used for subsequent commercialisation of the drug.

Clinical Supplies/ Drug Product Development: Covers early stage and late-stage formulation development and manufacture. As the molecule moves further along the development cycle, the formulation becomes increasingly nuanced in line with the data being generated through the trials. The key formulation types are oral solid dosage forms (tablets, capsules, drug-in-capsule), oral liquid dosage forms (solutions and suspensions), injectable dosage forms (solutions and lyophilised), and modified release oral dosage forms (functionally coated mini-tablets, drug layered beads as well as matrix tablet formulations).

Commercial Manufacturing:

Manufacturing facilities must be carefully designed so that the commercialised product can be consistently and efficiently produced at the highest level of quality. High standards to ensure safety and quality in the manufacturing process are to be used. Companies must adhere to FDA or all other relevant regulations for manufacturing.

1.2.2 Global Pharmaceutical Innovator R&D Spend Trends

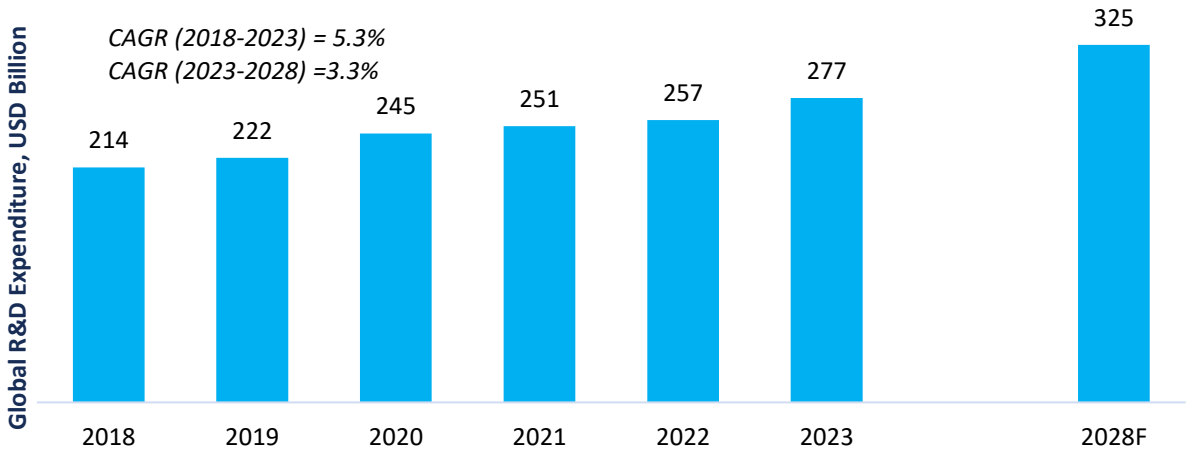
Global pharmaceutical innovator R&D spending is expected to increase at a CAGR of 3.3% between 2023 and 2028. Pharmaceutical R&D spending includes R&D spends by both pharmaceutical companies as well as biotechnology companies (together referred to as "Pharma innovators")

Global spending on pharmaceutical R&D has increased significantly, from $213.8 billion in 2018 to $276.8 billion in 2023. This increase is attributed to the rising complexity of drug discovery and development processes, requiring significant investments in research infrastructure and advanced technologies. The average cost to develop and commercialize a new drug today exceeds USD 1 billion per drug, a tenfold increase since the 1970s.

With increasing market competition and shifting market dynamics, patent expirations and generic erosion, R&D is critical for pharmaceutical companies to sustain competitive advantage and driving future growth.

Source: Frost & Sullivan

Exhibit 1.6: Global R&D Expenditure, 2018 - 2028F

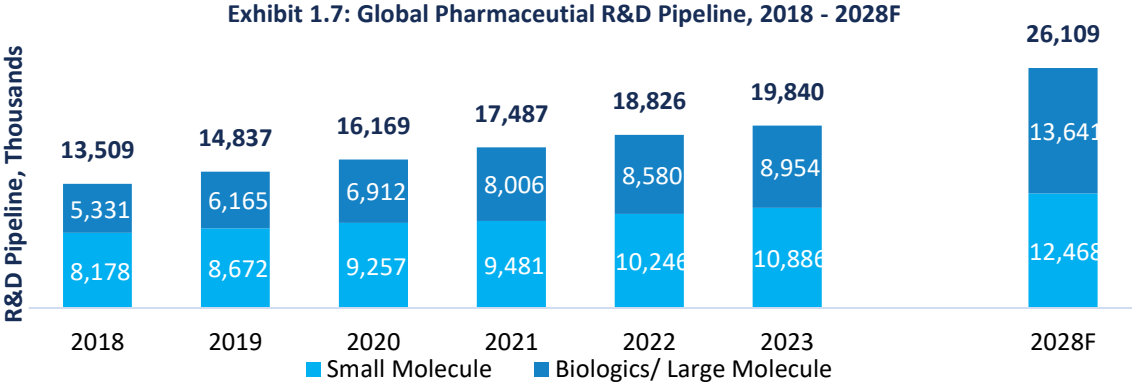


Source: Pharmaprojects, Evaluate Pharma, Frost & Sullivan

R&D Pipeline by Modality

Number of molecules in R&D stage on the rise; Small molecules will continue to have a significant share: In the year 2023, nearly 20,000 molecules were in different stages of development (from Preclinical to launch). Small molecules currently comprise a large proportion of the molecules under development. While biologics/large molecules R&D pipeline is expected to grow faster, small molecules will continue to comprise c.48% of the R&D pipeline in 2028F.

Exhibit 1.7: Global Pharmaceutial R&D Pipeline, 2018 - 2028F

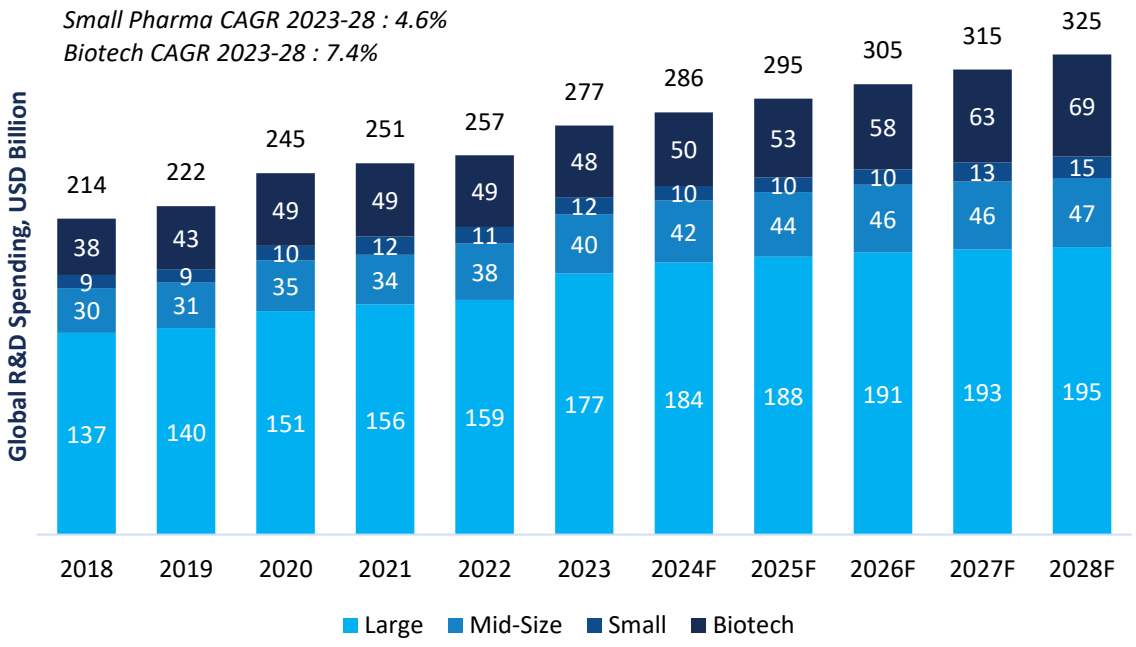


Source: Pharmaprojects, Evaluate Pharma, Frost & Sullivan

R&D Spending by Company Type

R&D spend by Large Pharma form the largest segment of R&D spends; Small pharma and biotechs R&D spend expected to register the fastest growth over 2023-28F

Exhibit 1.8: Global R&D Spending by Company Size, 2018-2028F



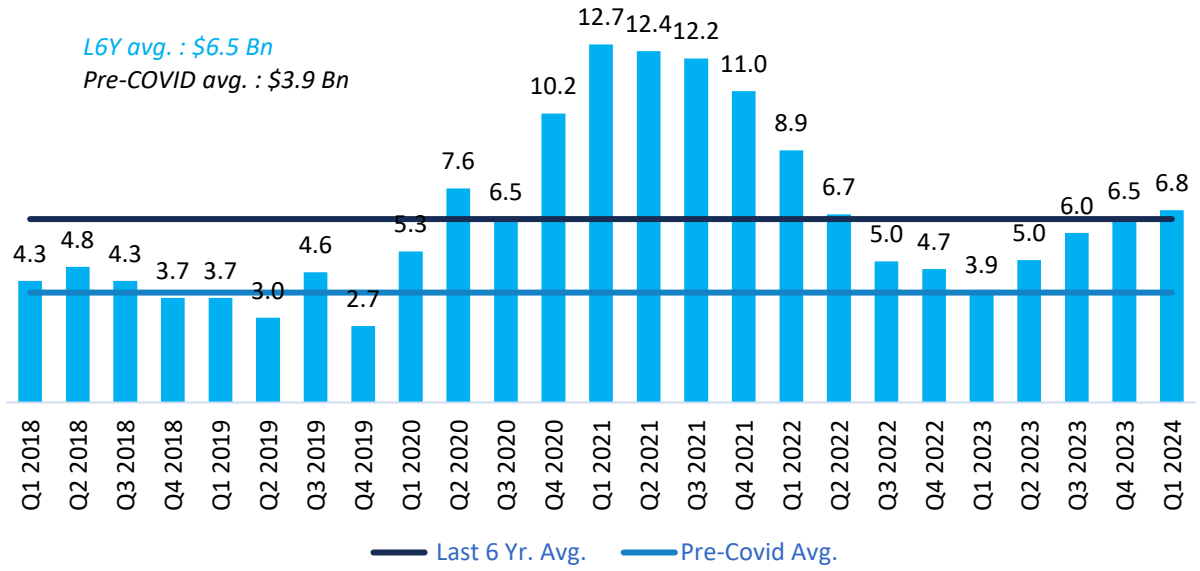
Source: Pharmaprojects, Evaluate Pharma, Frost & Sullivan

Large pharma companies contributed c.64% of R&D expenditures in 2023 and growing at a CAGR of 5.3% during 2018-23. Going forward, R&D spend by small pharma and biotech companies is expected to grow faster and their combined share is expected to grow from 22% of global R&D expenditure in 2023 to 26% by 2028. The small pharma and biotech companies are expected to register a healthy growth rate of 4.6% and 7.4% respectively over 2023-2028. The share of R&D spends by biotechs are robust, led by the availability of venture capital (VC) funding for early-stage biotech companies.VC investments in this sector have surged from USD 17.1 billion in 2018 to USD 21.4 billion in 2023. Increasing ease of technology access and drug discovery is also enabling higher innovation from small pharma and biotech companies.

Biotech VC funding remains above pre-covid levels

Biotech VC funding has remained at a much higher levels as compared to the pre-covid averages despite slowdown post-covid. The funding has now started to pick-up pace and has crossed 6-year average mark in Q1 2024. With uptick in Biotech funding in the recent quarters, R&D spend by these companies is expected to drive growth in overall Pharma R&D.

Exhibit 1.9: PE/VC Funding in Biotech, 2018-2024 (USD Bn)



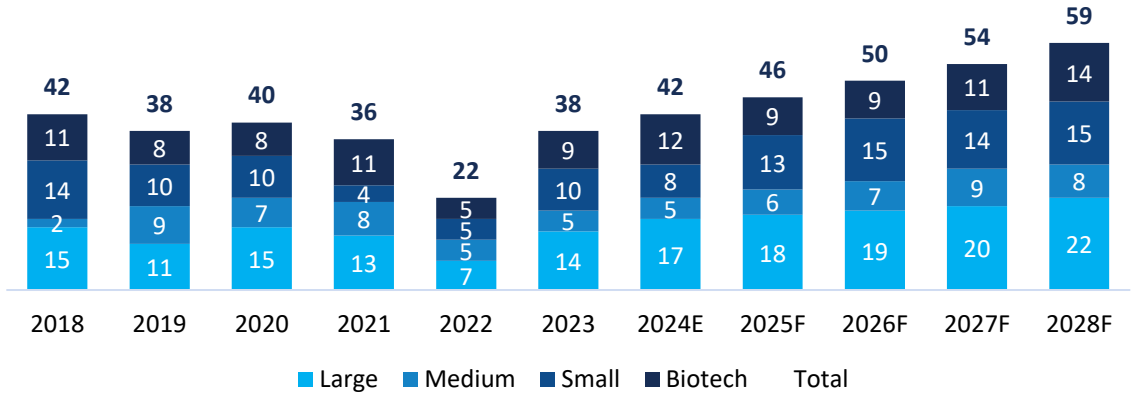
Note: 2018-2019 were considered under pre-COVID years

Source: Bay Bridge Bio, S&P Global, GlobalData, Pharma Intelligence Center, Frost & Sullivan

Biotechs and small pharma have led the new drug approvals in the last 5 years and this trend will continue

Biotechs and small venture-capital-backed pharma startups have been the key drivers of innovation in recent years. From 2018-2023, the FDA approved 216 small molecule (NCE) drugs, of which 105 (49%) were developed by small pharma companies and biotechs. The trend is expected to continue and over 2024-2028F, c.48% of NCEs will be by small pharma companies and biotechs, with biotech comprising c.22% of the NCEs.

