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Biologics - Market Insights, Competitive Landscape and Market Forecast–2026

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Abstracts

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Biologics Market By Product Type (Cell-Based Biologics, Gene-Based Biologics, Monoclonal Antibodies, Vaccines, Recombinant Protiens, And Others), By Application (Oncology, Immunology, Infectious Diseases, Neurological Diseases, And Others), By Manufacturing Type (In-House And Outsourced), and by geography is expected to grow at a steady CAGR forecast till 2026 owing to rising prevalence of autoimmune disorders such as rheumatoid arthiritis and genetic disorders

Global biologics market was valued at USD 303.95 billion in 2020, growing at a CAGR of 9.59% during the forecast period from 2021 to 2026, in order to reach USD 525.84 billion by 2026. The biologics market is witnessing a positive market growth owing to the factors such as rising prevalence of autoimmune disorders such as rheumatoid arthritis, rising prevalence of cancers, increasing prevalence of infectious diseases, increasing cases of genetic disorders, and increasing product development activities with latest innovation with respect to biologics among others.

Biologics Market Dynamics:

One of the main drivers of the biologics market is the rising prevalence autoimmune disorders such as rheumatoid arthritis. According to the World Health Organization factsheet (2021), approximately 14 million people have rheumatoid arthritis (RA). RA is a systemic autoimmune disorder that causes pain, swelling, and deformation of the joints and may be accompanied by systemic symptoms. Biologics are being preferred as a choice of treatment in autoimmune diseases such as RA due to their target-specific action unlike conventional small-molecule drugs. The key biologics used for treating

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rheumatoid arthritis are Humira (Adalimumab) and Remicade (Infliximab), Abatacept (Orencia), Anakinra (Kineret), and Rituximab (Rituxan). The demand for biologics is set to witness an increase owing to the increasing incidence of RA in coming years owing to increasing aging population and obesity which are considered as major risk factors of RA, thereby positively impacting the global biologics market growth during the forecast period (2021-2026).

Another key factor responsible for the growth of the biologics market is the rising prevalence of genetic disorders. As genetic disorders occur due to anomalies of genetic origin, there has been a growing demand for gene therapies. Gene therapy holds promise for treating a wide range of diseases, such as cancer, cystic fibrosis, heart disease, diabetes, hemophilia and AIDS. For instance, the US Food and Drug Administration approved Zolgensma (onasemnogene abeparvovec-xioi), the first gene therapy for the treatment of children less than two years of age with spinal muscular atrophy (SMA), the most severe form of spinal muscular atrophy and a leading genetic cause of infant mortality. ZOLGENSMA is an adeno-associated virus vector-based gene therapy. Gene therapy based biologics has a wide range of applications, from gene replacement and knockdown to vaccination in genetic diseases such as cancer, hemophilia, hypercholesterolemia, and neurodegenerative diseases, with different gene administration requirements.

Furthermore, gene therapy offer a more sustainable treatment approach, thereby becoming one of the popular choices in the management of genetic diseases. This has resulted in a large number of potential gene therapies being in clinical development. As per the data cited by the American Gene & Cell Therapy, till May 2021, there were 1,745 gene therapies in development from preclinical through preregistration phases of drug development. This indicates the plethora of potential therapies that may reach the market in coming years, further boosting the growth of biologics market during the forecast period.

Along with the factors mentioned above, the COVID-19 pandemic presented another major opportunity for growth for the manufacturers operating in the biopharmaceutical domain. The effect of the pandemic accelerated the drug development activities for the SARS-Cov-2 virus across the globe. The dire need for developing a vaccine in order to contain the pandemic led to the approval and emergency use authorization of numerous vaccines for prophylactic use across the globe. For instance, COVISHIELD, manufactured by the Serum Institute of India is a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. It is one of the eight COVID-19 vaccines approved by the World Health Organization.

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Furthermore, there are more than 80 different candidates in development as a potential therapy for COVID-19 infection.

However, challenging manufacturing process and high cost of biologics, and availability of biosimilars may prove to be major deterrent in biologics market growth.

The biologics market was one of the few domains that exhibited positive growth during the COVID-19 pandemic. Even though lockdown restrictions severely affected production capacities in various industries across the globe, the urgency of developing vaccines for COVID-19 infection presented huge growth opportunities for the biopharmaceutical manufacturers. With the development and the emergency authorization of the first COVID-19 vaccine (the Pfizer-BioNTech COVID-19 Vaccine) in late December 2020, the development and approvals of such vaccines picked up pace across the globe. This led to numerous collaborations and partnerships among pharmaceutical companies and contract manufacturing organizations in order to meet the global supply of these vaccines in the short span of time, which presented a positive outlook for the biologics market despite the disruption of supply chains among other factors.

