Biopharmaceutical Contract Manufacturing Market - Global Outlook & Forecast 2022-2027

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Report description:

The biopharmaceutical contract manufacturing market is expected to grow at a CAGR of 14.37% during 2022-2027.

Biopharmaceutical companies rely on contract manufacturing organizations (CMOs) to provide capabilities and skills as needed. The CMO has provided most of the company's production in some cases. The market is mainly growing owing to the uptake of branded biologics and biosimilars, mandatory immunization programs for newborns and children to prevent a wide range of diseases, and ongoing global covid-19 vaccine programs to curb the spread of the pandemic.

Biopharmaceutical manufacturing comprises advanced technology, new scientific advances, and highly complex research and development (R & D) companies. A contract manufacturing organization (CMO), also known as a contract development and manufacturing organization (CDMO), is a company that provides the pharmaceutical industry with contract-based drug development and drug manufacturing services. With time, the CMO provides pharmaceutical and biopharmaceutical manufacturers with one of the essential assets in today's fast-paced world. By outsourcing the manufacturing process, pharmaceutical and biopharmaceutical manufacturers can prioritize internal capabilities and free up the internal resources needed to improve process efficiency.

The CMO gave several reasons for the optimistic outlook. These reasons include increasing small, well-funded virtual biotechnology companies, increasing demand for manufacturing services that support cell and gene therapy, and more robust growth in Asia.

MARKET TRENDS AND DRIVERS

Robust Biopharmaceuticals Pipeline

Cell & Gene therapies are emerging as one of the most dynamic fields in medicine with an increased number of ongoing research and development activities. Many vendors and research organizations are engaged in the R&D of cell & gene therapies. The key vendors increasingly conduct clinical trials to gain regulatory approval in the United States with largely untapped potential.

The pipeline for biosimilars continues to grow with the FDA approval of 30 biosimilars and 21 biosimilars launched in the US by July 2021. The total number of biosimilars in the pipeline database grew by 208% in 2020. The number of marketed biosimilars also increased by 226% in the past seven years. The present number of biosimilars in the preclinical phase in 2020 vs. 2013 has increased similarly by 200%. By 2018, the European Union had approved more than 40 biosimilars, and many went on to be commercialized successfully in Australia, Canada, Japan, and South Korea.

Increase in Manufacturing of cell and gene therapy

In the past several years, Gene therapies have continued their rising trend in the biopharmaceutical industry. Biopharma companies are investing in these therapies, and the FDA has encouraged gene therapy development. As gene therapies cost time and money to develop and manufacture, many biopharmaceutical companies are turning to CMOs. For biopharmaceutical companies with no practical manufacturing experience, adopting an established CMO can reduce these operational risks and reduce the manufacturing time. This can be achieved by leveraging the CMO's expertise and skills in installing facilities and navigating regulatory systems.

Biologics Manufacturing Outsourcing by Pharma and Biotech Companies

Larger and more established companies continue to look for partners to outsource established products to free up internal capacity for new and upcoming developments in the pipeline. This trend is not so surprising. Pharma R&D Outsourcing helps enterprises save on resources, infrastructure, and other overhead.

SMEs are still a significant source of innovation, with an active pipeline of products under development. Many SMEs do not have the manufacturing capacity and often do not plan to develop these core competencies, so they want to move their products to the clinical stage and ultimately to commercial manufacturing operations.

Overall, pharmaceutical and biotechnology companies' decision to outsource manufacturing directly impacts the contract manufacturing market for bio pharmacy. In this analysis, CMO customers are categorized into
a) companies that do not do in-house biomanufacturing (virtual companies)
b) companies with in-house biomanufacturing.

For virtual businesses, outsourcing all production is usually part of the overall corporate strategy. Most virtual businesses lack the resources and products to justify ownership of a manufacturing facility. On the other hand, companies with organic production bases or resources to build internal capabilities are adopting different production strategies depending on the specific situation and strategy.

A Surge in Manufacturing Capacity Expansion Post Covid by CDMOs and CMOs

Over the next three years, the total capacity will increase by 60% as the CMO invests to meet future demand. Most of this new capacity supports the production of mammalian cell cultures. Given these expansion plans, capacity utilization rates remain in the low 70% range throughout the forecast period.

In addition to expanding production capacity, CMOs invest in other services to meet future customers' needs. CMO plans to invest heavily in manufacturing, analytical, new research centers, and productivity and quality improvements in cell and gene therapy.