Exhibit 1.10: FDA Approved NCE by Originator, 2018-2028F

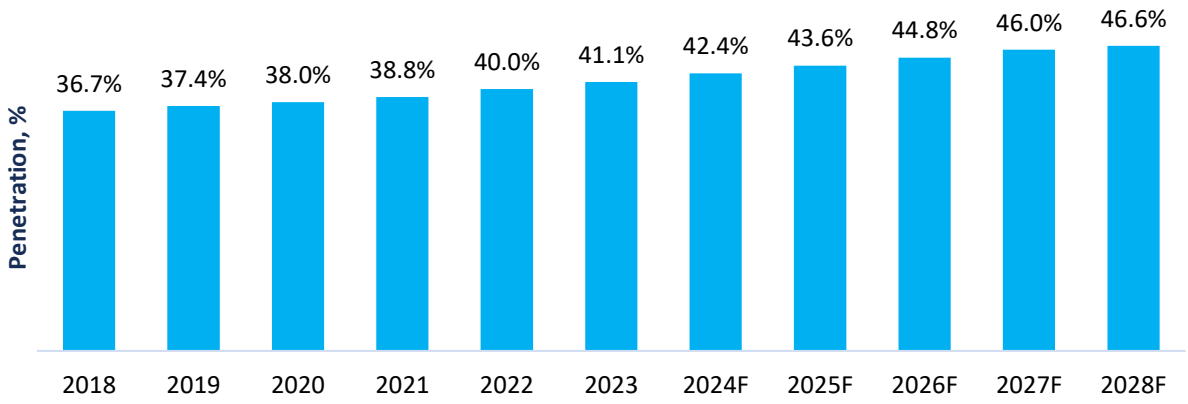


Source: USFDA, Frost & Sullivan. The 2024-2028 numbers are indicative only.

1.2.3 Global Pharmaceutical Innovator R&D – Increasing Trend of Outsourcing

The pharmaceutical and biotech industry is characterized by certain challenges, notably the R&D expertise and associated costs required to develop portfolio of increasingly complex drugs, the high capital expenditure required to establish and maintain manufacturing units, the need for technical know-how and trained workforce, increasing pricing pressure from payors and governments alike, navigating disruptions within the supply chain, and regulatory compliance, among others. As a result of these challenges, global pharmaceutical companies have sought to control their costs and improve their efficiency, and the industry has witnessed a trend of increased R&D outsourcing by pharmaceutical companies.

Exhibit 1.11: Outsourcing penetration in Overall R&D Spend, 2018-2028F



Source: Frost & Sullivan

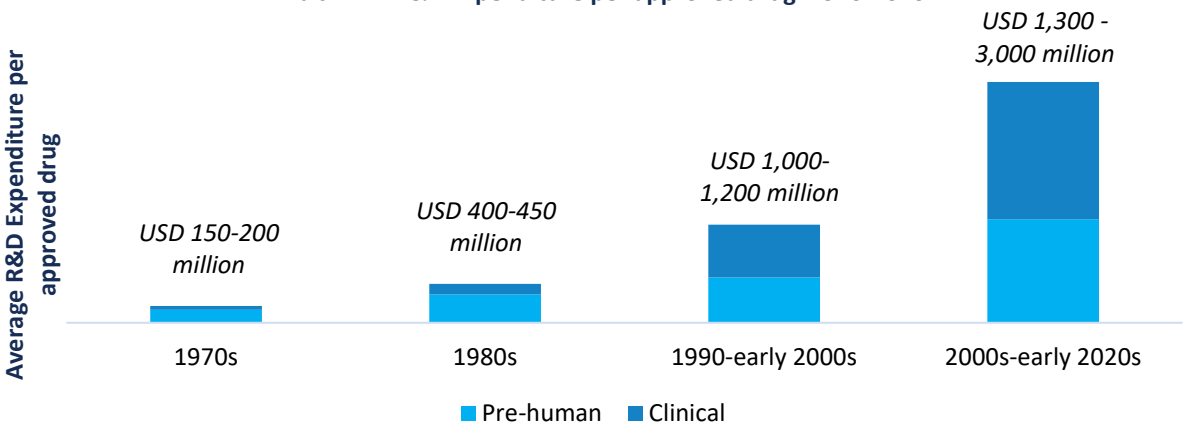
The overall penetration of the global R&D outsourcing services market increased from 36.7% in 2018 to 41.1% in 2023. The penetration is further expected to grow to 46.6% by 2028F.

Challenges faced by pharmaceutical innovators prompting outsourcing

Below are details on key challenges faced by pharmaceutical companies leading to increasing preference for outsourcing in recent years:

1. **Increased Costs**: Drug discovery is a complex and costly process comprising several stages. The average cost to develop and commercialize a new drug today exceeds USD 1 billion per drug, a tenfold increase since the 1970s. Setting up own manufacturing facilities to produce commercial and in-pipeline drugs is not cost effective for pharma innovators. The pharmaceutical innovators have responded to R&D productivity challenges by seeking to improve the return on investment for R&D spending by realising efficiencies through outsourcing.

Exhibit 1.12: R&D Expenditure per approved drug: 1970-2020



Source: Frost & Sullivan

2. **Lengthy R&D processes with low success rates**: With increasing complexity in drug technology and stringent regulations, drug discovery to commercialization timelines have significantly increased and doubled from average 6 years in the 1970s to 13.5 years in the 2000s.

   Only a small fraction of experimental drugs, ranging between one in 10,000 to 15,000, successfully transition from preclinical trials to regulatory approval and commercialization. Specifically, the composite success rate across Phase I through regulatory submissions was at a decade-low of 5.9% in 2023, compared to 6.3% in 2022 and 7.5% in 2010. This further deters pharmaceutical companies from making investments in their own manufacturing facilities, as there is uncertainty on which of their pipeline drugs will be approved.

3. **Constraint of resources for biotechs and small pharma companies**: Biotechs and small innovator pharmaceutical companies are mainly dependent on funding by financial sponsors. These companies generally are lean on resources, have limited infrastructure and may not have thorough experience in every aspect of drug discovery, development, and manufacturing. Overall in 2023, VC funding for biotech startups was c.$21 billion. They had over $150 billion aggregate funding over 2018-2023. With greater access to capital, biotech and small pharma firms are increasingly outsourcing their services, especially discovery and development to contract service providers.

4. **Increasing focus on reducing fixed expenses**: Rising costs of R&D, profit pressures arising from patent expirations and the need for greater flexibility have reduced the willingness of pharmaceutical companies to incur large upfront fixed costs associated with large scale R&D programs. Outsourcing allows them to convert a portion of their R&D budgets from an upfront fixed cost to a variable cost, giving them greater flexibility to shift strategic and development priorities in response to market conditions.

5. **Increasing regulatory challenges**: The pharmaceutical industry is subject to stringent regulatory oversight and compliance requirements, which necessitate extensive expertise. Changing geopolitical dynamics can lead to new challenges such as IRA and Biosecure Act in recent times, making the environment for the pharma companies and biotechs even more challenging. The recently introduced Biosecure Act aims to prevent Chinese manufacturers from accessing US federal funding. This may lead to increasing diversion of business from US companies to other countries. IRA (Inflation Reduction Act) introduced in 2022 allows negotiation of some of

the expensive drugs bought by the US national health insurance providers impacting the pricing power of the pharma companies.

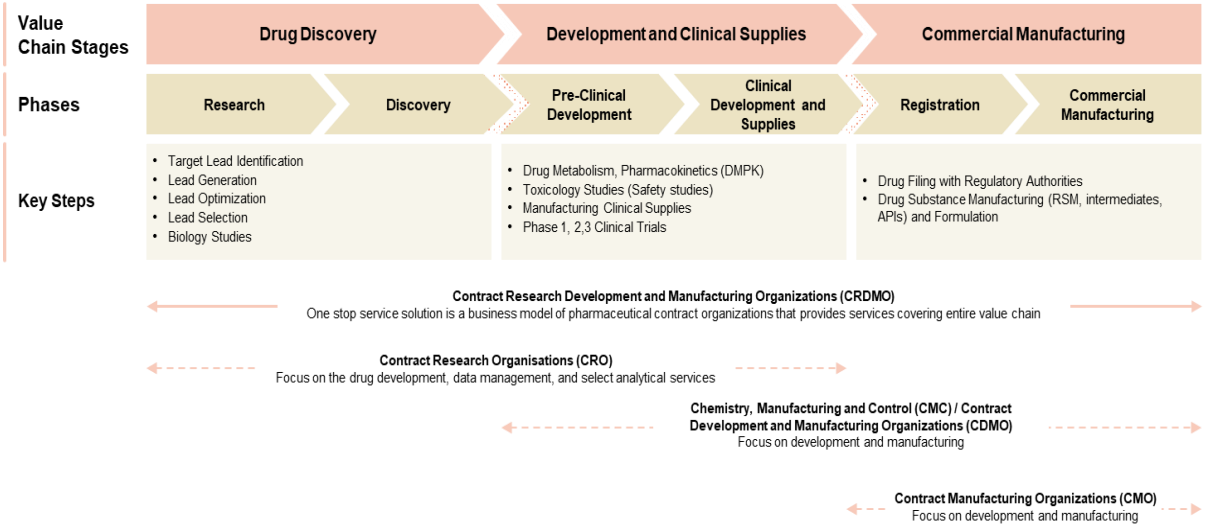
2 CONTRACT RESEARCH DEVELOPMENT AND MANUFACTURING ORGANIZATION (CRDMO) INDUSTRY

CRDMOs, who serve as outsourcing partners to pharma innovators, are playing an increasingly prominent role in the pharma value chain, from drug discovery to commercialization across multiple geographies, in response to increasing outsourcing demands from pharma innovators

2.1 Key Player Archetypes in CRDMO Industry

CRDMO industry primarily comprises of 3 key types of players: CRDMOs (Contract Research Development and Manufacturing Organizations), Contract Research Organizations (CROs) and Contract Development and Manufacturing Organizations (CDMOs). CRDMOs are integrated contract service organizations which provide end-to-end services spanning the entire drug discovery, development, and manufacturing lifecycle. They provide pharmaceutical innovators with economically viable and tailored solutions for the various challenges they face across the value chain. By leveraging their expertise, infrastructure, and resources, pharmaceutical innovators can accelerate the drug development process, reduce costs, and access specialized capabilities that may not be available in-house.

CROs specialize in offering various scientific functions of the discovery, preclinical and clinical stages of pharmaceutical R&D. CDMOs provide commercialization manufacturing as well as process/formulation development to support the preclinical and clinical stages (also known as Chemistry, Manufacturing and Control (CMC) services).



Source: Frost & Sullivan

2.2 Emergence of CRDMOs: Integrated Discovery, Development and Commercial Manufacturing Services Across the Pharma Value Chain

CRDMOs with integrated services have gained significant traction in recent times, with an increasing inclination among pharmaceutical innovators to engage a singular partner for services covering the entire pharmaceutical value chain. This is even more relevant for small pharma innovator companies and biotechs which have a lean team with a few decision makers. Pharmaceutical companies generally collaborate with Contract Research Organizations (CROs) for drug discovery and Contract Development and Manufacturing Organizations (CDMOs) for drug development and manufacturing, with some overlap in services such as API and formulation development. However, pharmaceutical innovators are increasing leveraging integrated CRDMOs for several benefits. By providing research, development, and manufacturing capabilities under one roof, integrated CRDMOs offer a seamless and efficient approach to drug development, from early-stage research to commercial production, enhanced collaboration, technology transfer and communication throughout the drug development process, leading to expedited decision-making, heightened efficiency, and improved project outcomes.

Integrated CRDMOs offer significant benefits:

1. **End to End Capabilities**: CRDMOs cover all services provided by CRO to CDMOs / CMOs, and have access to infrastructure, skilled talent and specialized technologies required for different services across the entire value chain from drug discovery to manufacturing. This provides multiple benefits including enabling streamlined transition from bench to market, enhanced collaboration with customers, cost savings, improved success rates, and accelerated time-to-market for pharmaceutical products. Also, end to end capabilities provide CRDMOs with cross-selling and up-selling opportunities across the value chain by leveraging existing relationship with customers.

2. **Efficiency**: CRDMOs eliminate the need for pharma innovators to select different outsourcing service providers for different stages in R&D and manufacturing respectively, thus enhancing coordinating and eliminating the associated risk of transferring technology between multiple service providers. Having one single partner across the value chain is more cost-efficient vs employing multiple partners across the chain and provides customers with the benefits of speed, cost and innovation through continuity of in-depth knowledge and rapid transition through the various phases of drug development. For instance, during the discovery phase, having Chemistry and Biology capabilities with one CRO enables efficient transfer of compounds for testing as well as quick feedback on the properties of each drug-like molecule to enable redesign of better molecules. Similarly, having discovery chemistry and process chemistry under one roof helps ensure that principles of scalable manufacturing are incorporated even at the pre-clinical stages, which reduces time taken to transition to clinical stages. Also, having process development and manufacturing within the same organization ensures that not only efficient chemistry is developed, but also ensures that the right equipment and manufacturing conditions for high volume commercial manufacturing are selected.

3. **Multiple entry points for client engagement**: An integrated approach broadens the opportunity landscape for CRDMOs, allowing them to enter new drug development programs with existing or new customers and to expand their involvement in these programs from inception to commercialization. Integrated CRDMOs are able to take over programs that are partially developed at other CROs, CDMOs or in-house labs, and as such offers multiple entry points for client across the pharma value chain, leading to higher customer win rates, increased share of wallet, and improved customer retention.

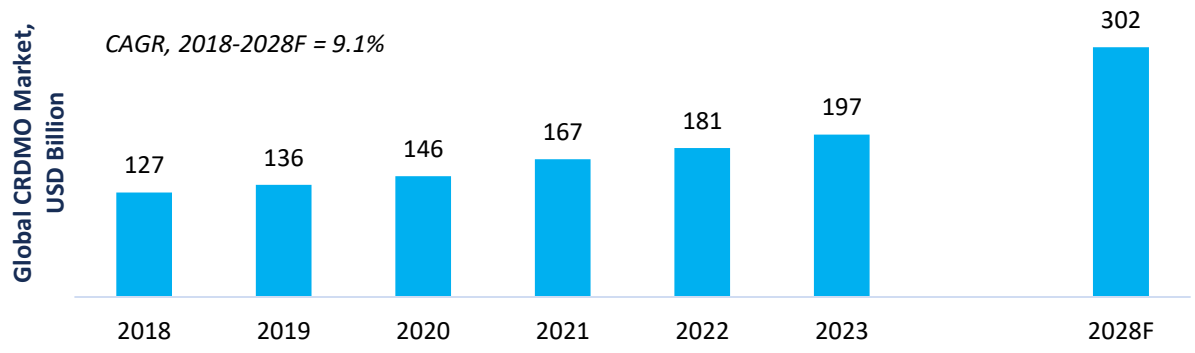
4. **High barriers to entry:** Functioning as a full-service CRDMOs with global capabilities presents a distinctive advantage, underscored by the notable barrier to entry inherent in this sector. While limited service CROs

and CDMOs may find ingress into certain service segments relatively attainable due to fewer barriers, the full-service CRDMO model necessitates establishing a comprehensive, robust, and sophisticated infrastructure. This infrastructure is crucial for providing end-to-end solutions, managing complex projects across multiple locations, forming strategic partnerships, and cultivating expertise across the value chain to meet the diverse needs of clients. Moreover, successfully functioning as a full-service CRDMO mandates a requisite scale and capital allocation to achieve scale, digitalize, and drive change in the ecosystem.

