

Biologics Outsourcing Global Market - Forecast to 2030

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Abstracts

Biologics are the therapeutic entities composed of sugars, proteins, or nucleic acids and made from natural sources such as human, animal or microorganisms. Biologics also include live attenuated microorganisms (vaccines), allergenic extracts (allergy shots), human cells and tissues (for transplantation), cell and gene therapeutics. Similar to the conventional therapeutics, these drugs help in treating several diseases but are highly specific and more efficient in their disease healing mechanisms. The biologic entities like monoclonal antibodies and recombinant proteins target specific areas during their molecular mechanism of disease curing.

Even though biologics are highly expensive when compared to the conventional small molecule drugs, these target specific therapeutics have proven to be very beneficial for patients and also ensure higher profit margins to the drug manufacturers. The escalating adoption of biologics and elevating demand for the highly efficient biotherapeutics from the value-centric patient population across the globe, increasing investments on research and developmental activities of biologics and advanced, next-generation biotherapeutics, a favorable and streamlined regulatory environment that is expediting the novel product approval process and the expansion of biosimilar market have all led to the rapid growth of the biopharmaceutical market. Due to the increasing demand for biologics drugs and increased regulatory approvals for these drugs, there is huge demand for biologics manufacture and testing at various levels of clinical studies as well as commercial supply. This fast pacing biologic industry coupled with insufficient or lack of in house biologic development and manufacturing capabilities and capacities of biopharmaceutical companies has spurred these companies to outsource the different parts of biologic development and manufacturing process to highly efficient service providing organizations. The Large Biopharma companies are coming up with strategies to cut down on their operational costs and concentrate more on their core

competencies by outsourcing this piece of work to contract research organizations (CROs), contract development and manufacturing organizations (CDMOs) and contract manufacturing organizations (CMOs). These organizations bridge the gap between demand and supply and ensure the drug discovery and manufacturing process gets much faster and convenient; thus bringing the life-saving drugs to the market and the needy patients at the earliest.

The biologics outsourcing global market is expected to grow at a double digit CAGR from 2022 to 2030 to reach \$106.7 billion by 2030. Major drivers for the biologics outsourcing market include increasing trend of outsourcing among the biopharma companies for gaining an economical access to advanced biologics development and manufacturing capacities and capabilities, advanced bioprocessing capabilities of bioservice providers, increasing approvals and adoption of biologics, increasing R&D spend of biopharma companies and escalating approvals and uptake of biosimilars. Factors like emergence of next generation biotherapeutics, development of personalized and orphan indication therapies and the persistently escalating prevalence of chronic, communicable and autoimmune diseases are expected to boost the market growth. However, increasing focus on in-house biologics manufacturing, huge capital investments for capacity and capability development and compliance with stringent regulatory guidelines are restraining the market.

The biologics outsourcing global market has been segmented based on the developmental phase, product, end users and geography. Among the discovery, pre-clinical, clinical and commercial phases of biologics development, Commercial Phase outsourcing commanded the highest revenue in 2022 and is expected to grow at a double digit CAGR from 2022 to 2030. Clinical outsourcing segment is expected to grow at an early teen CAGR from 2022 to 2030. The biological outsourcing market by product type is segmented into Antibody, Proteins, Vaccines, Gene therapy, cell therapy and others. Among these, the antibody outsourcing segment accounted for the highest revenue in 2022 and is expected to grow at a high single digit CAGR from 2022 to 2030. Gene therapeutics segment is expected to grow at a high double digit CAGR from 2022 to 2030. Based on end-users, biologics outsourcing global market is segmented into Therapeutics, Diagnostics and Research. Among these, Therapeutics accounted for the highest revenue in 2022 and is expected to grow at a double digit CAGR from 2022 to 2030. Based on geography, biologics outsourcing global market is segmented into North America, Europe, Asia-Pacific and RoW. North America dominated the biologics outsourcing market with the highest revenue in 2022 and is expected to grow at a high single digit CAGR from 2022 to 2030. Whereas, Asia Pacific region is expected to grow at an early teen CAGR from 2022 to 2030.

The report specifically emphasizes on the rapidly evolving and high growth potential biologics contract manufacturing services market and cell line development services market. The biologics contract manufacturing global market is expected to grow at double digit CAGR from 2022 to 2030. The contract biomanufacturing global market is driven by the increasing trend of outsourcing among the biopharmaceutical companies, availability of advanced bioprocessing capabilities among the contract bioservice providers, expansion of manufacturing facilities, and the escalating approval and adoption of biologics and the cost effective biosimilars among the value centric global patient pool leading to huge volume demand for biologics. Emergence of advanced biotherapeutics, increasing R&D investments by the biopharma companies, development of precision and orphan indication therapies and the persistently increasing prevalence of chronic, communicable and autoimmune diseases are also boosting contract biomanufacturing market growth.

