

Global Contract Development and Manufacturing Organization (CDMO) Market: Analysis By Type (Chemical Drugs & Biologics), By Product (API/Bulk Drugs Drug Product Manufacturing (Inc. Dosage & Formulation Development) & Packaging), By Sourcing (In House & Outsourced), By Application (Oncology, Cardiovascular Disease, Diabetes, Hormonal, Glaucoma & Others), By Region, Size and Trends with Impact of COVID-19 and Forecast up to 2029

<https://marketpublishers.com/r/GA6E23B4185CEN.html>

Date: February 2024

Pages: 180

Price: US\$ 2,450.00 (Single User License)

ID: GA6E23B4185CEN

Abstracts

The global contract development and manufacturing organization (CDMO) market was valued at US\$124.38 billion in 2023, and is expected to be worth US\$256.90 billion in 2029. Post-millennium, the biopharmaceutical sector has advanced significantly, witnessing the development of novel drugs and blockbuster medications. The "contract development manufacturing organization (CDMO)" model has emerged in response to growing demand. CDMOs, third-party providers, specialize in developing and manufacturing production processes for pharmaceutical firms, offering support throughout the drug-making journey. These entities, primarily focused on active pharmaceutical ingredient (API) manufacturing, have surged in the past decade due to mergers and acquisitions. While larger pharmaceuticals may opt for in-house capacities, smaller firms prefer CDMO outsourcing, reducing investment risks and providing access to specialized expertise. This trend enhances the efficiency and success of drug development endeavors.

The rise of innovative modalities, such as mRNA technologies, is propelling CDMOs to invest in cutting-edge manufacturing capabilities to meet evolving pharmaceutical

needs. Additionally, increased outsourcing by pharmaceutical companies to streamline operations and reduce costs is boosting the CDMO sector. The growing importance of specialized services, spanning early-stage development to commercial manufacturing, underscores the expanding role of CDMOs in the entire drug development lifecycle. Furthermore, the emphasis on flexible and scalable manufacturing processes, coupled with advancements in digital technologies and data analytics, is shaping the future landscape of the CDMO market, offering efficiency and adaptability in meeting diverse and complex pharmaceutical requirements. The global CDMO market is expected to grow at a CAGR of 12.85% over the years 2024-2029.

Market Segmentation Analysis:

By Type: The report identifies two segments on the basis of type: Chemical Drugs and Biologics. The chemical drugs segment dominated the market in 2023, due to the continued prevalence of small-molecule drugs in various therapeutic areas, such as cardiovascular diseases, infectious diseases, and pain management. The well-established regulatory pathways for chemical drugs contribute to the segment's growth, providing a clear framework for development and commercialization. Additionally, the demand for efficient and cost-effective manufacturing processes for chemical drugs propels pharmaceutical companies to engage CDMOs for expertise in synthesis, formulation, and analytical testing. However, it is expected that the biologics segment would grow at the fastest growth rate during the forecasted period.

By Product: The global CDMO market by product can broadly be divided into three segments namely, API/bulk drugs, drug product manufacturing (inc. dosage & formulation development) and packaging. The API/Bulk Drugs segment accounted for the highest share in the CDMO segment. This segment is witnessing significant growth due to the rising demand for both generic and innovative drugs globally. As APIs are an essential part of formulated pharmaceuticals, CDMOs, and CMO, have made major investments to increase their capacity for producing APIs in response to the rising demand for them. Factors such as the increasing prevalence of chronic diseases, the need for cost-effective pharmaceutical solutions, and the surge in outsourcing by pharmaceutical companies to streamline production processes are driving the growth of this segment. Simultaneously, the drug product manufacturing (inc. dosage & formulation development) segment is anticipated to exhibit the fastest CAGR during the forecasted period.

By Sourcing: The global CDMO market by sourcing can broadly be divided into two segments namely, In House and Outsourced. The in house segment dominated the

market in 2023. Factors driving the growth of the In-House segment include the desire for greater control over proprietary processes, intellectual property, and a direct hand in quality assurance. Some companies opt for in-house capabilities to safeguard sensitive information and maintain a competitive edge by closely managing their entire product lifecycle. The outsourced segment is anticipated to exhibit the fastest CAGR during the forecasted period.

By Application: In terms of application, the CDMO market can be divided into six segments namely, Oncology, Cardiovascular Disease, Diabetes, Hormonal, Glaucoma and Others. The oncology segment in the CDMO market is witnessing a surge due to the escalating demand for precision medicines and innovative cancer therapies. Factors driving this growth include the increasing incidence of cancer worldwide, the emergence of targeted therapies, and the expanding role of immunotherapy. CDMOs specializing in oncology play a crucial role in developing and manufacturing complex biologics and personalized medicine.

By Region: In the report, the global CDMO market is divided into four regions: Asia Pacific, North America, Europe, and ROW. Asia Pacific had a dominating share in the CDMO market in 2023, and provides lucrative opportunities during the forecasted period. The CDMO market in Asia Pacific is booming, driven by factors such as rising pharmaceutical demand, cost-effectiveness, and a skilled workforce. The region is home to a rapidly growing pool of scientists and engineers, coupled with investments in cutting-edge biopharmaceutical technologies. This creates a robust ecosystem for CDMOs to thrive. The market is dominated by China, with its vast capacity and competitive pricing. However, other countries like India and Singapore are emerging as potential contenders. The future of the APAC CDMO market remains bright, with its continued growth, technological advancements, and evolving regulatory landscape, the region is poised to play a leading role in the global pharmaceutical industry.

