

Global Biologics CMO (Contract Manufacturing Organization) Services Market Growth (Status and Outlook) 2026-2032

<https://marketpublishers.com/r/G59384C3B094EN.html>

Date: October 2026

Pages: 184

Price: US\$ 3,660.00 (Single User License)

ID: G59384C3B094EN

Abstracts

The global Biologics CMO (Contract Manufacturing Organization) Services market size is predicted to grow from US\$ 27254 million in 2025 to US\$ 49875 million in 2032; it is expected to grow at a CAGR of 9.0% from 2026 to 2032.

Biologics CMO (Contract Manufacturing Organization) Services refer to manufacturing services provided by contract manufacturing organizations under client agreements to biopharmaceutical companies, pharmaceutical companies, and other drug development organizations. These services primarily include biologic drug substance manufacturing, drug product manufacturing, aseptic fill-finish, and other GMP manufacturing activities. The service scope covers antibodies, vaccines, cell and gene therapies, and other biologics, and may support both clinical-stage and commercial-stage production. The market includes contract manufacturing services provided by independent third-party CMOs as well as external manufacturing services offered by in-house CMO business units of pharmaceutical and biopharmaceutical companies. Compared with CDMO services, CMO services are primarily focused on manufacturing execution and production capabilities and generally do not emphasize early-stage drug development, comprehensive process development, formulation development, or other R&D-intensive activities.

Biologics CMO (Contract Manufacturing Organization) services refer to GMP manufacturing services provided under contract to pharmaceutical companies, biotechnology companies, and other drug development organizations. These services primarily cover biologic drug substance (DS) manufacturing, drug product (DP) manufacturing, aseptic fill-finish, packaging, and related quality control activities. By provider type, the industry includes both independent CMOs whose core business is

third-party contract manufacturing and in-house CMO business units of large pharmaceutical and biopharmaceutical companies that provide manufacturing capacity to external customers. Compared with CDMOs, CMOs place greater emphasis on process execution following technology transfer, scale-up manufacturing, quality control, and reliable supply, while early-stage drug discovery, systematic process development, and formulation development are generally not their primary functions.

By product type, biologics CMO services mainly cover antibodies, vaccines, cell and gene therapies, and other biologics. Antibodies represent one of the more mature contract manufacturing segments and typically involve mammalian cell culture, harvest, chromatography purification, viral clearance, and drug substance preparation. Vaccine manufacturing involves a wider range of production platforms and process technologies. Cell and gene therapies generally feature smaller batch sizes, more complex processes, stringent quality requirements, and highly customized manufacturing workflows. Consequently, facility design, equipment configuration, biosafety requirements, and quality systems vary significantly across different biologic modalities.

By manufacturing stage, the industry can be divided into biologic drug substance manufacturing and biologic drug product manufacturing. Drug substance manufacturing is generally the more technology- and capital-intensive segment and includes cell culture or microbial fermentation, separation, purification, and bulk drug substance storage. Drug product manufacturing primarily covers formulation, aseptic filling, lyophilization, and filling into vials, prefilled syringes, or cartridges. Some large CMOs have established integrated DS-to-DP manufacturing networks, while other specialized providers focus on large-scale drug substance manufacturing or specific activities such as sterile fill-finish.

Direct customers primarily include large pharmaceutical and biopharmaceutical companies, small and mid-sized pharmaceutical and biotechnology companies, and other drug development organizations. Large pharmaceutical companies generally maintain internal manufacturing capabilities but may outsource production due to capacity constraints, new product introductions, regional supply requirements, specialized manufacturing needs, or efforts to reduce fixed-asset investment. Small and mid-sized biotechnology companies tend to rely more heavily on external manufacturing resources, with CMOs supporting clinical supply, scale-up, and commercial production.

Biologics CMO is an industry characterized by high capital, technical, and regulatory barriers. Mammalian cell culture is a core platform for antibodies and many recombinant proteins. Commercial manufacturing commonly utilizes individual bioreactors ranging

from approximately 2,000 L to 20,000 L, while large-scale commercial facilities typically combine multiple bioreactors into a production train. Effective annual capacity per production line depends on the number of bioreactors, culture cycle, product titer, batch success rate, and facility utilization. Single-use bioreactors offer shorter construction timelines, greater flexibility for product changeover, and lower cross-contamination risk, while large stainless-steel systems continue to provide significant economies of scale for mature, high-volume commercial products.

The upstream supply chain primarily consists of cell culture media, single-use bioprocess consumables, bioreactors, filtration systems, chromatography resins and columns, buffer materials, and sterile packaging components. Critical materials such as culture media, single-use consumables, and high-performance chromatography media can materially affect batch consistency and product quality. Major CMOs therefore typically establish multi-supplier strategies and safety stocks for critical materials while increasing facility utilization through standardized platform processes.