Biologics Market Segment Analysis:

Biologics Market by Product Type (Cell-Based Biologics, Gene-Based Biologics, Monoclonal Antibodies, Vaccines, Recombinant Proteins, and Others), by Application (Oncology, Immunology, Infectious Diseases, Neurological Diseases, and Others), by Manufacturing Type (In-House and Outsourced), and by Geography (North America, Europe, Asia-Pacific, and Rest of the World)

In the product type segment of the biologics market, the monoclonal antibodies category is estimated to register significant share in market revenue during the forecast period (2021-2026). This can be attributed to the specific features associated with them. Monoclonal antibodies are considered to be highly specific thereby resulting in fewer side effects in patients. One exceptional advance that accelerated the approval of therapeutic mAbs was the generation of humanized antibodies by the complementary-determining region (CDR) grafting technique. The recent development of bispecific antibodies offers attractive new opportunities for the design of novel protein therapeutics, mAbs are increasingly used for a broad range of targets; oncology, immunology, and hematology remain the most prevalent medical applications.

In recent years, many monoclonal antibodies have also been approved for other

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indications such as migraine, rheumatoid arthritis, HIV infection among others. Keeping the development of COVID-19 pandemic in focus, there have been increased efforts in the development of therapies for treating COVID-19 infection. For instance, in November 2021, Cellitron Group received the marketing authorization for their monoclonal antibody- Regkirona in patients over the age of 12 years and do not require supplemental oxygen and are at increased risk of their disease becoming severe. Therefore, considering the advantages associated with monoclonal antibodies, this product category is expected to witness a considerable growth eventually contributing the overall growth of the global biologics market in the forecast period.

North America is expected to dominate the Overall Biologics Market:

Among all the regions, North America is expected to account for the largest share in the global biologic drugs market. This can be ascribed to the high focus on therapy development for rare diseases with orphan designations, rising prevalence of cancers, and a supportive regulatory environment among other factors in the region. Furthermore, high disposable income, sophisticated healthcare infrastructure, and increased awareness regarding new treatments coupled with extensive insurance coverage for these treatments are also expected to aid in the biologics market growth in this region.

One of the key supporting factors for the growth of the North America biologics market is the increasing focus on developing therapies for rare diseases in North American countries, particularly in the United States. As per the data provided by the US Food and Drug Administration (FDA) (2021), there are more than 7,000 rare diseases affect more than 30 million people in the United States. Depending on the huge number of indications and such small patient population for each indication on an average, the pharmaceutical companies find it difficult to develop therapies for such indications which prompted the US FDA to implement the Orphan Drug Act and Orphan Product Grants Program.

The Orphan Drug Act is a law passed in 1983 that incentivizes the development of drugs to treat rare diseases. This has resulted in a considerable number of companies in the country developing therapeutics aimed at treating rare diseases. For instance, in 2019, the US FDA granted an approval for a gene therapy to treat pediatric patients younger than two years of age with spinal muscular atrophy. As per the US FDA, in 2019, the FDA approved 76 orphan indications, which included 22 novel drugs and biologics with orphan designation. Therefore, the increasing focus of the US FDA and the US government in catering to the medical needs of people suffering from rare

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diseases in the country is also expected to drive the US biologics market in coming years.

Furthermore, the increasing prevalence of various cancers has also resulted in growing demand for biologics in the country. As per the data provided by the American Cancer Society, in 2021, an estimated 1.9 million new cancer cases diagnosed and 608,570 cancer deaths in were expected to be reported in the United States. The high cancer prevalence of various etiologies has led to the development of different immunotherapies owing to their advantages in cancer treatment. Immunotherapy has been an effective treatment for patients with certain types of cancer that have been resistant to chemotherapy and radiation treatment. Moreover, it has been established that immunotherapy can provide long-term protection against cancer as it stimulates the immune system in recognizing and differentiating cancer cells.

This has led to the development and launch of numerous novel immunotherapies in the country. For instance, in April 2021, the US FDA granted accelerated approval to JEMPERLI (dostarlimab-gxly) manufactured by GlaxoSmithKline for the treatment of recurrent or advanced mismatch repair-deficient endometrial cancer.

