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U.S. Small Molecule CDMO Market Size, Share & Trends Analysis Report By Drug Type (Generics, Innovators), By Product (APIs, Finished Drug Products), By Application (Oncology, CVD, CNS Conditions), And Segment Forecasts, 2025 - 2033

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Abstracts

U.S. Small Molecule CDMO Market Summary

The U.S. small molecule CDMO market size was estimated at USD 26.85 billion in 2024 and is projected to reach USD 47.38 billion by 2033, growing at a CAGR of 6.68% from 2025 to 2033. The growth of the market is due to the rising demand for outsourcing across the pharmaceutical value chain. Pharmaceutical companies, especially small to mid-sized firms and virtual biotech's, increasingly rely on CDMOs to reduce time-to-market, optimize R&D expenditure, and access specialized capabilities in formulation, process development, and regulatory compliance.

In addition, consolidation in the pharmaceutical industry and growing cost pressures have pushed both innovator and generic drug companies to streamline internal operations and focus on core competencies. This has expanded opportunities for U.S.-based CDMOs to support not only domestic but also clients seeking quality and compliance with stringent FDA regulations. Increasing investments in capacity expansion, continuous manufacturing, and green chemistry processes by leading CDMOs are also contributing to long-term growth.

The U.S. small molecule CDMO market is mainly driven by the ongoing dominance of small molecule drugs in FDA approvals and active pipelines. In 2023, over 60% of the new molecular entities (NMEs) approved by the U.S. FDA were small molecules, including drugs like Ogsiveo (for desmoid tumors) and Zurzuvae (for postpartum

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depression). This steady trend creates a significant and recurring demand for CDMOs that can provide comprehensive services such as formulation, scale-up, and regulatory batch manufacturing. Small and mid-sized biotech companies, which make up most of the early-stage R&D in the U.S., often lack in-house manufacturing capabilities and instead depend on CDMOs for both preclinical and commercial production. The need to reduce time-to-market for high-value therapeutics-especially in fields like oncology, rare diseases, and CNS disorders-further speeds up outsourcing to flexible, U.S.-based CDMOs with Phase I-III support capabilities.

Moreover, the strategic investment by CDMO companies to expand their U.S. manufacturing and development footprint, catering to both domestic innovators and foreign biopharma looking for U.S. market access. For instance, Cambrex invested over $50 million in its High Point, North Carolina facility to expand process development and API manufacturing capacity for small molecules. Similarly, Thermo Fisher Scientific has been expanding its U.S. capacity through its acquisition of Patheon and subsequent upgrades across its U.S. network. There's also a strong regulatory and logistics advantage for U.S.-based CDMOs, as manufacturing within the U.S. reduces supply chain complexity and supports compliance with FDA current Good Manufacturing Practices (cGMP).

U.S. Small Molecule CDMO Market Report Segmentation

This report forecasts revenue growth at country levels and provides an analysis of the latest industry trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the U.S. small molecule CDMO market report based on product, drug type, application and region.

Product Outlook (Revenue, USD Million, 2021 - 2033)

Active Pharmaceutical Ingredients (API)

Finished Drug Products

Drug Type Outlook (Revenue, USD Million, 2021 - 2033)

Innovators

Generics

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Application Outlook (Revenue, USD Million, 2021 - 2033)

Oncology

Cardiovascular Disease

Central Nervous System (CNS) Conditions

Autoimmune/Inflammation

Others

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Contents

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CHAPTER 7. U.S. SMALL MOLECULE CDMO MARKET: REGIONAL ESTIMATES & TREND ANALYSIS BY PRODUCT, DRUG TYPE, APPLICATION

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CHAPTER 8. COMPETITIVE LANDSCAPE

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List Of Tables

LIST OF TABLES

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List Of Figures

LIST OF FIGURES

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