Regulatory compliance and quality systems constitute major competitive barriers. Biologics manufacturing must continuously comply with GMP requirements and maintain robust systems for quality management, data integrity, contamination control, process validation, and batch release. Once a commercial product has received regulatory approval and its manufacturing process has been validated at a specific CMO facility, transferring production to another site generally requires additional technology transfer, validation, and regulatory change procedures. The associated time and cost create relatively high customer stickiness and long contract durations for established commercial products.

Key competitive factors include commercial manufacturing experience, GMP compliance track record, manufacturing scale, capacity utilization, technology transfer efficiency, batch success rates, delivery reliability, and global manufacturing networks. Large CMOs with extensive bioreactor capacity and multiple manufacturing sites are well positioned to serve high-volume commercial antibody products, while mid-sized and specialized CMOs differentiate themselves through flexible capacity, small-batch manufacturing, complex molecule capabilities, or specialized technology platforms.

Profitability varies significantly depending on product type, manufacturing scale, capacity utilization, and development stage. Mature commercial biologics generally provide more stable batch demand and higher equipment utilization, whereas clinical-stage projects involve smaller batch volumes, frequent product changeovers, and greater project attrition. Gross margins for established biologics CMO manufacturing

operations can generally fall within approximately 20%–40%. Large-scale antibody drug substance manufacturing can achieve stronger economies of scale at high utilization rates, while cell and gene therapy manufacturing and small-batch sterile fill-finish may command higher unit pricing but also require greater labor, quality control, and facility costs.

Future industry growth will be supported by the continued expansion of biologics pipelines, increasing commercialization of antibody drugs and emerging biologic modalities, efforts by pharmaceutical companies to reduce fixed-asset investment, and deeper specialization across pharmaceutical manufacturing networks. At the same time, major CMOs continue to add large-scale 20,000 L-class mammalian cell culture capacity, resulting in greater capacity availability in certain regions. Competition is therefore expected to gradually shift from pure capacity expansion toward a broader focus on capacity utilization, manufacturing efficiency, quality consistency, supply reliability, and lifecycle manufacturing capabilities.

Report Scope

LPI (LP Information)' newest research report, the “Biologics CMO (Contract Manufacturing Organization) Services Industry Forecast” looks at past sales and reviews total world Biologics CMO (Contract Manufacturing Organization) Services sales in 2025, providing a comprehensive analysis by region and market sector of projected Biologics CMO (Contract Manufacturing Organization) Services sales for 2026 through 2032. With Biologics CMO (Contract Manufacturing Organization) Services sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world Biologics CMO (Contract Manufacturing Organization) Services industry.

This Insight Report provides a comprehensive analysis of the global Biologics CMO (Contract Manufacturing Organization) Services landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on Biologics CMO (Contract Manufacturing Organization) Services portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global Biologics CMO (Contract Manufacturing Organization) Services market.

This Insight Report evaluates the key market trends, drivers, and affecting factors

shaping the global outlook for Biologics CMO (Contract Manufacturing Organization) Services and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Biologics CMO (Contract Manufacturing Organization) Services.

This report presents a comprehensive overview, market shares, and growth opportunities of Biologics CMO (Contract Manufacturing Organization) Services market by product type, application, key players and key regions and countries.

Market Segmentation

Segmentation by Type:

Cell and Gene Therapies

Antibodies

Vaccines

Others

Segmentation by CMO Provider Type:

In-house CMO

Independent CMO

Segmentation by Manufacturing Stage:

Drug Substance (DS) Manufacturing

Drug Product (DP) Manufacturing

Segmentation by Application:

Large Pharmaceutical and Biopharmaceutical Companies

Small and Mid-sized Pharmaceutical and Biotechnology Companies

Others

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

Lonza Group AG

Samsung Biologics Co., Ltd.

FUJIFILM Biotechnologies

Boehringer Ingelheim BioXcellence

WuXi Biologics (Cayman) Inc.

Thermo Fisher Scientific – Patheon Pharma Services

Catalent, Inc.

AGC Biologics

National Resilience, Inc.

Vetter Pharma International GmbH

Rentschler Biopharma SE

KBI Biopharma, Inc.

LOTTE BIOLOGICS Co., Ltd.

Pfizer CentreOne

AbbVie Contract Manufacturing

Syngene International Limited

Avid Bioservices, Inc.

Recipharm Advanced Bio

Ajinomoto Bio-Pharma Services

Wacker Biotech GmbH

Bora Biologics

3PBIOVIAN

Fareva

Aenova Group

Siegfried Holding AG

GenScript ProBio

Chime Biologics (Wuhan) Co., Ltd.

MabPlex International

Pharmaron Beijing Co., Ltd.

Thousand Oaks Biologics Inc.

Cytovance Biologics, Inc.

Porton Pharma Solutions Ltd.

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