North America had a significant share in the CDMO market in 2023. The region's stricter regulation ensures the superior quality of manufacturing and end-product that the CDMOs adhere to. Pharmaceutical and biotech companies in North America continue to outsource various aspects of their drug development and manufacturing processes to CDMOs. The rise in biopharmaceuticals, as well as drug development pipelines, are expected to provide CDMOs with more opportunities in the future. The market is being driven by an increased emphasis on drug discovery and manufacturing outsourcing. Steady growth in the US pharmaceutical industry and increasing outsourcing by major pharmaceutical companies focusing on their core competencies to improve profit margins are driving the country's market. On 12 September 2022, US President Joseph

Biden issued an Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a sustainable, safe and secure American Bioeconomy. The order directs the government to invest in and coordinate R&D in biotechnology and biomanufacturing, improve upon and expand production capacity, and accelerate the translation of basic research to commercial products.

Market Dynamics:

Growth Drivers: The market has been growing over the past few years, due to factors such as aging population, rising healthcare expenditure, rising prevalence of genetic disorders, increasing pharmaceutical R&D expenses, increasing demand for active pharmaceutical ingredient (API) and increasing outsourcing trends. Over the last few years, the demand for Active Pharmaceutical Ingredient (API) manufacturing has been steadily increasing. It is expected to rise steadily in the future, with additional patent expirations and a significant increase in global generic production capacities.. The majority of the industry's companies are increasingly focusing on the development of biological APIs, which is propelling the API manufacturing.

Challenges: However, some challenges are also impeding the growth of the market such as biotech funding issues, varying regulatory requirements across regions and dependence on patents, copyrights, trademarks and trade secrets. Noncompliance of guidelines and regulations by the respective authority and inferior quality of manufactured drugs brings serious consequences to the business and the brand name. Hence, compliance with regulatory guidelines is paramount in the pharmaceutical industry. For CDMOs, the drug substance/formulation manufactured on a contract basis is sold under the contractor's brand. That requires large amounts of data to be submitted to the regulatory authority as the drug moves through phases of development and clinical trials. Hence, the handling of the data and submissions of different formulations across various countries becomes difficult for CDMOs and increases the risk of errors in regulatory filings. This factor will likely hamper the market growth of pharmaceutical CDMOs in the coming years.

Trends: The market is projected to grow at a fast pace during the forecast period, due to various latest trends such as growing biologics market, rising development of small molecule drugs, bringing orphan drugs to market, emerging markets, rise in investments and strategic collaborations and technological advancement in the CDMO. The CDMO market has witnessed a significant trend with a notable rise in investments and strategic collaborations. This surge can be attributed to the growing complexity of drug development processes, prompting pharmaceutical and biotechnology companies to

seek specialized expertise and resources. As the demand for innovative therapies continues to escalate, CDMOs play a pivotal role in providing end-to-end solutions for drug development, from early-stage research to commercial manufacturing. Many CDMOs are strongly focusing on capital investments for the development of novel compounds and expand their geographical footprints. For instance, CordenPharma International announced its strategic investment in its small molecule API manufacturing site located in Switzerland.

Impact Analysis of COVID-19 and Way Forward:

The COVID-19 pandemic significantly impacted the CDMO market. As the pharmaceutical industry raced to develop vaccines and treatments, CDMOs played a crucial role in providing manufacturing capabilities. Increased demand for vaccine production and the need for diversified supply chains elevated the importance of CDMOs. Despite challenges like supply chain disruptions, the CDMO market experienced growth, driven by accelerated research and development activities.

Vaccine development and manufacturing activity in the CDMO market has increased in the past years, owing primarily to the industry's response to the COVID-19 pandemic. This expansion is expected to continue in the coming years as well. Increased demand for new treatments, whether for COVID-19 or other critical medications, necessitates increased production. Many sponsors collaborate with contract development and manufacturing organizations (CDMOs) and contract manufacturing organizations (CMOs) to scale up and meet commercial capacity demands in order to get treatments to patients as soon as possible.

Competitive Landscape:

The CDMO market is fragmented since several vendors contribute to the market share. The existence of numerous competitors in the market has an impact on service pricing, making it a direct source of competition, particularly for small-scale providers. The vendors in the market are anticipated to concentrate on offering one-stop-shop services to gain a competitive edge. Players in the market are adopting strategies such as partnerships, company expansions, innovations, and acquisitions to enhance their product offerings and gain sustainable competitive advantage. In June 2023, Catalent expanded the One Bio Suite solution, encompassing development, manufacturing, and supply for various biotechnological modalities, such as antibodies, recombinant proteins, cellular and gene therapy, and mRNA.

The key players of the global CDMO market are:

Catalent Pharma Solutions Inc.
Samsung Biologics Co. Ltd.
WuXi AppTec
Boehringer Ingelheim
WuXi Biologics (Cayman) Inc.
Jubilant Pharmova Limited
Lonza Group AG
Siegfried Holding AG
Thermo Fisher Scientific Inc.
FUJIFILM Holdings Corporation
Recipharm AB
Bushu Pharma
Piramal Group (Piramal Pharma Solutions)

Asian CDMOs are strategically expanding their capacities, becoming pivotal in global pharmaceutical and biotechnology sectors. This growth responds to escalating demand for manufacturing services in drug development and production. Companies in China, India, and South Korea are fortifying their capabilities to serve clients worldwide. Through investments in cutting-edge facilities, advanced technologies, and workforce training, the Asian CDMOs aim to augment production capacity, flexibility, and efficiency. Historically, the industry has faced excess demand, attributed to robust development pipelines and challenges in scaling capacity. More recently, Biologics CDMO companies (particularly Samsung Biologics and Wuxi Biologics) have been seen investing in massive production capacity expansion projects.

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