2.3 Global CRDMO Industry Size

In 2023, the global CRDMO industry was assessed at an estimated value of USD 197 billion. The industry is anticipated to expand at a CAGR of 9.1% over the forecast period, culminating in USD 302billion by 2028.

Exhibit 2.1: Global CRDMO Industry, 2018 - 2028F



Source: Frost & Sullivan

The CRDMO industry comprises of discovery, preclinical, development and commercial manufacturing services. Traditionally, pharmaceutical companies retained in-house control over discovery and preclinical stages due to intellectual property (I.P.) sensitivities while outsourcing these activities. However, with the emergence of smaller

Exhibit 2.2A: Global CRDMO Industry by Functions, 2018 - 2028F

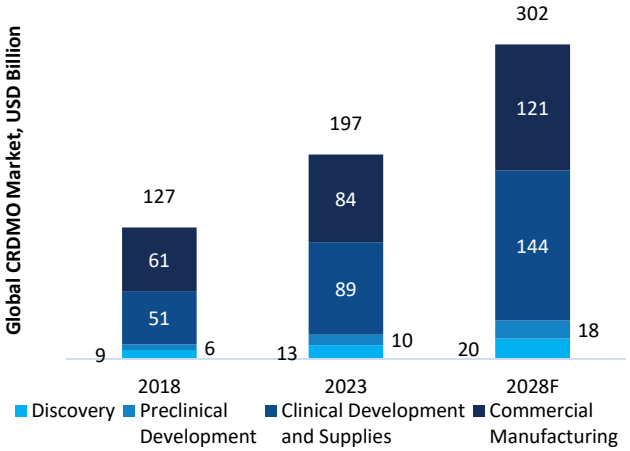
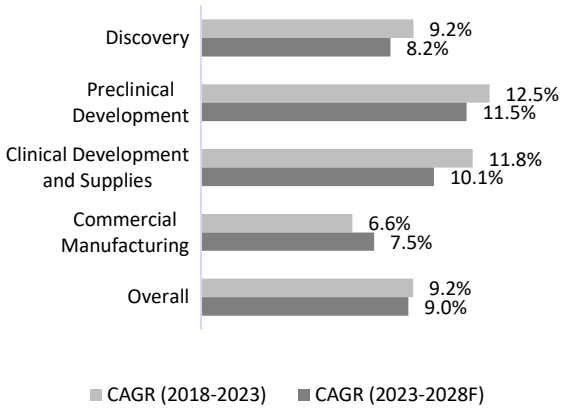


Exhibit 2.2B: Growth Rate of Global CRDMO Industry by Functions, 2018 - 2028F



Source: Frost & Sullivan

pharmaceutical and biotech firms and enhanced IP protection protocols at CRDMOs, there has been a noticeable surge in the outsourcing of these services. The drug discovery industry stands at USD 13 billion in 2023, while the

Source: Frost & Sullivan

preclinical development market was at USD 10 billion in the same year. In line with the growth in the overall Research and Development (R&D) spending, the discovery and preclinical services industry is projected to reach a cumulative value of $37 billion in 2028 and comprise 41% of total R&D spend in these areas.

2.4 Key Success Factors for CRDMOs

Pharma innovators seek reliability, scientific capabilities, technical as well as problem solving capabilities and compliance track record while selecting the right partner in this highly fragmented CRDMO industry. For large pharma players, Environment, Health & Safety (EHS) controls are also a key criteria while for biotechs who operate with lean skeleton teams and are smaller in scale, price, one stop offering and reliance by large pharma companies are key differentiators. Below are some key criteria that help CRDMOs stand out and emerge as long-term partners for pharmaceutical innovators.

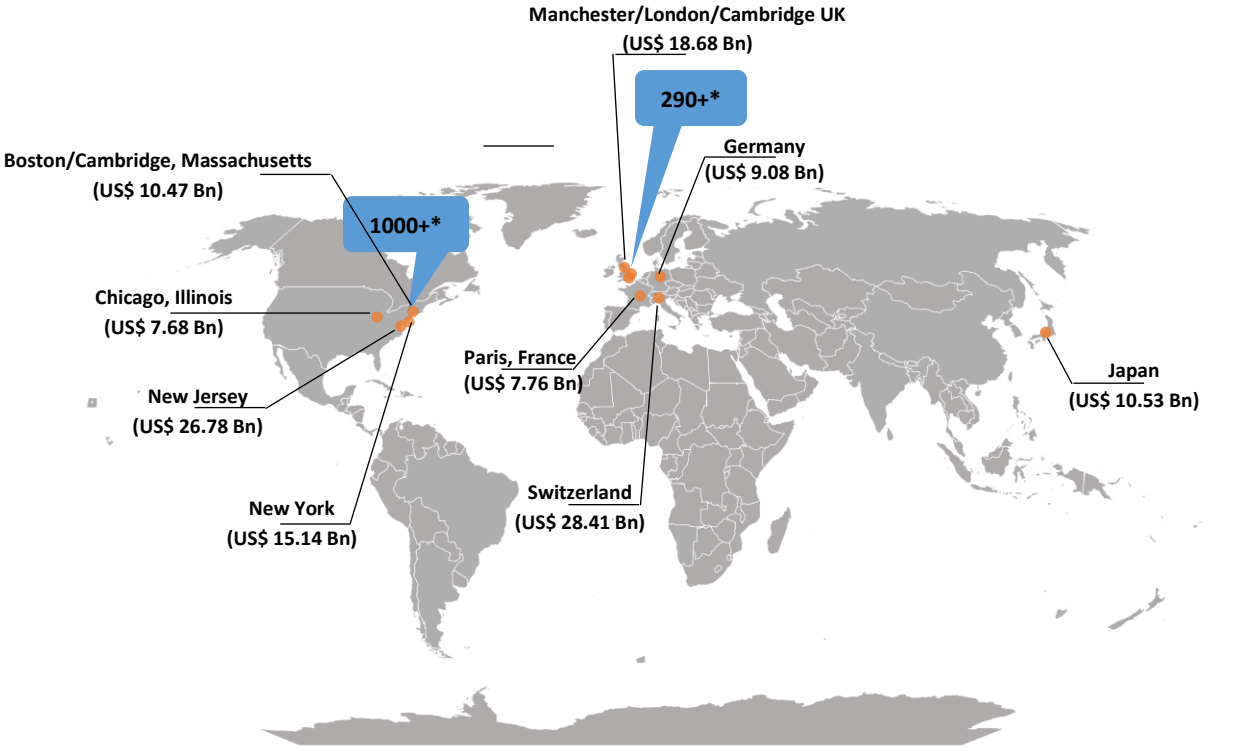
1. **Full service offering**: Pharma innovators highly value expertise across the various stages of the value chain ranging from drug discovery, development to manufacturing. Integrated, one-stop service solutions are increasingly being preferred by pharma innovators as it eliminates the need for them to select different contract service providers for different stage of R&D and manufacturing respectively, reducing the cost, time, and risk of technology transfer among different outsourcing organizations.

   CRDMOs with the capability to provide integrated solutions have scientific insights and know-how across different scientific functions and disciplines at different drug R&D stages. For example, pharma innovators prefer co-located technical competencies spanning across chemistry, biology, DMPK services for their integrated drug discovery projects, where all these scientific services are conducted by a single service provider for time and cost efficiencies. With more comprehensive understanding from various scientific disciplines on the specific molecule profile, the same service provider will be able to provide R&D services on such molecule in a more efficient manner and achieve project excellence.
   This is even more important for biotechs who operate with lean skeleton teams, have limited infrastructure, and are smaller in scale, making price and one stop offering the key criteria for them in selecting outsourcing partners.
   CRDMOs due to their capabilities across the value chain get inherent benefit against any market volatility in any of the areas of the value chain. The integrated presence allows them to balance any fluctuation in demand, as downturn in CRO operations due to slowdown in funding can be offset by steady demand from manufacturing services, and vice versa. This diversification ensures a more stable revenue stream and offers increased business resilience.

2. **Strategic Presence Close to Customers**: CRDMOs can gain competitive advantage by adopting a balanced approach that combines onshore research expertise and customer proximity with the scalability and cost advantages of offshore delivery. A global presence enables CRDMOs to cater to a diverse global client base, leveraging their expertise and resources to meet clients' unique requirements in different regions and

maintaining the requisite connection and trust. Also, companies can access super-specialized expertise and resources, facilitating innovation and enhancing their competitive edge in the market.

Global Pharma and Biotech Innovation Hubs



Source: Frost & Sullivan

*Note: *Number of Biotech and Pharma companies*
Figures mentioned in the bracket are total R&D spending in US$ Bn.
In 2022, approximately 57% of global R&D spending were in these nine pharma hubs. Boston, London and Manchester do carry out significant Pharma & Biotech activities with ~11% of global R&D spending in these regions.

There have been numerous success stories of CRDMOs establishing labs and research facilities closer to customers with larger R&D and manufacturing in low-cost geographies. Presence in innovation hubs facilitates access to the latest research trends, talented global workforce, and potential collaboration within innovation hubs, while their facilities in low-cost geographies like India offer a cost-competitive advantage for conducting drug discovery research activities at scale, development and large-scale commercial production of products. For example, in drug discovery, biology assay development can happen in these innovation hubs and these assays can be transferred to cost-competitive locations to enable faster and cost-effective screening of large numbers of compounds. Companies like Wuxi and Pharmaron have gained immensely by establishing labs and smaller operations in proximity to innovation hubs in US and Europe while retaining larger delivery operations in China. Wuxi and Pharmaron have seen significant revenue growth (Wuxi Revenue CAGR 2019-2023; 32.4% and Pharmaron Revenue CAGR: 29.5%) between 2019 and

2023, some of their growth is also attributed to their proximity to innovation hubs where a lot of R&D activities are conducted. Sai is also one of the few Indian CRDMOs to combine discovery and development operations in the US, the UK and India, with large scale research and manufacturing capabilities in India. It has strategic presence in close proximity to innovation clusters in Boston, United States and Manchester, United Kingdom. They are the only CRDMO amongst the listed Indian peers that can conduct development activities in proximity to their customers and transfer technology for manufacturing back to India. They have established a fully integrated CRDMO platform with access to the best talent from across the world

3. **Strong Operational Capabilities**
    a. **Technical Capabilities:** Comprehensive technical capabilities including awareness of latest technologies provide a strong competitive edge to CRDMOs. They must build a strong and experienced team and make continued investments to broaden their scientific expertise and service offerings, which helps them retain existing customers, attract new customers and expand their collaboration with their customers.
    b. **Infrastructure capabilities**: CRDMOs must be agile in responding to different volume needs and proficient in handling multiple drug modalities, including complex active ingredients, formulations, routes of delivery, and dosage forms, amongst others. They should be able provide equipment and researchers specializing in different areas needed for different services across the entire value chain from drug discovery to manufacturing. In manufacturing, drug volume requirements can vary greatly, for instance from 10 tons per year to less than half a ton annually. Ability to optimize manufacturing resources accordingly improves profitability of the companies.
    c. **Compliance with global quality standards and IP protection requirements:** Clean track record of regulatory compliances is one of the critical factors in evaluation by any pharma innovator. Maintaining quality standards designed to meet global requirements is essential to attract customers especially the large pharma companies who in some cases have requirements which may be more stringent than regulatory requirements. Adequate systems and processes in place to protect confidential information in addition to a verifiable track record of IP protection is also important.
    d. **Strong Delivery Track Record**: A successful project delivery track record is a key criterion for pharma innovators while selecting a CRDMO partner. Since efficiency and cost-effectiveness are the primary drivers for outsourcing, CRDMOs must adhere to pharma innovators' budgets while ensuring timely delivery.

4. **Ability To Manage Risks And Challenges**: CRDMOs face several challenges, such as recruiting and retaining skilled professionals in fields such as chemistry, biology, engineering, and regulatory affairs; fluctuations in global economic conditions and trade policies, currency exchange rates; disruptions in the supply chain across a complex network of suppliers and vendors for raw materials and equipment; managing excess capacity in case of demand depressions, among others. Proactive risk identification and mitigation are also essential to prevent timeline delays and maintain trust in the customers. Robust risk management methodologies, transparent communication regarding timelines and budget goals are pivotal for fostering strong and reliable relationships with clients.

5. **Investments For Continuous Improvement**: To remain competitive, CRDMOs must continually enhance their capabilities and infrastructure. They should keep pace with rapid technological advancements in areas such as automation, data analytics, and bioprocessing. This involves developing expertise in emerging areas and investments to scale up infrastructure to serve multiple companies simultaneously. Moreover, adapting

Source: Frost & Sullivan

to industry trends like the increased use of highly potent compounds necessitates investments in improved containment, process automation, and skilled labor. Furthermore, embracing green and sustainable manufacturing practices is imperative to comply with increasingly stringent environmental regulations.

In addition to investing in their capabilities and infrastructure, CRDMOs also need to focus on improving their speed, efficiency, and overall performance in order to remain competitive. To achieve this, CRDMOs need to implement lean and agile methodologies that streamline their processes and eliminate waste. They also need to adopt a holistic approach to project management that integrates planning, execution, monitoring, and control. This can help them increase their asset utilization, reduce their cycle times, and enhance their customer satisfaction. Moreover, they need to invest in programs that reduce their cost and consumption of raw materials, solvents, energy, and other consumables. This can help them improve their margins as well as their environmental sustainability.