The expansion includes a new GMP cleanroom for mRNA development and production, a new process development laboratory for microbial protein and cell and gene therapy (C& GT) projects and additional storage capacity. Expanded capabilities will enable CDMOs to meet the growing demands of the fast-growing C> market.

The new facility is one of several announced or ongoing biomanufacturing investments by Fujifilm Diosynth. In December 2021, the company announced plans to invest the US $533 million to include a viral gene therapy facility and a mammalian cell culture facility in Billingham, Teesside, UK. The new facility is scheduled to be ready by the end of 2023. This investment is part of the $ 977 million global investment package that the company first outlined in June 2021.

In January 2022, Samsung Biologics will begin constructing new manufacturing facilities for C& GT and vaccines using messenger RNA (mRNA), plasmid DNA (pDNA), viral vectors in one place, and multimodal products such as gene therapy and vaccines. The facility complements the RNA vaccine manufacturing facility currently being added to the existing facility in Matsushima, South Korea, and is scheduled to be ready earlier this year (2022).

Product Launches & Regulatory Approvals

Vendors strategically focus on developing and marketing single-use bioprocessing products to remain competitive and gain a foothold in the market. Product approvals and launches, coupled with R&D activities, help vendors to expand their footprint, drive market growth, and maintain their position in the US gene therapy market. Vendors are also aggressively bringing innovative, advanced therapies to penetrate and harness the tremendous growth potential of the market.

MARKET SEGMENTATION
-The finished dosage form (FDF) segment reported a major share of around 50.52% in 2021. The FDF segment is estimated to be higher because it is an important stage in the product life cycle and can only be achieved if the manufacturing facilities of the pharmaceutical company or outsourced manufacturing organization are of a high standard. This is the main reason for licensing by companies that do not have a standard manufacturing facility for manufacturing dosage forms.
-The demand for the biologics has tremendously increased. Among the biologics industry, the monoclonal antibodies (mAbs) sector reported a significant share in the market. The mAbs segment is estimated to be higher due to the looming entry of several companies, including big pharma, small biotech, and generic participants, into the global biosimilars development will boost the market exponentially. Antibodies occur naturally in our blood and help fight infections. MAB therapy mimics natural antibodies but is done in the laboratory. Many different mAbs are available for the treatment of cancer. They work in different ways, some in multiple ways.
-The mammalian segment holds a higher market share under the impression system category because the central pillar of the biotechnology and pharmaceutical industry continues to be the development of biopharmaceuticals made from transgenic mammalian cell lines. In addition, mammalian-expressed biopharmaceuticals make up the largest proportion of candidates for the biopharmaceutical pipeline. Thus, pharmaceutical companies and contract service providers are investing in additional cell cultural manufacturing capabilities in surveillance systems with smaller footprints and solutions that allow more efficient, more efficient, and more efficient productivity.
-Among scale of operation, the commercial segment reported a major share in the market. The commercial segment is estimated to be higher due to the growing infectious diseases and the onset of epidemics and pandemics; there is a huge demand for manufacturing billion doses of biotechnology products within months. It is a highly challenging task with limitations in small-scale manufacturing for clinical trials, clinical testing timelines involving multiple phases, and large-scale drug substance and drug product manufacturing.
-Based on company size, large sized companies segment reported a significant share of around 58.66% in 2021. The large company?s segment is estimated to be higher because large biopharmaceutical companies rely on CMOs for large-scale biologics production. The large biopharmaceutical companies focus on drug development over manufacturing; CMOs can provide access to

capacity without investing in facilities.

Segmentation by Product Type
-Finished Dosage Form (FDF)
-Active Pharmaceutical Ingredients (APIs)

Segmentation by Biologics
-Monoclonal Antibodies (mAbs)
-Vaccines
-Others

Segmentation by Expression System
-Mammalian
-Non-Mammalian

Segmentation by Scale Of Operations
-Commercial
-Research (Clinical & Preclinical)

Segmentation by Company Size
-Large & Very Large Companies
-Small & Mid-Sized Companies