Therefore, the North America biologics market is expected to witness a significant growth in revenue during the forecast period.

Biologics Market Key Players:

Some of the key market players operating in the biologics market includes GlaxoSmithKline, Eli Lilly & Company, F. Hoffmann-La Roche Ltd, AbbVie Inc., Amgen Inc, Sanofi, Merck & Co., Inc, Novo Nordisk, Novartis AG, Pfizer Inc, AstraZeneca, Bristol Myers Squibb., Regeneron Pharmaceuticals Inc., Gilead Sciences, Inc., Boehringer Ingelheim International GmbH., Genentech, Inc, Biogen., bluebird bio, Inc, Janssen Global Services, LLC,., Cellitron Group and others.

Recent Developmental Activities in Biologics Market:

In October 15, 2021, the US FDA approved atezolizumab (Tecentriq) by Genentech, Inc. for adjuvant treatment following resection and platinum-based chemotherapy in patients with stage II to IIIA non-small cell lung cancer (NSCLC).

In August 2021, Bristol Myers Squibbs received the conditional marketing

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authorization for Abecma (idecabtagene vicleucel) by the European Commission for the treatment of adult patients with relapsed and refractory multiple myeloma. It is a irst-in-class B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy.

In June 2021, the US FDA approved the product approval to Biogen Inc's Aduhelm (aducanumab) for the treatment of Alzheimer's disease in an accelerated approval pathway.

Key Takeaways from the Biologics Market Report Study

? Market size analysis for current biologics market size (2020), and market forecast for 5 years (2021-2026)

? The effect of the COVID-19 pandemic on this market is significant. To capture and analyze suitable indicators, our experts are closely watching the biologics market.

? Top key product/services/technology developments, merger, acquisition, partnership, joint venture happened for last 3 years

? Key companies dominating the global biologics market.

? Various opportunities available for the other competitor in the biologics market space.

? What are the top performing segments in 2020? How these segments will perform in 2026.

? Which is the top-performing regions and countries in the current biologics market scenario?

? Which are the regions and countries where companies should have concentrated on opportunities for biologics market growth in the coming future?

Target Audience who can be benefited from this Biologics Market Report Study

? Biologics products providers

? Research organizations and consulting companies

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? Biologics-related organizations, associations, forums, and other alliances

? Government and corporate offices

? Start-up companies, venture capitalists, and private equity firms

? Distributors and Traders dealing in biologics

? Various End-users who want to know more about the biologics market and latest technological developments in the biologics market.

Frequently Asked Questions for Biologics Market:

1. What are Biologics?

Biologics are products that are produced from living organisms or contain components of living organisms. There are several types of biologic drugs which include blood, blood components, vaccines, cells, genes, allergens, tissues, and recombinant proteins.

2. What is the market for Global Biologics?

Global biologics market was valued at USD 303.95 billion in 2020, growing at a CAGR of 9.59% during the forecast period from 2021 to 2026 to reach USD 525.84 billion by 2026.

3. What are the drivers for Global Biologics Market?

The biologics market is witnessing a positive market growth owing to the factors such as rising prevalence of autoimmune disorders such as rheumatoid arthritis, rising prevalence of cancers, increasing prevalence of infectious diseases, increasing cases of genetic disorders, and increasing product development activities with latest innovation with respect to biologics among others.

4. Who are the key players operating in Global Biologics Market?

Some of the key market players operating in the biologics market includes GlaxoSmithKline, Eli Lilly & Company, F. Hoffmann-La Roche Ltd, AbbVie Inc, Amgen Inc, Sanofi, Merck & Co., Inc, Novo Nordisk, Novartis AG, Pfizer Inc, AstraZeneca,

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Bristol Myers Squibb., Regeneron Pharmaceuticals Inc., Gilead Sciences, Inc., Boehringer Ingelheim International GmbH., Genentech, Inc, Biogen., bluebird bio, Inc, Janssen Global Services, LLC,., Cellitron Group and others.

5. Which region has the highest share in Biologics Market?

North America is expected to hold the highest share in the revenue in the Biologics market during the forecast period. This can be ascribed to the high focus on therapy development for rare diseases with orphan designations, rising prevalence of cancers, and a supportive regulatory environment among other factors in the region. Furthermore, high disposable income, sophisticated healthcare infrastructure, and increased awareness regarding new treatments coupled with extensive insurance coverage for these treatments are also expected to aid in the biologics market growth in this region.

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