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United States Biopharmaceuticals Contract Manufacturing Market By Source (Mammalian, Non-mammalian), By Service (Process Development, Fill & Finish Operations, Analytical & QC studies, Packaging & Labelling, Others), By Product (Biologics, Biosimilars), By Therapeutic Area (Oncology, Autoimmune Diseases, Infectious Diseases, Cardiovascular Diseases, Metabolic Diseases, Neurology, Others), By Region, Competition, Forecast & Opportunities, 2020-2030F

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Abstracts

Market Overview

The United States Biopharmaceuticals Contract Manufacturing Market was valued at USD 10.58 billion in 2024 and is anticipated tgrow significantly, reaching USD 19.52 billion by 2030 at a CAGR of 10.72%. This growth is largely fueled by rising demand for biologics and biosimilars used ttreat complex diseases through advanced therapies. Evolving manufacturing technologies—such as single-use systems and continuous processing—are improving efficiency and scalability. These innovations enable contract manufacturers tdeliver cost-effective, high-quality solutions while supporting the increasing need for flexible, specialized production capabilities, especially for cell and gene therapies and personalized medicines.

Key Market Drivers

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Rising Demand for Biologics and Biosimilars

The growing demand for biologics and biosimilars is a key factor accelerating the expansion of the United States Biopharmaceuticals Contract Manufacturing Market. Biologics, including monoclonal antibodies, recombinant proteins, vaccines, and cell and gene therapies, are vital in treating complex and chronic conditions like cancer and autoimmune disorders. These therapies offer high precision and effectiveness, making them valuable in personalized medicine. As of April 1, 2025, the FDA has licensed 69 biosimilars, with 49 launched for 17 reference molecules, reflecting their growing adoption. Additionally, the FDA's Center for Biologics Evaluation and Research reported approving 17 new biologics and 26 supplements in 2024, showcasing strong regulatory support and a thriving development pipeline.

Key Market Challenges

High Capital Investment and Operational Costs

Establishing and operating a compliant biopharmaceutical manufacturing facility in the United States involves considerable financial outlay. Building state-of-the-art infrastructure with advanced equipment, controlled environments, and stringent quality control systems leads thigh initial capital expenses. Ongoing costs, including energy consumption, maintenance, skilled labor, and regulatory compliance, further intensify the financial pressure. Contract manufacturers must meet cGMP and other regulatory standards, requiring continuous investment in validation and training tavoid penalties, product recalls, or operational disruptions. These financial demands pose a major challenge, especially for organizations aiming tscale rapidly.

Key Market Trends

Adoption of Single-Use Technologies

Single-use technologies (SUTs) are increasingly being embraced in the U.S. biopharmaceutical contract manufacturing landscape for their benefits in flexibility, cost-effectiveness, and scalability. These systems—comprising disposable bioreactors, filters, and chromatography devices—help minimize contamination risks and eliminate complex cleaning requirements, thus streamlining operations. This is especially critical for CMOs handling multiple client projects and products. The growing use of SUTs reduces downtime and accelerates production timelines, which is particularly beneficial in manufacturing biologics like monoclonal antibodies, vaccines, and gene therapies

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where speed and compliance are essential.

Key Market Players

Lonza Group Ltd.

WuXi Biologics Co., Ltd.

Boehringer Ingelheim International GmbH

ThermFisher Scientific Inc.

Rentschler Biopharma SE

JRS PHARMA GmbH & Co. KG

AGC Biologics

ProBioGen AG

Samsung Biologics

FUJIFILM Diosynth Biotechnologies

Report Scope:

In this report, the United States Biopharmaceuticals Contract Manufacturing Market has been segmented intthe following categories, in addition tthe industry trends which have alsbeen detailed below:

United States Biopharmaceuticals Contract Manufacturing Market, By Source:

Mammalian

Non-mammalian

United States Biopharmaceuticals Contract Manufacturing Market, By Service:

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Process Development

Fill & Finish Operations

Analytical & QC studies

Packaging & Labelling

Others

United States Biopharmaceuticals Contract Manufacturing Market, By Product:

Biologics

Biosimilars

United States Biopharmaceuticals Contract Manufacturing Market, By Therapeutic Area:

Oncology

Autoimmune Diseases

Infectious Diseases

Cardiovascular Diseases

Metabolic Diseases

Neurology

Others

United States Biopharmaceuticals Contract Manufacturing Market, By Region:

North-East

Mid-West

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West

South

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the United States Biopharmaceuticals Contract Manufacturing Market.

Available Customizations:

United States Biopharmaceuticals Contract Manufacturing Market report with the given market data, TechSci Research offers customizations according ta company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up tfive).

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