Additionally, CRDMOs can leverage automation and digitalization to optimize their processes and workflows. Automation can help reduce human errors, increase productivity, enhance quality, and lower costs. Digitalization can enable better data collection, analysis, and sharing, leading to improved decision making, collaboration, and innovation. By using tools such as artificial intelligence, machine learning, and internet of things, CRDMOs can gain deeper insights into their operations, identify and resolve bottlenecks, and implement best practices across their projects. Automation and digitalization can also help CRDMOs adapt to changing customer demands and regulatory requirements, as well as create new value propositions and strengthen competitive advantage.

2.5 Challenges and risks for CRDMOs

The evolving landscape of CRDMOs in pharma industry brings forth additional challenges and risks. The industry is moving towards a collaborative model, with companies forming strategic partnerships and building deeper relationships. This is likely driven by a demand for more efficiency and expertise throughout the drug development process. CRDMOs are required to adapt to this changing environment through investments in newer technologies, and better infrastructure. They also need to tackle the complex and ever-changing regulatory environment to remain compliant and competitive. The following are some of the key challenges and risks for the CRDMOs

1. **Excess Production Capacity and Associated Costs:** Excess production capacity can lead to CRDMO facilities not operating at optimal levels. This underutilization of resources can result in increased fixed costs per unit of production, driving up the overall cost structure. CRDMOs may struggle to cover these fixed costs, leading to financial strain and potentially affecting their ability to invest in innovation and expansion. These additional costs can erode profit margins and reduce the competitiveness of CRDMOs in the market.

2. **Need of Experienced and Skilled Workforce:** Skilled staff is a critical asset for CROs and CDMOs. Limited availability of experienced and skilled talent pool can impact the quality and timeliness of services provided, potentially leading to delays in drug development and manufacturing. This challenge is further exacerbated by the increasing demand for specialized expertise in emerging areas. Life Sciences sector has seen significant voluntary turnovers in recent years. In 2019, the global average voluntary turnover rate stood at 13.2% in the life sciences sector, whereas in India this industry average rate ranges from 25-30%. To address the challenge of shortage of experienced and skilled workforce, CRDMOs must focus on attracting and retaining top talent, investing in training and development programs, and creating a positive work culture that fosters innovation and collaboration. Additionally, they must also consider implementing flexible work arrangements and competitive compensation packages to remain competitive in the market. For example, Thermo Fisher has a training hub to reskill and upskill their employees, as they anticipate a resource scarcity.

3. **Regulatory Compliance Risks:** The advantages of CRDMOs are decentralized value chain management and connectivity, helping pharma speed up the process from end to end. However, the increasing decentralization of the supply chain poses additional challenges for CRDMOs. One of the key regulatory standards for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (CGMP) regulations. These provides for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to these regulations is also critical for receiving approvals from USFDA, PMDA Japan, and other such regulatory bodies. CRDMOs are also required to comply with regulations and Good Document Practices (GDP) while collaborating with global partners. Also, regulations keep changing and are increasingly becoming more stringent, challenging the compliance of CRDMOs. For example, the ever-changing regulatory frameworks under the International Committee for Harmonization (ICH) require outsourcing providers to constantly adapt. In addition, sustainable manufacturing, which was largely good-to-have earlier, has now become imperative for CDRMOs. Pharmaceutical innovators can no longer operate without considering how their manufacturing process impacts the environment. Pharmaceutical companies are increasingly factoring in compliance to EHS and ESG standards as one of the key criteria for selection of outsourcing partner. It is thus crucial for CRDMOs to stay updated on current compliance standards and ESG policies while maintaining their commitments to their partnerships. In order to ensure that CRDMOs are prepared to pass regulatory audits, pharmaceutical companies routinely conduct strict GMP, Safety and Sustainability audits or inspections, either directly or receive access to audits conducted by the Pharmaceutical Supply Chain initiative (The Pharmaceutical Supply Chain Initiative (PSCI) is a group of pharmaceutical and healthcare companies who share a vision of excellence

Source: Frost & Sullivan

in safety, environmental, and social outcomes) or Ecovadis (EcoVadis is one of the world's largest and most trusted provider of business sustainability rating), of their current and prospective CRDMO partners. The ability to face and pass such customer audits is a critical risk for CRDMOs.

The CRDMO industry faces pressure to adapt and innovate in the competitive pharma sector. Shortage of skilled staff, excessive production capacity and associated costs, and complex global supply chains are some of the key risks that can hamper the overall efficiency of the CRDMOs.

2.6 Global CRDMO Industry by Modality

Exhibit 2.3A: Global CRDMO Industry by Modality, 2018 - 2028F

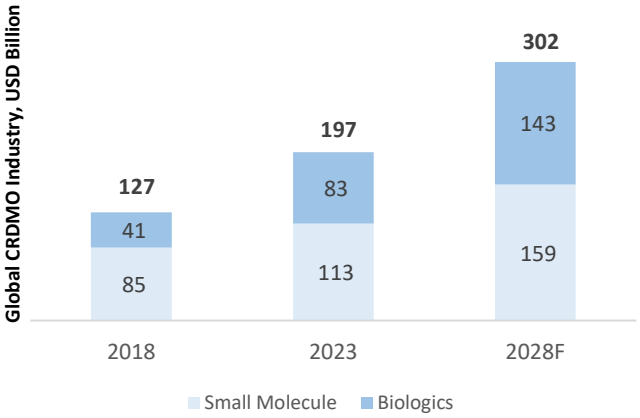
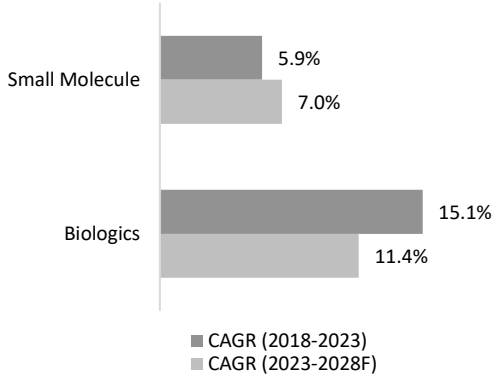


Exhibit 2.3B: Growth Rate of Global CRDMO Industry by Modality, 2018 - 2028F



Source: Frost & Sullivan

The global small molecule CRDMO industry size was estimated at USD 113 billion in 2023 and is expected to expand at a compound annual growth rate (CAGR) of 7.0% from 2023 to 2028. Key drivers for this growth are increasing pharmaceutical and biotech R&D outsourcing, continued demand for small molecules, and growing demand for cost-effective drugs. The global small molecule CRDMO industry is expected to reach USD 159 billion by 2028F, comprising c.53% of the overall CRDMO industry globally.

2.7 Global CRDMO Industry by Geography

Exhibit 2.4A: Global CRDMO Industry by Region, 2018 - 2028F

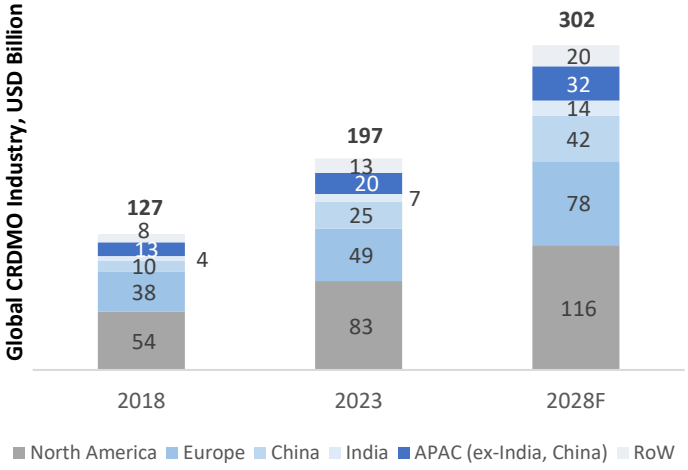
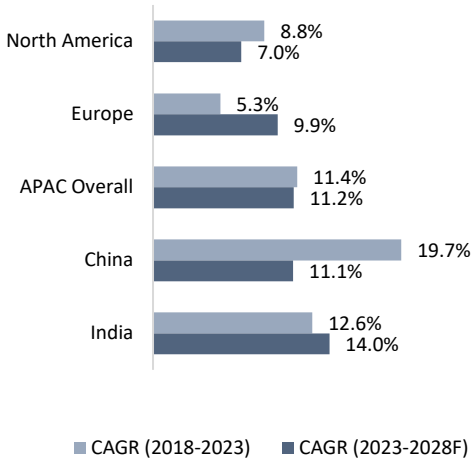


Exhibit 2.4B: Growth Rate of Global CRDMO Industry by Region, 2018 - 2028F



Source: Frost & Sullivan

CRDMO industry by geography refers to the revenues of CRDMOs located in these geographies. Today, North America is the dominant geography for CRDMOs. Being the largest pharmaceutical market by consumption as well as the global innovation hub, several of the largest global CROs and CDMOs have established bases in the region to cater to local needs. Due to the region's strong R&D infrastructure, thriving pharmaceutical sector, and welcoming regulatory climate, North America will continue to account for largest share of the global industry for CRDMOs. However, the highest contributor to overall growth in CRDMOs has been APAC. The region's CRDMO industry is expected to grow at a much faster rate of 11.2% during 2023-28 driven by of cost-effective manufacturing capabilities, availability of skilled manpower and regulatory compliance capabilities. Major regions for CRDMO services include China, India, South Korea, and Singapore, which provide a blend of technical know-how, trained labour, and affordable prices. Amongst, these regions India is expected to be highest contributor of growth for APAC region as it become an emerging hub for the pharma innovators and is gaining significant prominence driven by multiple growth tailwinds. India CRDMO industry will grow faster than the overall APAC CRDMO industry, growing at a CAGR of 14.0% over 2023-28.

2.8 Growing Prominence of India CRDMOs

India's CRDMO industry has undergone significant expansion in recent years. The India CRDMO industry was amongst the fastest growing industries in APAC over 2018-2023. This growth is expected to continue, with Indian industry projected to grow by 14.0% between 2023 and 2028, faster than the growth of APAC industry and the global CRDMO industry, reaching an estimated value of USD 14.1 Bn in 2028. Significantly higher growth rate for Indian CRDMO industry is expected to lead to increase in market share of Indian companies. Increase in scale and market

share is expected to attract more companies to increase their outsourcing from Indian companies leading to a sustainably higher demand. Shift in geopolitical factors with pharma companies increasingly adopting China plus one policy is expected to increase demand for Indian CRDMOs. Beyond the China + 1 sentiment, new draft policies such as the Biosecure Act that aims to prevent Chinese manufacturers from accessing US federal funding will further divert business to Indian CRDMOs.

2.8.1 India CRDMO Industry by Value Chain Function

India CRDMO industry stood at USD 4.0 billion (INR 336 billion) in 2018 and reached USD 7.3 billion (INR 609 billion) in 2023, growing at a CAGR of 12.6% between 2018 and 2023. By 2028, the industry is anticipated to reach USD 14.1 billion (INR 1,173 billion) by growing at a CAGR of 14.0% over the period of 2023 to 2028. Indian CRDMO industry has observed a significant growth in the recent years on the back of increased collaborations, partnerships and collaborations in the industry. Amongst the value chain functions, pre-clinical development is expected to grow at a significantly faster pace at 15.7% during FY23-28F, driven by significant improvement in technical capabilities of Indian companies driving R&D outsourcing demand from global pharma innovator companies. Bolstering of integrated offerings by Indian companies with increase in Biology and DMPK capabilities is driving significant growth in discovery and pre-clinical segments.

Exhibit 2.5A: India CRDMO Industry by Functions, 2018 - 2028F

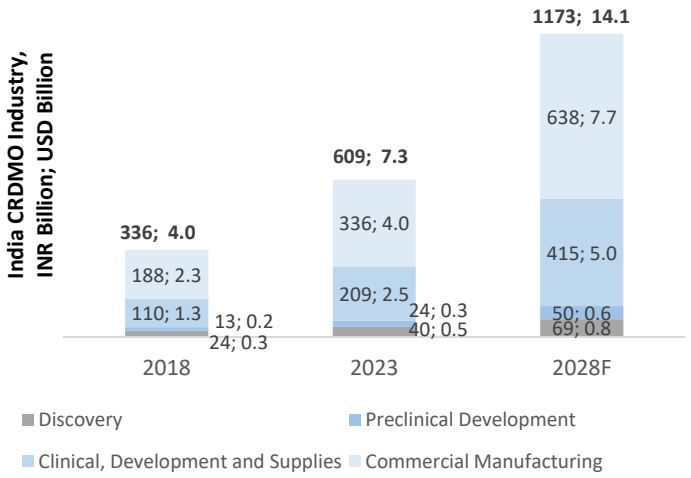
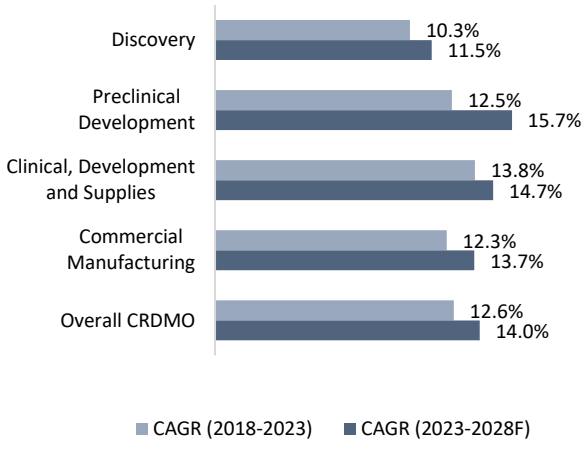


Exhibit 2.5B: Growth Rate of India CRDMO by Functions, 2023 - 2028F



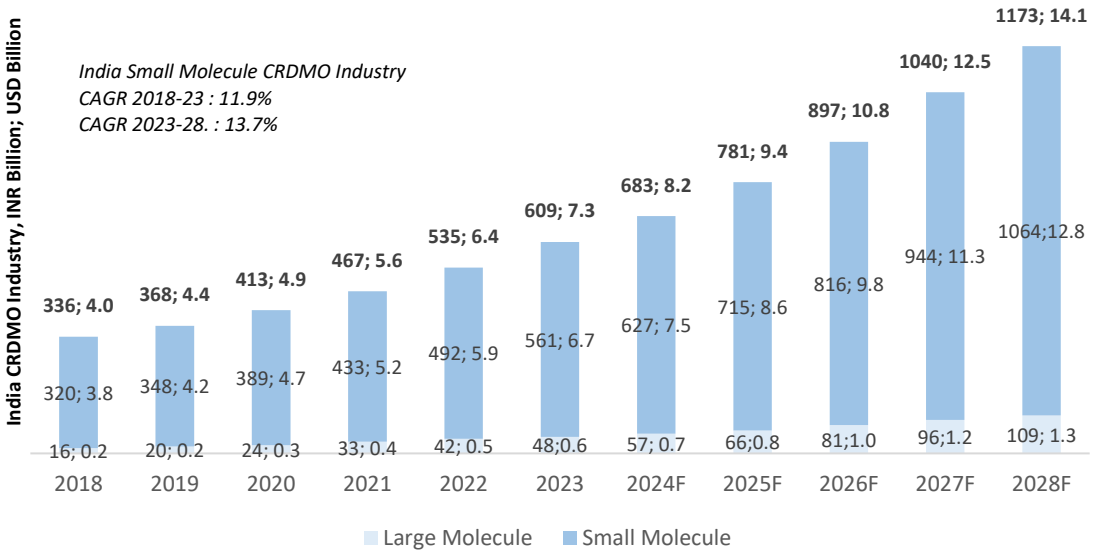
Source: Frost & Sullivan, Note: Conversion factor for USD to INR is 83.3739 as on March 28th, 2024 (RBI)

2.8.2 India CRDMO Industry by Modality

Indian CRDMO industry has largely been dominated by small molecules with their proportion constituting 90%+ of the total industry in 2023. With increasing prominence of Indian CRDMOs in the global markets and increased outsourcing of small molecules, the dominance of small molecules is expected to continue despite increasing demand of large molecules. The Indian small molecule CRDMO industry size is estimated to increase to USD 12.8

billion (INR 1,064 billion) by 2028 and with a compound annual growth rate (CAGR) of 13.7% from 2023 to 2028.