The biologics contract biomanufacturing services global market is classified based on product, developmental phase, process, end users and geography. Based on the product, the biologics CMO global market divided into Drug substance manufacturing and Drug product manufacturing. Among these, drug substance manufacturing accounted for the highest revenue in 2022 and is expected to grow at a double digit CAGR from 2022 to 2030. The Drug Product manufacturing is expected to grow at an early teen CAGR from 2022 to 2030. Based on the developmental phase, the contract Biomanufacturing global market has been segmented as clinical phase contract biomanufacturing and commercial phase contract biomanufacturing. Among these phases, the commercial phase contract biomanufacturing accounted for the highest revenue in 2022 and is expected to grow at a double digit CAGR from 2022 to 2030. Clinical segment is expected to grow at an early teen CAGR from 2022 to 2030. Based on the process of contract biomanufacturing, the global market has been grouped into mammalian contract biomanufacturing, microbial contract biomanufacturing and other contract biomanufacturing processes (plant or insect cell based). Among these, mammalian cell culture CMO market is accounted for the highest revenue in 2022 and is expected to grow at an early teen CAGR from 2022 to 2030. The contract biomanufacturing services global market, based on end-users has been segmented into contract biomanufacturing for diagnostics, research reagents and therapeutics. Among these, contract biomanufacturing of therapeutics accounted for the highest revenue in 2022 and is expected to grow at an early teen CAGR from 2022 to 2030. Research segment is expected to grow at an early teen CAGR from 2022 to 2030. The vectors are basic important components in the development of biological modalities such as gene therapy, cell therapy, vaccines and also in the development of recombinant cell lines

CHO and others for the production of biologics such as monoclonal antibodies, recombinant proteins and others. The Viral Vector & Plasmid DNA Contract Manufacturing global market is estimated to be \$XX million in 2022 and is expected to grow at early teen CAGR from 2022 to 2030. Based on vector type, Viral Vector & Plasmid DNA Contract Manufacturing global market is divided into viral vector and plasmid DNA manufacturing. Among these, Plasmid DNA Contract Manufacturing segment is accounted for the highest revenue in 2022 and is expected to grow at a mid single digit CAGR from 2022 to 2030. Viral vector Contract Manufacturing is expected to grow at a high teen CAGR from 2022 to 2030. Based on modalities, Viral Vector and Plasmid DNA contract manufacturing global market is segmented into Vaccines, Cell & Gene Therapies and Others. Among these, Vaccines segment is accounted for the highest revenue in 2022 and is expected to grow at a high single digit CAGR from 2022 to 2030. Cell & Gene Therapies is expected to grow at a high double digit CAGR from 2022 to 2030. Based on the facility type, it can be categorized into Stainless steel and Single-use. Stainless steel CMO global manufacturing capacity is estimated to be XX million L in 2022 and is expected to grow at a high single digit CAGR from 2022 to 2030. Single-Use CMO global manufacturing capacity is expected to grow at a high double digit CAGR from 2022 to 2030. The contract biomanufacturing services global market based on geography is segmented into North America, Europe, Asia-Pacific and the Rest of the world (ROW). North America contributed highest revenue in 2022 and is growing at a high single digit CAGR from 2022 to 2030. Asia Pacific region is expected to grow at a early teen CAGR from 2022 to 2030.

The cell line development service market is expected to grow at a double digit CAGR from 2022 to 2030 to reach \$2,093.2 million by 2030. Increasing demand for monoclonal antibodies, recombinant proteins and vaccines, growing incidence rate of oncology, autoimmune disorders, infectious diseases & genetic disorders and growth in research activities related to the diseases and also recombinant cell lines for the production recombinant biopharmaceutical proteins are driving the market. Technological advancements in cell line engineering (gene editing tools) & cell line development technologies, screening technologies and process development are giving immense growth opportunities for the market. However, complexities in the development of stable cell lines and high risk of contamination due to complex purification methods are restraining the market. Furthermore, stringent and complex regulations and the high cost and technical requirement to adhere to accreditations such as GMP are posing threat to the industry.

Cell line development service global market is classified based on the expression system, cell line type, application and geography. Based on expression system, cell line

development service global market is segmented into microbial, mammalian and others. Among these, mammalian expression system is accounted for the highest revenue of in 2022 and is expected to grow at a double digit CAGR from 2022 to 2030. Based on the cell line type, global cell line development service market is segmented into CHO, Mouse Myeloma (NS0; Sp2/0), Human Embryonic Kidney (HEK), Baby Hamster Kidney (BHK), Hybridoma, Human Embryonic Retina (PER.C6) and others. Among these, CHO cell line accounted for the highest revenue in 2022 and is expected to grow at an early teen CAGR from 2022 to 2030. Based on application, cell line development service global market is segmented into research, bio production and diagnostics. Among these, bioproduction segment accounted for the highest revenue in 2022 and is expected to grow at a double digit CAGR from 2022 to 2030. Based on the geography, cell line development service global market is segmented into North America, Europe, Asia-Pacific and Rest of the world. North America commanded the highest revenue in 2022. The market is expected to grow at a high single digit CAGR from 2022 to 2030. Asia Pacific is expected to grow at an early teen CAGR from 2022 to 2030.

The top players in biologics outsourcing global market are Lonza (Switzerland), Catalent (U.S.), SamSung Biologics (South Korea), WuXi Biologics (China), Thermo Fisher (Patheon N.V.+Brammer Bio) (U.S.), FUJIFILM Holdings Corporation (FujiFilm Diosynth) (Japan), Merck KGaA (Germany), Boehringer Ingelheim (Germany), Laboratory Corporation of America Holdings (U.S.), Charles River Laboratories (U.S.), JSR corporation (U.S.), WuXi Apptech (China), Genscript Biotech Corporation (China), Emergent Biosciences (U.S.), Asahi Glass Company (AGC Biologics) (Japan) and others.

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