GEOGRAPHICAL ANALYSIS

-North America dominates the global biopharmaceutical contract manufacturing market. The global market is categorized into North America, Europe, APAC, Latin America, and the Middle East & Africa.
-The North American biopharmaceutical contract manufacturing market is well established, with prominent biopharmaceutical manufacturing companies based in the region. The rise in drug development has dramatically increased the biopharmaceutical contract manufacturing demand in this region. The US is the major revenue contributor in North America mainly due to increased demand for cell and gene therapy.
-APAC is the fastest-growing region for biopharmaceutical contract manufacturing. Emerging countries such as China and Japan are the major players due to low labor costs and increased outsourcing of biologics manufacturing.
-The increasing elderly population, the prevalence of autoimmune diseases, respiratory disorders, cancer, etc., are increasing demand for biopharmaceuticals, and expanding biopharma and biotech industry are significant factors contributing to the growth of biopharmaceutical contract manufacturing in Europe. More significant investments due to the high focus of government bodies on R&D across European regions are driving the biopharmaceutical outsourcing market.
-Increasing expenditure on regenerative medicine development and clinical trials gives new hope for growth in cell and gene therapy drugs. Also, increasing clinical trials of stem cell therapies and gene therapies drive the growth of manufacturing companies, which will trigger the growth of the biopharmaceutical contract manufacturing market in Latin America.

Segmentation by Geography
-Europe
oGermany
oUK
oFrance
oSwitzerland

o Italy
o Spain
- APAC
o China
o Japan
o South Korea
o Australia
o India
- North America
o US
o Canada
- Latin America
o Brazil
o Mexico
- Middle East & Africa
o Saudi Arabia
o UAE
o South Africa
o Turkey

COMPETITIVE LANDSCAPE

- The global biopharmaceutical contract manufacturing market is highly competitive, with a large pool of global, regional, and local vendors involved in the contract manufacturing of various biopharmaceuticals. Vendors in this market compete based on a wide range of services offered, pricing, quality, and scale-up production of biopharmaceuticals.
- The market is concentrated with key players such as Samsung biologics, Lonza and Boehringer Ingelheim GmbH.
- Other emerging players in the biopharmaceutical contract manufacturing market include AbbVie, Inc., Catalent, Emergent BioSolutions, FUJIFILM Diosynth Biotechnologies, Merck KGaA, Pfizer CentreOne, Serum Institute of India, and WuXi biologics. These companies hold a significant share in the global market and focus on continuous expansion in biopharmaceutical contract manufacturing, further intensifying the competition in the worldwide market.
- Samsung Biologics is one of the active contract manufacturers that invested a considerable amount in enhancing their manufacturing capacity by volume. The company is investing around $2 billion in its super plant in Incheon, South Korea, with 256,000 liters.
- Vendors are actively involved in strategic acquisitions and agreements to develop their proprietary technologies and increase their brand image in the market. Catalent made one such acquisition and expanded its early development capabilities through the acquisition of Pharmatek Laboratories.

Key Vendors
- Boehringer Ingelheim
- Lonza
- Samsung Biologics

Key Companies
- AbbVie
- Catalent
- Emergent BioSolutions
- FUJIFILM

-Merck KGaA
-Pfizer
-Serum Institute of India
-WuXi Biologics

Other Prominent Vendors
-AGC Biologics
-Ajinomoto
-Albany Molecular Research (AMRI)
-Asymchem
-Biocon
-Cobra Biologics
-Charles River Laboratories
-Goodwin Biotechnology
-KBI Biopharma
-Sanofi
-Bavarian Nordic
-Wacker Biotech B.V
-Jubilant HollisterStier
-National Resilience
-Novasep
-Kemwell Biopharma
-Midas Pharma
-Alcami
-Cambrex
-Pharmaceutics International
-Singota Solutions
-Thermo Fisher Scientific
-Binexc
-Canton Biologics
-ChemPartner
-Cytovance Biologics

KEY QUESTIONS ANSWERED

1.WHAT IS THE GLOBAL BIOPHARMACEUTICAL CONTRACT MANUFACTURING MARKET SIZE?
2.WHAT IS THE EXPECTED GROWTH RATE OF THE GLOBAL BIOPHARMACEUTICAL CONTRACT MANUFACTURING MARKET?
3.WHO ARE THE MARKET LEADERS IN THE GLOBAL BIOPHARMACEUTICAL CONTRACT MANUFACTURING MARKET?
4.WHICH TRENDS ARE DRIVING THE GROWTH OF THE GLOBAL BIOPHARMACEUTICAL CONTRACT MANUFACTURING MARKET?
5.WHICH REGION HOLDS THE HIGHEST GLOBAL BIOPHARMACEUTICAL CONTRACT MANUFACTURING MARKET SHARE?

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30 APPENDIX
30.1 ABBREVIATIONS

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