Exhibit 2.6: India CRDMO Industry by Large and Small Molecules, 2018-2028F

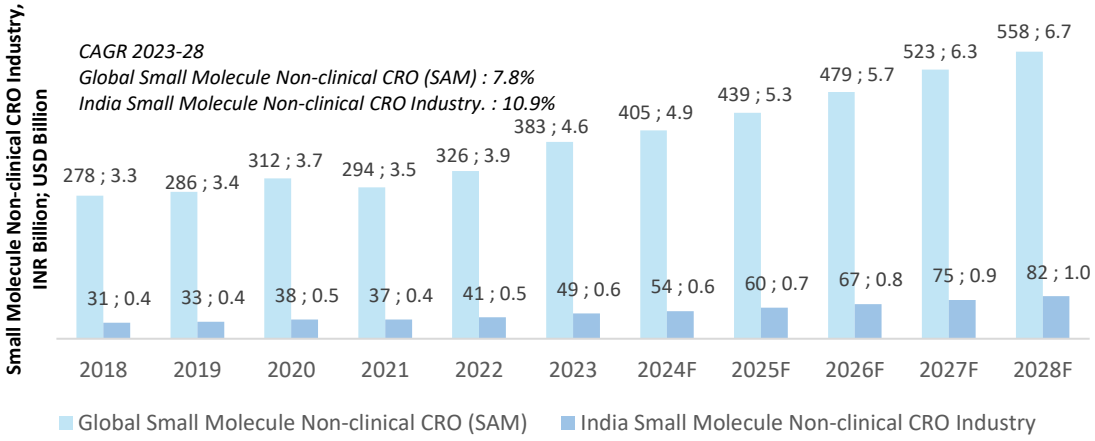


Source: Frost & Sullivan, Note: Conversion factor for USD to INR is 83.3739 as on March 28th, 2024 (RBI)

2.8.3 India Small Molecule Non-Clinical CRO Industry and Serviceable Addressable Market (SAM)

Non-Clinical CRO SAM refers to the global small molecule Non-Clinical CRO industry. Driven by shift in global dynamics due to China plus one, Biosecure act and other factors and increasing capabilities of Indian companies, India small molecule Non-Clinical CRO is expected to grow at a faster rate and become a USD 1.0 billion (INR 82 billion) industry by 2028.

Exhibit 2.7: Small Molecule Non-clinical CRO Industry, 2018-2028F

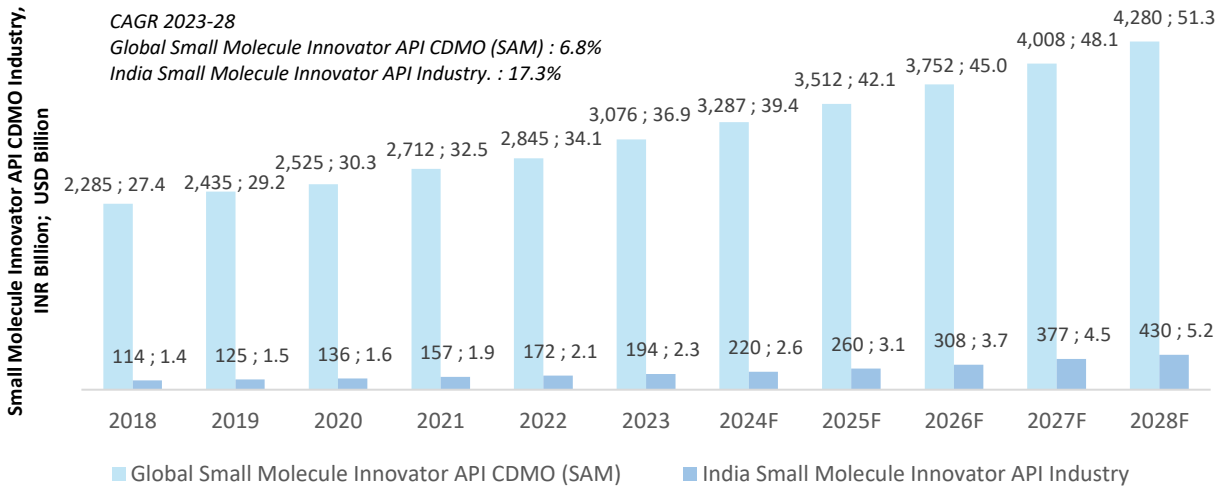


Source: Frost & Sullivan, Note: Conversion factor for USD to INR is 83.3739 as on March 28th, 2024 (RBI)

2.8.4 India Small Molecule Innovator API CDMO Industry and Serviceable Addressable Market (SAM)

Small Molecule Innovator API CDMO SAM refers to the global small molecule innovator API CDMO industry. With multiple growth tailwinds for the India CDMO industry, it is expected to gain market share and become a larger proportion of CDMO SAM, accounting for 10%+ share by 2028F.

Exhibit 2.8: Small Molecule Innovator API CDMO, 2018-2028F



Source: Frost & Sullivan, Note: Conversion factor for USD to INR is 83.3739 as on March 28th, 2024 (RBI)

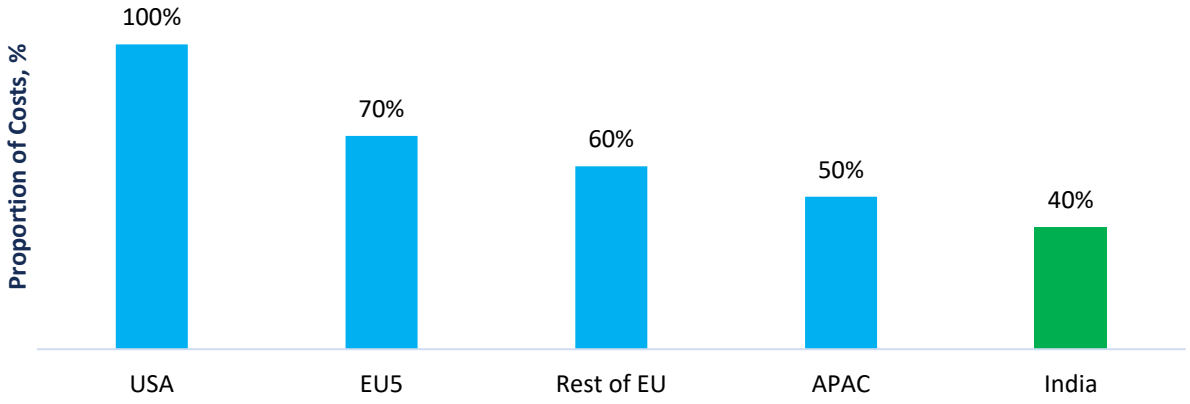
2.8.5 Key success factors for India CRDMOs

Indian CRDMOs have demonstrated enhanced capabilities including availability of skilled talent, economical cost base, quality infrastructure and systems adhering to GLP and cGMP standards, positioning them to benefit from increased R&D and manufacturing outsourcing by pharmaceutical innovators. Tightening of IP protection laws have further strengthened confidence in Indian CRDMO providers among global pharmaceutical companies. Geographically, Indian CRDMOs are strategically best positioned to be part of a de-risked supply chain sought by European and American companies.

Key factors that have contributed to the success of Indian CRDMOs include:

1. **Cost Advantage**: Amidst escalating global price pressures, the imperative for cost efficiency has intensified. Indian CRDMOs distinguish themselves as preferred partners owing to substantial cost advantages over their global counterparts. Notably, wage costs in the Indian pharmaceutical industry are substantially lower than in Europe and the US

Exhibit 2.7: Cost Comparison with US manufacturing due to Outsourcing by Region, 2023



Source: Frost & Sullivan

2. **Strong Infrastructure and Availability of Skilled Manpower**: India has a legacy in pharma manufacturing for regulated markets with presence of over 3,000 drug companies and 10,500 manufacturing units. It contributes to 20% of the global pharma supply chain and meets almost 60% of the global vaccine demand. It also meets 40% of the generic demand in the US and provides 25% of all medicines in the UK. Indian companies have extensive experience working with regulatory agencies like the FDA and EMA, and India has the highest number of US-FDA-approved plants outside the US. This allows Indian firms to use transferrable knowledge of working at global standards with different regulatory bodies and offer superior services. India also has a strong base of STEM graduates, more than the US and UK, crucial for science-intensive drug discovery work. India creates an average of 24,000 Ph.Ds annually, ranking among the top five nations.

3. **Shifting Geopolitical Dynamics**: India is increasingly becoming a favorable partner for global companies, in light of the shifting geopolitical dynamics. For instance, global pharmaceutical companies are embracing a diversified approach away from sole dependence on Chinese manufacturing (China + 1 policy). New draft policies such as the Biosecure Act will further divert business to Indian CRDMOs. Indian CRDMOs providing integrated services are expected to see a significantly increasing demand driven by shifting geopolitical factors, such as the “China plus one” strategy, effect of the Biosecure Act and Inflation Reduction Act, among others. India's strategic geographic positioning provides convenient access to key markets, minimizing logistical complexities and costs, thereby enhancing the appeal of Indian CRDMOs to international firms seeking operational efficiency without compromising quality. Lastly, as diplomatic and trade relations strengthen between India and developed economies, collaborative opportunities in contract services are poised to expand further.

4. **Improving ease of business and fiscal incentives**: According to the Economist Intelligence Unit (EIU) Business Environment Rankings (BER) for Ease of Doing Business, of the 17 economies in the Asian region, India is ranked 10th in the 2023- 27 forecast period, jumping by 4 places from previous period. Conducive government policies play a pivotal role in bolstering the India pharmaceutical sector, offering tax incentives, and expediting regulatory processes. Concurrently, initiatives like the Biotechnology Industry Research Assistance Council (BIRAC), Bio-NEST, and Biotech Science Clusters encourage pharmaceutical R&D and support biotech startups. India has grown to be a leading biotechnology destination with over 5000 biotech enterprises. Furthermore, governmental efforts extend to incentivizing pharmaceutical manufacturing. Schemes such as the Production Linked Incentive (PLI) scheme offer incentives ranging from INR 20 crore to INR 400 crore for bulk drug park development, aiming to spur local formulation and active pharmaceutical ingredient (API) manufacturing.

5. **Favorable IP protection laws**: With stronger IP protection legislation, India has become a more trusted partner for outsourcing research and development for the pharma companies. India's 1995 GATT accession and its 2005 compliance with TRIPS regulations—which changed the focus from process to product patents—are notable turning points. As a result, worries about patent infringement have subsided, increasing India's appeal for pharmaceutical R&D and manufacturing. India topped the list of major and middle-income nations with the most IP filings in 2022, according to the World Intellectual Property Organization.

Source: Frost & Sullivan

3 CRO AND CRDMO INDUSTRY

3.1 Global CRO Industry

The CRO industry includes outsourced R&D services provided to pharmaceutical and biotech companies for drug discovery and early development. CROs have been widely used by the life sciences industry since the 1970s. As the CRO industry gained significant momentum, services offered by CROs have evolved from basic supporting services to a wide range of lab and analytical services across the R&D value chain, enabling them to become preferred strategic partners to pharma innovators. Some of the CROs are also setting up dedicated R&D facilities for their customers. These dedicated facilities demonstrate ability to serve customer with comprehensive set of capabilities and long-term commitment by the customers.

CROs now provide integrated solutions for challenges across the entire R&D value chain

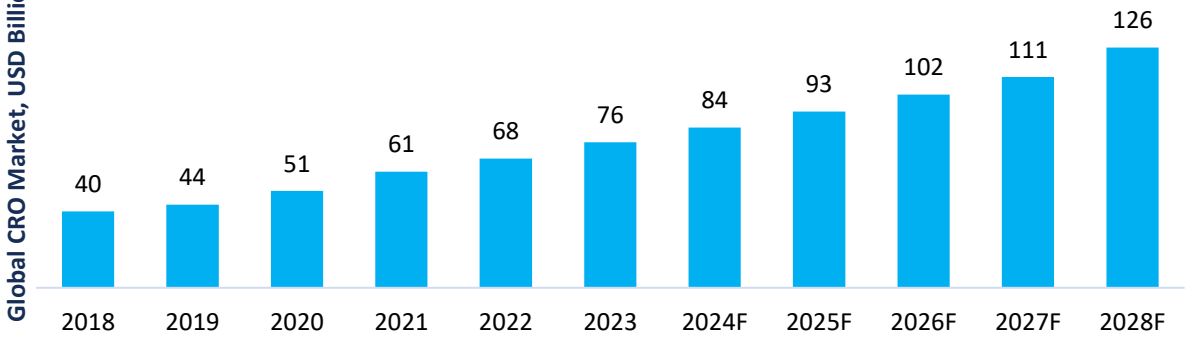
Drug discovery begins with disease target identification and validation. The next step is an iterative process of lead identification and optimization culminating in drug candidate nomination. This is followed by pre-clinical studies as an input to an IND Application. Different scientific skill sets are required at each of these stages of drug discovery. For example, sophisticated biology understanding is required during target identification and validation, while deep medicinal and synthetic chemistry capabilities combined with high throughput and high-quality biology studies are critical for lead generation and nomination. ADME and Toxicology studies become very important as lead candidates get narrowed down to select development candidates and pre-clinical data is generated to enable IND Applications. Integrated CROs are well equipped to handle all of these activities in a rapid and seamless manner by transferring samples, data, knowledge and technical feedback between scientists of various disciplines.

CROs can help significantly lower drug development costs, facilitate a more seamless and timely entry into new markets with varying regulatory requirements, avoid the expense and labor of managing capital-intensive infrastructure and allow pharmaceutical sponsors to concentrate on their core skills while proactively mitigating any development risks. CROs have elevated their role and often emerged as co-innovators led by the expansion of small and frequently virtual biotech companies with lean teams, that rely almost entirely on an outsourcing partner for their drug discovery and development needs. By utilizing their extensive range of services, CROs can help lower drug development costs by approximately 30% when compared to in-house research.

The global CRO industry size increased from $40.1 Bn in 2018 to $76.5 Bn in 2023, representing a CAGR of 13.7%, and is expected to reach $126.4 Bn in 2028, representing a CAGR of 10.6% primarily driven by increasing outsourcing, improving technological capabilities and global expertise.

Source: Frost & Sullivan

Exhibit 3.1:Global CRO Market, 2018-2028F
CAGR, 2018-23 - 13.7%
CAGR, 2023-28 - 10.6%



Source: Frost & Sullivan

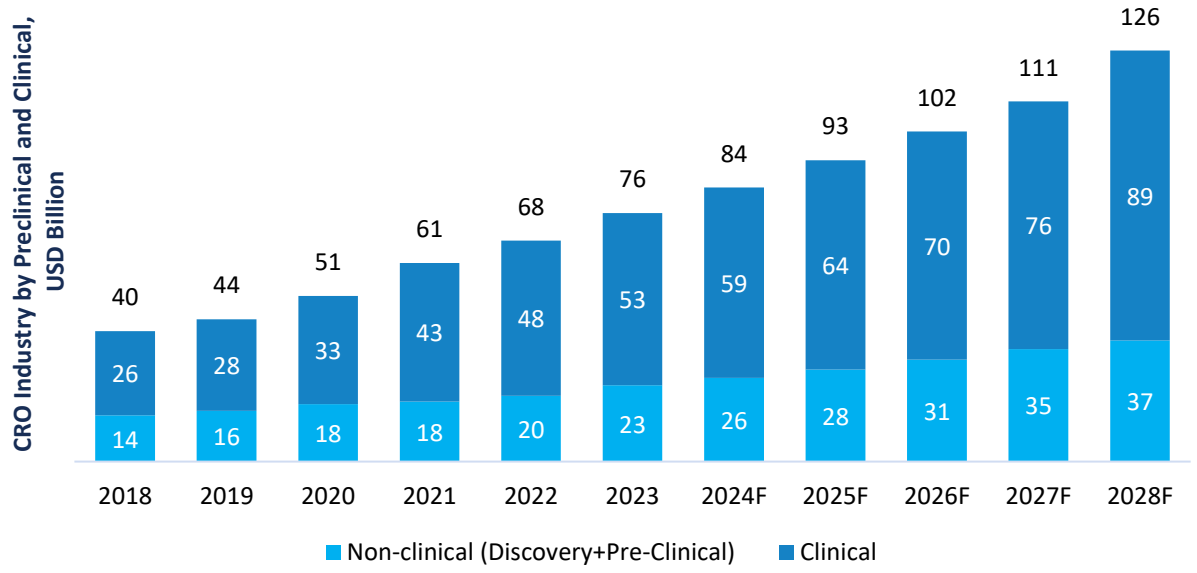
3.1.1 Global CRO Industry by Value Chain Service Type

There are further 2 CRO player archetypes: Non-clinical CROs (comprising Discovery and Pre-clinical services) and Clinical CROs. In the early drug discovery stages of clinical research, non-clinical CROs are responsible for not only identifying potent drug candidates, but also for designing and conducting laboratory tests, analysing the resulting data, and confirming that the safety of the potential drug is suitable to proceed to the next stage of development and human clinical trials. Clinical CROs, in contrast, are involved in the later stages of drug development, encompassing the stages of clinical research that involve testing a drug on human subjects from phase I to phase III or IV trials. The clinical phase of drug research tests the findings from preclinical studies in real-life conditions within the target disease population with human volunteers.

Pharmaceutical companies have historically outsourced clinical trials more than discovery and preclinical work. This is because the need for patent protection and maintaining control over the fundamental discovery process is higher during the early discovery and pre-clinical phases. With strengthening IP protection laws and increasing focus on R&D productivity, pharmaceutical companies have begun to increasingly rely on CROs for early discovery and preclinical studies. Also, in the last decade, there has been a noticeable increase in the outsourcing of nonclinical services due to the emergence of smaller pharmaceutical businesses and biotechs that rely more on CROs and enhanced intellectual property protection procedures at CROs. By 2028, the preclinical and discovery industries are projected to have grown to a combined value of USD 37.3 billion, growing at a CAGR of c.10% over 2023-28F.

Source: Frost & Sullivan

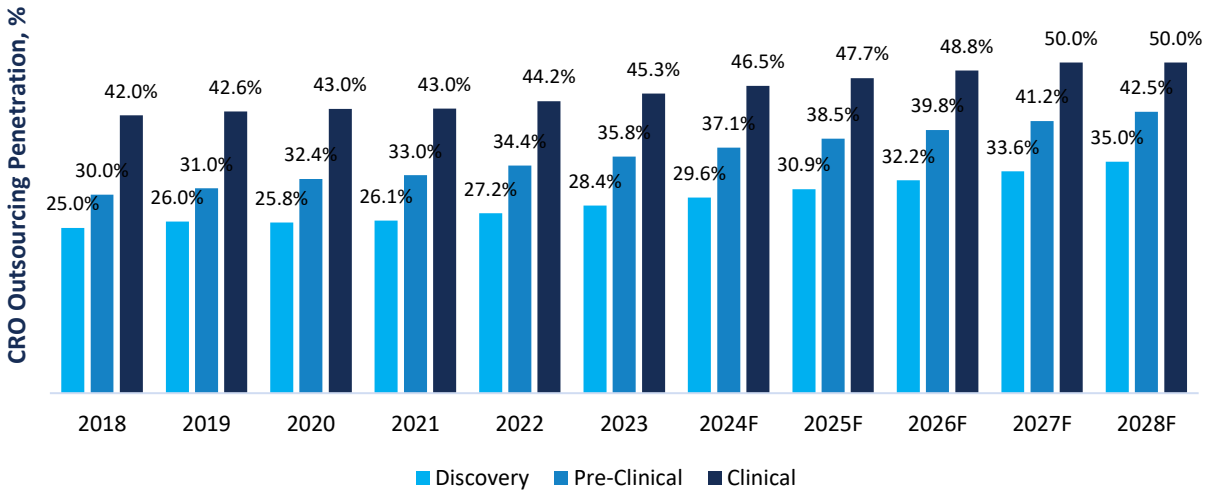
Exhibit 3.2:Global CRO Industry by Non-clinical and Clinical, 2018-2028F



Source: Frost & Sullivan

The discovery related outsourcing penetration was at 25% in 2018 and expected to reach 35% by 2028. Similarly pre-clinical activities are poised to see significant growth from 30% in 2018 to 42.5% in 2028.

Exhibit 3.3:Outsourcing Penetration to CROs in Discovery, Pre-Clinical and Clinical Phase, 2018-2028F

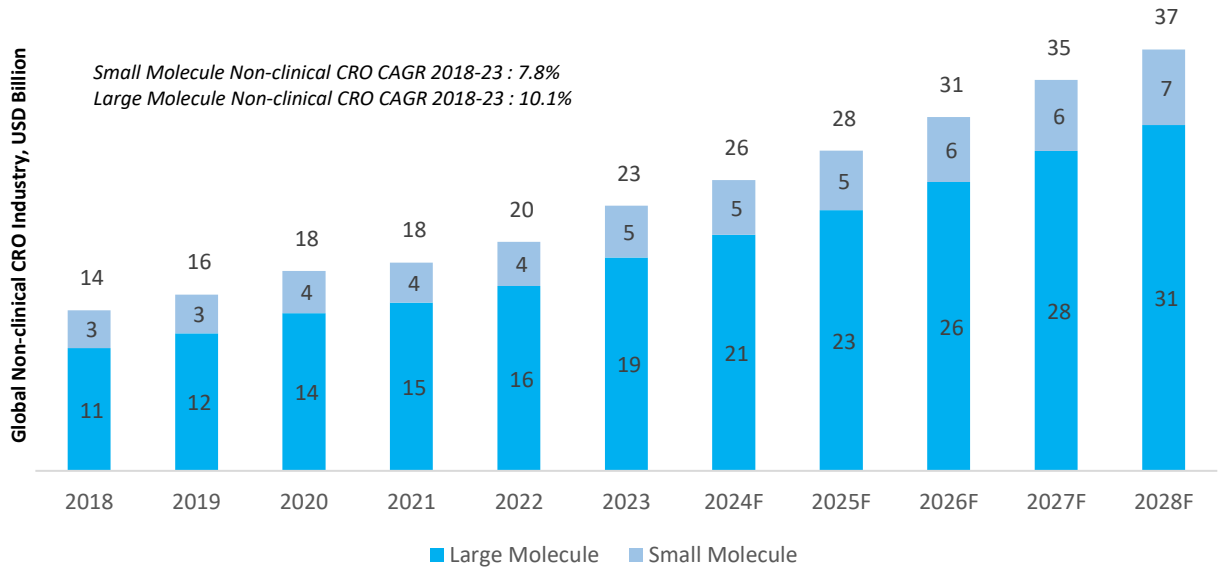


Source: Frost & Sullivan

3.1.2 Global Non-clinical (Discovery + Pre-Clinical) CRO Industry by Modality

As we look at non-clinical CRO industry by modality, small molecule non-clinical CRO is expected to grow at CAGR of 7.8% during 2023-28F. Apart from increasing technical expertise of CROs to take more complex project, the intertwined nature of the small and large molecule sector such as the use of small molecules with increased complexity (new solubility profile, highly potent, target new disease pathways) in combination with large molecules, such as antibody-drug conjugates (ADC) is expected to drive further growth of small molecule CRO industry.

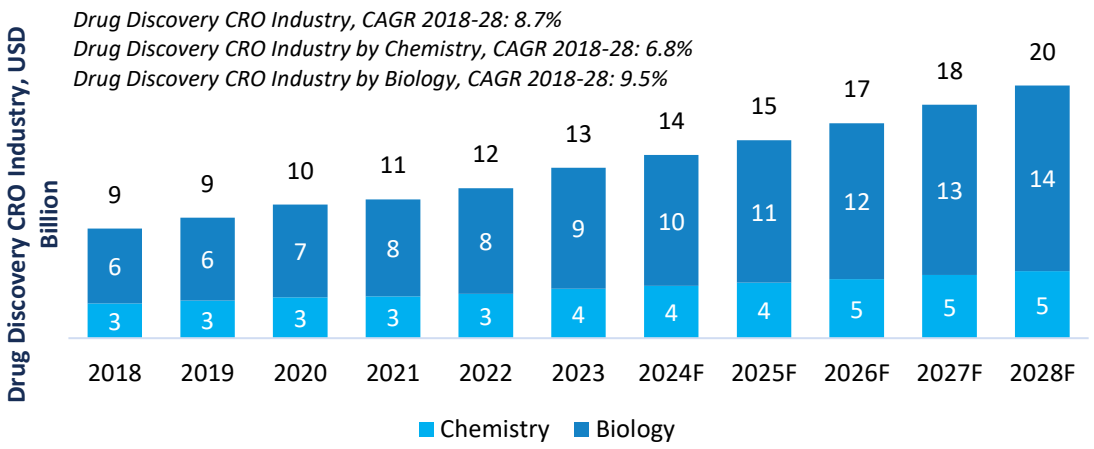
Exhibit 3.4: Global Non-clinical CRO Industry by Large and Small Molecules, 2018-2028F



Source: Frost & Sullivan

Within the non-clinical services, drug discovery is a key component which demands CROs to have advanced biology and chemistry capabilities. The key steps in drug discovery which require biology expertise include target identification and validation (targets refer to DNA, enzymes, receptors, and ion channels for diseases by conducting laboratory experiments), assay development and assay testing (assays are laboratory testing methods). Similarly, chemistry capabilities are required for steps in the discovery process like analyzing data and designing new molecules (medicinal chemistry) and synthesizing sample quantities of the compounds designed by medicinal chemists (synthetic chemistry).

Exhibit 3.5:Drug Discovery CRO Industry by Biology and Chemistry, 2018-2028F



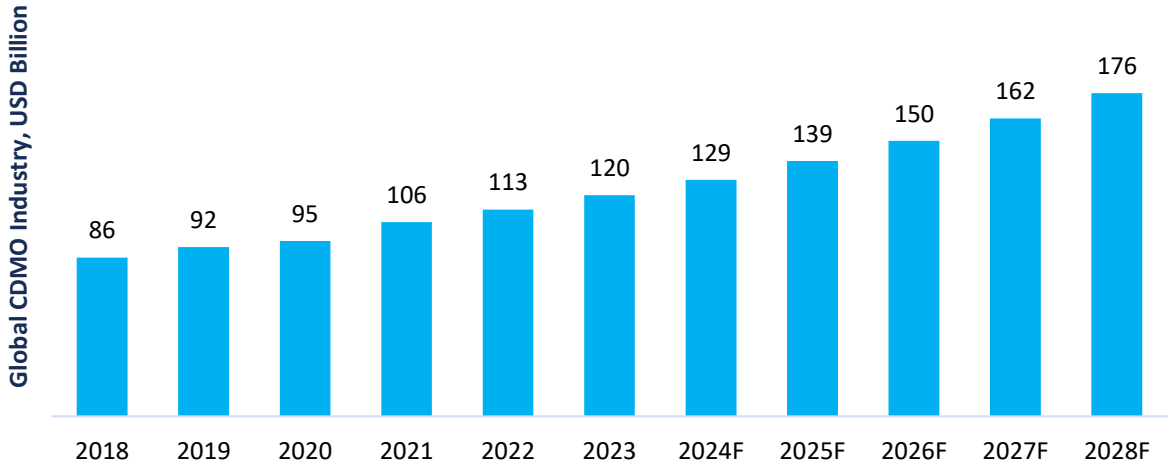
Source: Frost & Sullivan

Similarly, DMPK (Drug Metabolism and Pharmacokinetics) and toxicology capabilities are key for a CRO, as these are key steps which help to identify drugs that are likely to be suitable for advancement through the drug development process. It considers how the drug is metabolized and processed by the body. In vitro toxicology and in vivo toxicology studies are conducted to enable making a go-no-go decision regarding if a drug should be selected as a drug candidate and moved into late-stage preclinical and clinical programs.

3.2 Global CDMO Industry

The CDMO industry includes services provided for drug development and commercial manufacturing. Historically, pharma has often concentrated on selling high-volume products and used contracts with CDMOs to leverage increased manufacturing capacity. But as the mass-distribution blockbuster pharmaceuticals faded and precision medicine, specialty indications, and more R&D in complicated treatments took center stage, pharmaceutical sponsors are starting to view CDMOs as strategic partners rather than vendors. Pharma innovators increasingly leverage cost efficiencies, specialist knowledge, latest manufacturing technologies and other benefits from CDMOs. In addition, the growing pipeline of sophisticated pharmaceutical products and the increased focus on efficiency and innovation has further driven the global outsourcing of research and manufacturing tasks to CDMOs. The reliance on CDMOs will further grow going forward as they continue to offer innovator pharmaceutical companies commercially feasible solutions for a range of drug development and manufacturing services, such as pharmaceutical formulation, analytical development, process optimization, and scale-up manufacturing. Strong technical and R&D infrastructure capabilities, availability of skilled scientific talent and quality manufacturing with clean track record of regulatory compliance, are some of the key success factors for a CDMO. The global CDMO industry size increased from $86 Bn in 2018 to $120 billion in 2023, representing a CAGR of 6.9%, and is expected to reach USD 176 billion in 2028, representing a CAGR of 7.9%.

Exhibit 3.6:Global CDMO Industry, 2018-2028F
CAGR, 2018-23 - 6.9%
CAGR, 2023-28 - 7.9%

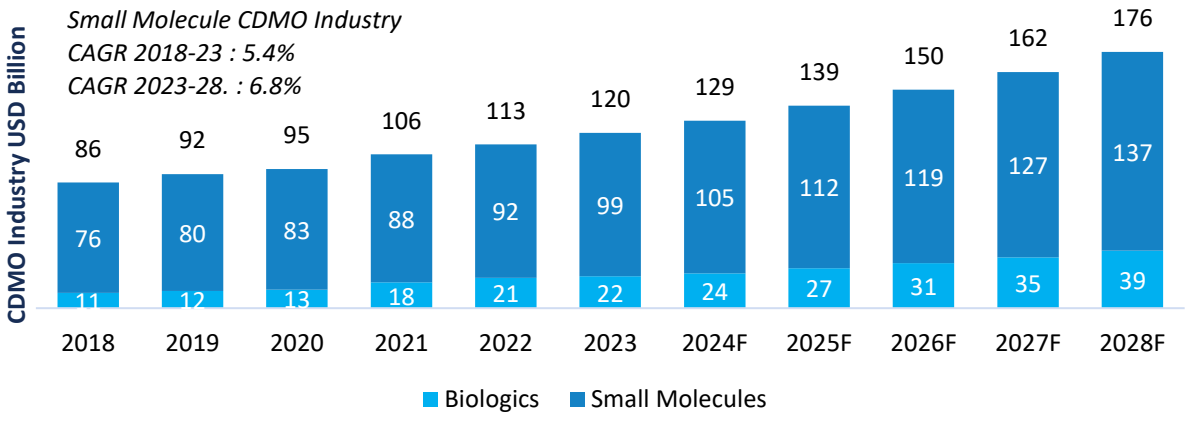


Source: Frost & Sullivan

3.2.1 Global CDMO Industry by Modality

In the CDMO industry, small molecules currently dominate the industry with 80%+ proportion, as they can target a wide range of diseases and disorders and remain a fundamental component of pharmaceutical markets. With increase in outsourcing and growing complexity and diversity of small molecules, Small molecule CDMO industry is expected to grow at a faster rate of 6.8% during 2023-28 to reach a $137 Bn by 2028, as compared the historical growth rate of 5.4% during 2018-23.

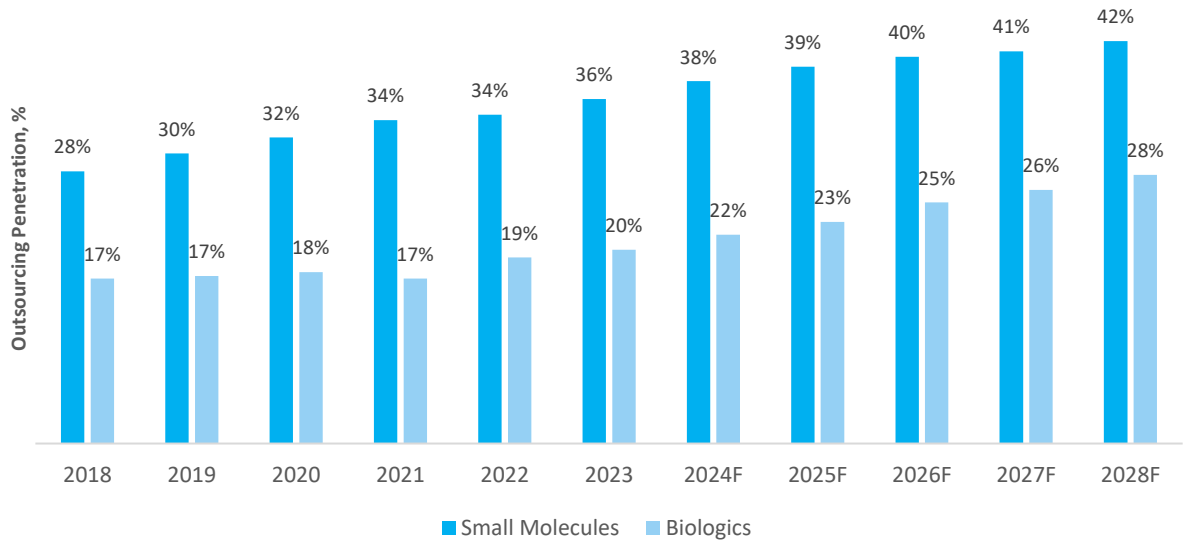
Exhibit 3.7:Global CDMO Industry by Small Molecule and Biologics, 2018-2028F



Source: Frost & Sullivan

Outsourcing of development and manufacturing of drugs has significantly increased in the historical period due to significant benefits the contract service providers offer. The penetration of outsourcing for small molecules historically has grown at a much faster pace from 28.5% in 2018 to 36.0% in 2023 than biologics, which grew from 17.2% in 2018 to 20.2% by 2023, due to the end products being relatively simpler and involvement of less complicated processes. Trend of increasing outsourcing penetration is expected to continue for both the drug types as pharma innovators increasingly realize benefits. However, as large molecule based modalities are still evolving, innovator companies tend to develop these technologies in-house. As a result, even on a higher base, the penetration for small molecules is expected to grow from 36.0% in 2023 to 42.0% by 2028.

Exhibit 3.8:CDMO Outsourcing Penetration by Small Molecules and Biologics, 2018-2028F

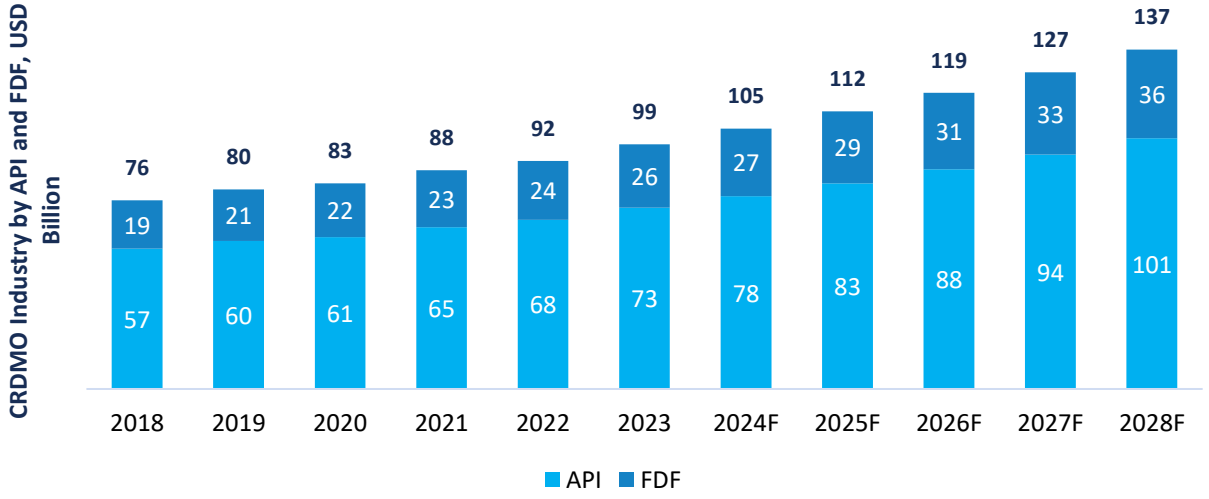


Source: Frost & Sullivan

3.2.2 Global Small Molecule CDMO Industry Split between API and FDFs

Small molecules or synthetic compounds account for around 70% of APIs on the market today. Due to the considerable economic benefits of outsourcing API manufacturing, there has always been a substantial reliance on CDMOs for APIs (many worldwide APIs are produced in China, India, and Italy). Outsourcing is anticipated to rise further in the next decades because to the increasing complexity of APIs, which are increasingly potent and need expert handling. API and intermediates are expected to continue to dominate the CDMO market in 2023-28 period. In the API category, the small molecule CDMO market revenue was USD 73 billion in 2023 and is expected to reach USD 101 billion by 2028, growing at a CAGR of 6.7% between 2023 and 2028.

Exhibit 3.9:Global Small Molecule CDMO Industry by API and FDF, 2018-2028F

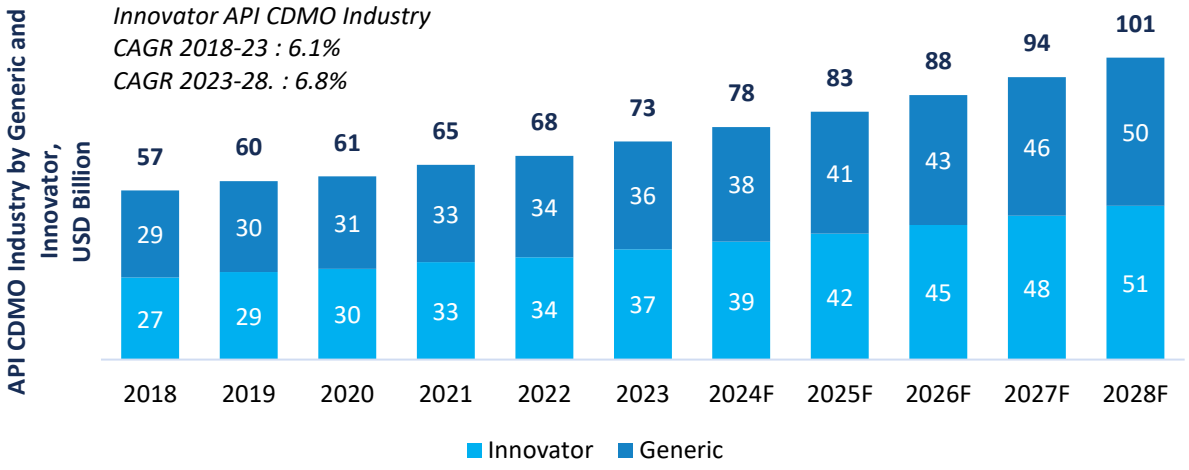


Source: Frost & Sullivan

3.2.3 Global Small Molecule API CDMO Industry Split by Drug Type

Generic manufacturing has historically comprised a large pie of CDMO outsourcing, as it is a relatively simpler duplication of current manufacturing processes once patents expire. In the recent years, there is a discernible trend toward outsourcing the production of innovative drugs as well. The increasing complexity of innovative drugs, the need to use cutting-edge machinery, technologies, and knowledge for innovative drug manufacturing, globalization concerns for easier and faster market access, and the importance of resource optimization for small and mid-sized businesses leading the way in innovation are all contributing factors to this. The innovator drug API CDMO industry grew by 6.1% between 2018 and 2023 and is anticipated to grow by 6.8% over 2023-28F, faster than the generics CDMO industry, comprising 52% of the API CDMO industry in 2028.

Exhibit 3.10:API CDMO Industry by Generic and Innovator, 2018-2028F



Source: Frost & Sullivan

4 COMPETITIVE LANDSCAPE OF CRDMOS

The global CRDMO industry is marked by high fragmentation, with over 1000 global players competing for market share. This landscape encompasses a diverse range of players, including various CROs and CDMOs and limited number of pure-play full-service CRDMOs.

The Indian CRDMO industry constitutes a limited number of scaled up companies. With increase in demand of Indian CRDMOs significantly driven by shifting geopolitical factors such as China+1, Biosecure act amongst others, the scaled up CRDMO players in the industry are expected to gain disproportionally due to their preference by pharma companies as well as biotechs driving up their market share. Also, companies with large and marquee pharma innovators as clients have a strong competitive edge due to significant opportunities to cross-sell and have higher growth. The following is the list of Top 25 pharma companies globally by revenue.

Rank	Companies	2023 Overall Pharmaceutical Sales ($, Bn)
1	Johnson & Johnson	55.0
2	AbbVie	53.2
3	Novartis	52.5
4	Merck	50.8
5	Roche	49.1
6	Pfizer	48.2
7	Sanofi	46.4
8	Bristol-Myers Squibb	44.4
9	AstraZeneca	43.8
10	GlaxoSmithKline	36.8
11	Novo Nordisk	33.7
12	Eli Lilly	31.9
13	Takeda	22.7
14	Amgen	26.6
15	Gilead Sciences	26.5
16	Bayer	22.2
17	Boehringer Ingelheim	20.6
18	Viatris	15.4
19	CSL	14.3
20	Teva	12.5
21	Astellas Pharma	10.5
22	Daiichi SankyÅ	10.0
23	Vertex Pharmaceuticals	9.9
24	Sandoz	9.6
25	Merck KGaA	8.7

Source: Company filings, annual report, Frost & Sullivan

Some of the select global and Indian CRDMOs which operate in pharma value chain of discovery, development and commercial manufacturing of APIs and intermediates are discussed below.

Company	Service/Operational Overview
WuXi AppTec Co. Ltd. (Wuxi AppTec) Founded: 2000 HQ: China	WuXi AppTec a global outsourcing services provider operating through 5 different business segments, WuXi Chemistry, WuXi Testing, WuXi Biology, WuXi ATU and WuXi DDSU. The company has robust clientele (including pharma/ biopharma and medical devices companies), of over 6000 customers spread across 30+ countries. It stands out especially with its technology readiness in terms of the proprietary CDMS, CTMS and AI coding system. Whilst being the leader in drug discovery and pre-clinical CRO services, WuXi has gone above and beyond in further catering to clinical development phases, including the uptake of eClinical modalities for DCT based trials, further aligning itself with the ongoing industry trends.
Pharmaron Beijing Co Ltd (Pharmaron) Founded: 2004 HQ: China	Pharmaron is a China-based, fully integrated CRDMO not only showcases sound clinical development capabilities, but also stands out in understanding of the drug discovery chemistry (medicinal, synthetic), and has built a state-of-the-art DNA encoded Libraries Technology (DELT) platform enabling custom drug discovery solution such as synthesis and screening of billions of compounds against potential biological targets. Operating into four major business segments - Laboratory services, CMC (small molecule CDMO) services, Clinical development services, and biologics and CGT services. Most of its revenue comes from the Laboratory services segment.
Charles River Laboratories International, Inc. (CRL) Founded: 1947 HQ: US	Charles River Laboratories (CRL), is one of the leading global CRDMOs supporting essential drug research and non-clinical drug development activities, operating in over 21 countries with 150+ facilities across the globe. The company is supported by 3 key business segments – Discovery and Safety Assessment (DSA), Research Models and Services (RMS) and Manufacturing Solutions (Microbial Solutions and Biologics Solutions). Over the past five years, the company has seamlessly supported research on 80% of USFDA approved drugs further indicating its specific expertise in drug development services. DSA segment is the primary contributor to the revenue growth by means of non-clinical development and regulatory-required safety testing services, whilst the RMS segment caters to research models services such as CRADL™ (flexible turnkey vivarium services).
Divis Laboratories Limited (Divis) Founded: 1990 HQ: India	Incorporated in October 1990, Divi's Laboratories is pharmaceutical and Biotechnology company engaged in manufacturing of Generic API, Custom Synthesis of APIs and Nutraceuticals for Big Pharma companies. It is promoted by Dr Murli K. Divi. Divi's has is one of the leading companies in CRAMS and Generic APIs. It is catering to therapeutic segments like Cardiovascular, Anti-Inflammatory, anti-cancer and Central nervous system drugs. It operates 3 manufacturing facilities and 3 R&D facilities and employs c.17,000 employees.
Syngene International Ltd. (Syngene) (a subsidiary of Biocon Ltd.) Founded: 1993 HQ: India	Syngene International is one of the leading contract services players in India, especially in terms of drug discovery and preclinical CRO services. Its SynVent Integrated Drug discovery platform spans both small and large molecules conducting critical drug discovery activities including target validation, translational interrogation, therapeutic discovery, and preclinical development and many more, through easy to engage Full-Time Equivalent (FTE), Fee-for-Service (FFS), and outcome or milestone-based arrangements. The company enjoys a global clientele, with US based clients accounting to over 70%.
Aragen Life Science Ltd. (Aragen) Founded: 2001 HQ: India	Aragen, a vertically integrated CRO provides research, development and manufacturing services to a wide range of global pharmaceutical and biotechnology companies (almost 400 clients), and presence primarily in Asia pacific including Japan, South Korea, and India. The company holds a strong portfolio of early-stage discovery and development of new molecular entities (NMEs) as well as manufacturing services. The company operates three

Source: Frost & Sullivan

	other subsidiaries Aragen Bioscience Inc. (biologics R&D services – protein analytics, antibody research etc.), Intox Pvt. Ltd. (provides safety assessment studies), Aragen Life Sciences B.V. (provides marketing services)
Anthem Biosciences (Anthem) **Founded: 2006** **HQ: India**	Anthem Biosciences, a Bangalore-India based Contract Research Development Organization (CDMO). It offers a whole gamut of services dedicated to enabling and sustaining global research efforts in the discovery of new compounds by pharmaceutical, biotechnology, specialty chemicals, agriculture chemicals and material science companies. Anthem's core competencies are organic synthesis, process development, analytical chemistry, discovery biology and regulatory compliance. It works extensively with pharma leaders, mid-size to virtual companies across the globe. It commenced operations in 2007 and has 2 manufacturing facilities in Bengaluru. It employs c.2,000 people in its organization.
Sai Life Sciences Ltd. **Founded: 1999** **HQ: India**	Sai Life Sciences a pureplay fully-integrated, innovator focused, Contract Research and Development Organization (CRDMO). It served a diverse customer base of 280+ innovator pharmaceutical companies that includes global pharmaceutical companies and biotechnology firms in FY24. Its clientele includes 18 out of Top 25 pharmaceutical companies, in terms of revenue for the calendar year 2023, across regulated markets, including the US, the UK, Europe and Japan. They provide end-to-end services across the drug discovery, development, and manufacturing value chain, for small molecule new chemical entities. The company has a strong portfolio of drug discovery and development and commercialization services supported by over 2,800 employees across India, US, UK, and Japan. As of March 31, 2024, Sai's development and manufacturing portfolio constituted 38 APIs and intermediates used in the manufacturing of 28 commercial drugs, including seven blockbusters (drug products with annual sales of over US$1 billion in the Financial Year 2023 and 11 products for ten APIs that were either undergoing or had completed Phase III clinical trials. Sai is one of the few CRDMOs to have unique delivery model of having research labs for discovery and development located near overseas major overseas innovation hubs at Watertown (Greater Boston, MA), United States ("US") and Manchester, United Kingdom ("UK"), complemented by large-scale research laboratories and manufacturing facilities in cost competitive locations in India.

Source: Company sources, Frost & Sullivan

Exhibit 1.2: Competitive Landscape: Capabilities Map of Peers, Global and India

Sai is the only entity of scale in India to possess both contract research ("CRO") and contract development and manufacturing organization ("CDMO") capabilities. It is one of the largest integrated Indian CRDMOs among listed Indian peers in terms of revenue from operations for FY24, serving as a one-stop platform for discovery, development, and manufacturing. They are also one of the few CROs to have a dedicated R&D facility for one of their customers.

	Company	Drug Discovery	Drug Development	Commercial Manufacturing
Global CDRMOs	WuXi AppTec			
	Pharmaron			
	CRL			
Indian CRDMOs,	Divis			
	Syngene			
	Aragen			

Source: Frost & Sullivan

CROs and CDMOs	Anthem			
	Suven			
	Sai			

Legend: Dark Green – Strong Presence; Light Green – Limited Presence; Orange – Negligible Presence

Source: Company websites, Frost & Sullivan

	Global CDRMOs			Indian Contract Service Organizations					
Company	**WuXi AppTec**	**Pharmaron**	**Charles River Lab**	**Divis**	**Syngene**	**Aragen**	**Anthem**	**Suven**	**Sai LS**
Purely Innovator focused	✓	✓	✓	×	✓	✓	✓	✓	✓
R&D Presence in innovation hubs[1]	✓	✓	✓	×	×	✓	×	×	✓
# of Discovery Programs[2]	600+	750+	400+	Not Applicable	Undisclosed	Undisclosed	Not Applicable	Undisclosed	200+
# of customers in Top Pharma companies by Revenue	20+ /Top 25	20+ / Top 25	16+ / Top 25	12+ / Top 25	15+ / Top 25	7 / Top 10	Undisclosed	Undisclosed	18 / Top 25
Dedicated R&D centers with customer	×	×	×	×	✓	×	×	×	✓

1. Refer to Section 2.4 for details on Innovation hubs
2. Refers to any CRO related services availed by the customers

Source: Company websites, Frost & Sullivan

Sai is the fastest-growing Indian CRDMO among listed Indian peers in terms of revenue CAGR as well as EBITDA CAGR over FY22-24.

Exhibit 3.26: Financial Analysis of Select CRDMOs, 2023/ FY2024									
Parameter/ Company	Wuxi Apptec	Pharmaron	Charles River Lab	Divi's Lab	Syngene	Aragen*	Anthem*	Suven Pharma	Sai Life Sciences
Total Revenue from Operations, USD million (INR million)	5,632 (469,527)	1,611 (134,291)	4,129 (344,285)	941 (78,450)	419 (34,886)	208 (17,374)	127 (10,574)	126 (10,514)	176 (14,652)
Total Revenue CAGR (FY22 – FY24)	32.7%	24.5%	8.0%	-6.4%	15.7%	25.2%	-14.2%	-10.8%	29.8%
EBITDA, USD million (INR million)	1,875 (156,320)	396 (33,050)	931 (77,653)	268 (22,350)	120 (10,033)	60 (4,991)	60 (5,037)	50 (4,139)	36 (3,001)
EBITDA Margin (%)	33.3%	24.6%	22.6%	28.5%	28.8%	28.7%	47.6%	39.4%	20.5%
EBITDA CAGR(FY22-FY24)	55.4%	16.5%	4.3%	-24.5%	14.5%	22.1%	-13.0%	-19.4%	51.3%
PAT, USD million (INR million)	1,507 (125,676)	221 (18,410)	480 (40,050)	192 (16,000)	61 (5,100)	26 (2,200)	46 (3,854)	36 (3,003)	10 (828)
PAT Margin	26.8%	13.7%	11.6%	20.4%	14.6%	12.7%	36.4%	28.6%	5.7%
PAT CAGR(FY22 – FY24)	45.0%	-1.2%	9.7%	-26.5%	13.5%	11.3%	-5.0%	-18.7%	264.7%
ROCE	21.4%	10.6%	10.8%	16.0%	13.9%	19.4%	27.0%	19.5%	10.3%
Return on Equity	19.4%	11.9%	13.3%	11.8%	12.0%	17.9%	22.1%	14.6%	8.5%

Source: Annual Reports, Frost & Sullivan

***Note:** *Data available for FY22-FY23 only; For Global companies, data is for CY2021-2023; USD to INR conversion taken is 83.3739 (RBI rate on March 28, 2024 for Wuxi Apptec, Pharmaron, Charles River Lab, Aragen and Anthem)*
EBITDA= Aggregate of restated profit before tax, depreciation and amortization expense and finance costs, less other income (excluding forex gain), for the relevant year.
EBITDA Margin = Calculated as EBITDA divided by revenue from operations
EBIT= Calculated as aggregate of restated profit before tax, finance costs
PAT margin= Restated profit after tax divided by revenue from operations
Return on Equity= Profit for the year divided by total equity for the relevant year
Return on Capital employed= Calculated as EBIT divided by capital employed. Capital Employed is calculated as aggregate of total equity, total borrowings including lease liabilities
**For Aragen and Anthem, lease liabilities and forex gain used in above formulas are basis standalone numbers*

Currency Conversion rates:

Year	*USD to INR*	*USD to RMB*
2019	*69.4*	*7.0*
2020	*75.2*	*6.5*
2021	*73.0*	*6.4*
2022	*75.8*	*6.9*
2023	*82.0*	*7.1*
2024	*83.3*	*7.2*

FROST & SULLIVAN

DISCLAIMER

The market research process for this study has been undertaken through secondary/desktop research and primary research, which involves discussing the market status with leading participants and experts.

The research methodology used is the Expert Opinion Methodology. Quantitative market information was sourced from interviews through primary research and trusted portals. Therefore, the information fluctuates due to possible business and market climate changes. Frost & Sullivan's estimates and assumptions are based on varying levels of quantitative and qualitative analyses, including industry journals, company reports, and information in the public domain.

The data has been collated from publicly available sources such as the Ministry of Corporate Affairs (MCA) database, company published annual reports.

Forecasts, estimates, predictions, and other forward-looking statements contained in this report are inherently uncertain because of changes in factors underlying their assumptions, events, or combinations of circumstances that cannot be reasonably foreseen. Actual results and future events could differ materially from forecasts, estimates, predictions, or statements. All financial and operational details for Sai Life Sciences are for continuing operations and are provided by the company.

Frost & Sullivan has prepared this study independently and objectively and has taken adequate care to ensure its accuracy and completeness. We believe that this study presents an accurate and fair view of the Contract Research & Development Manufacturing Organization (CRDMO) Market in selected geographies within the limitations of, among others, secondary statistics and primary research, varying scenarios created due to the COVID-19 pandemic, and it does not purport to be exhaustive. Our research has been conducted with an "overall industry" perspective, and it may not necessarily reflect the performance of individual companies in the industry. Frost & Sullivan shall not be liable for any loss suffered because of reliance on the information contained in this study. This study should also not be considered a recommendation to buy or not to buy the shares of any company or companies as mentioned in it or otherwise."