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Biologics Market Report by Source (Microbial, Mammalian, and Others), Product (Monoclonal Antibodies, Vaccines, Recombinant Proteins, Antisense, RNAi and Molecular Therapy, and Others), Disease (Oncology, Immunological Disorders, Cardiovascular Disorders, Hematological Disorders, and Others), Manufacturing (Outsourced, In-House), and Region 2024-2032

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Abstracts

The global biologics market size reached US$ 349.6 Billion in 2023. Looking forward, IMARC Group expects the market to reach US$ 699.5 Billion by 2032, exhibiting a growth rate (CAGR) of 7.8% during 2024-2032. The rising prevalence of chronic diseases that necessitate more effective treatment options, continual technological advancements facilitating the development of increasingly targeted therapies, and the emergence of advanced drug delivery systems represent some of the factors that are propelling the market.

Biologics are complex molecules derived from living cells, which are used to diagnose, treat, and prevent diseases. These molecules are fundamentally different from small-molecule drugs, not only in terms of size but also in the intricacy of their structure. Characterized by a high degree of specificity, these medicinal solutions are tailored to interact with specific components within the human body, such as cells and proteins. This unique attribute enables them to target disease pathways more precisely, offering a higher potential for efficacy while minimizing side effects. The working mechanism often involves the modulation of biological pathways, either by blocking or enhancing the activity of naturally occurring molecules, to restore physiological function or

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eliminate pathological agents.

The global market for these complex molecules is primarily driven by the rising prevalence of chronic diseases that necessitate more effective treatment options. In line with this, continual technological advancements facilitating the development of increasingly targeted therapies, which in turn is providing an impetus to the market. Moreover, expanding healthcare budgets are resulting in a sustained demand for advanced therapeutic options, acting as a significant growth-inducing factor. In addition to this, the shift toward personalized medicine is leading to higher adoption rates of tailored therapies, thus expanding the market further. Some of the other factors contributing to the market's growth include an informed and educated patient base, the optimizing role of artificial intelligence in drug discovery, strategic collaborations between biopharmaceutical entities, and the emergence of biosimilars as off-patent versions become more accessible to a larger population.

Biologics Market Trends/Drivers:
Continual innovations in targeted therapies

A significant driver in the market for complex molecules is the continuous innovation in targeted therapies. These are therapies designed to specifically act on certain cells or molecules responsible for disease, thus increasing treatment effectiveness while minimizing side effects. Given the critical nature of diseases like cancer and autoimmune disorders, targeted therapies offer a novel and effective avenue for treatment. Extensive scientific research has enabled the understanding of disease mechanisms at the molecular level, paving the way for specialized treatments that are more effective and less toxic than traditional approaches. With increasing investments in research and development, coupled with a heightened focus on personalized medicine, these targeted therapies are poised to become mainstream. Their introduction and subsequent success can substantially elevate the demand for complex molecules, thus serving as a pivotal driver for the market.

The emergence of advanced drug delivery systems

Drug delivery systems play an increasingly crucial role in healthcare, often determining the effectiveness and patient compliance for complex molecular treatments. Innovation in this sector comes in various forms, from controlled-release mechanisms to nanotechnology-based delivery systems. Such advancements make it easier for patients to adhere to their treatment regimens, thereby improving clinical outcomes. For instance, newer delivery systems might replace daily injections with weekly or even

monthly doses, substantially enhancing patient convenience and willingness to continue treatment. Significant investments are flowing into the research and development of these technologies, with the aim to maximize the therapeutic effectiveness of complex molecules. These advances in drug delivery systems are contributing immensely to the market's resilience and growth potential, fulfilling a demand for more efficient and patient-friendly therapeutic options.

Regulatory changes and harmonization

Navigating through the labyrinthine regulatory environments has long been a daunting challenge for companies in the healthcare sector. However, the current trend toward regulatory harmonization is simplifying this complex landscape. With unified or mutually recognized approval processes across different countries, market entry barriers are substantially reduced. This means that new and existing products can reach a wider patient base much faster than before. The implications are manifold: not only is there an accelerated pace at which these innovative therapies are made available to patients, but there is also a significant expansion in the geographic reach of these products. This favorable alignment of regulatory practices, by expediting approvals and broadening market access, is driving substantial and sustained growth in the global market for complex biologics molecules.

Biologics Industry Segmentation:
IMARC Group provides an analysis of the key trends in each segment of the global biologics market report, along with forecasts at the global, regional and country levels for 2024-2032. Our report has categorized the market based on source, product, disease, and manufacturing.

Breakup by Source:
Microbial
Mammalian
Others

Microbial accounts for the majority of the market share

The report has provided a detailed breakup and analysis of the market based on the source. This includes microbial, mammalian, and others. According to the report, microbial represented the largest segment.

The microbial segment in the global market is mainly driven by its cost-effectiveness

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and shorter production times compared to mammalian cell cultures. The ability of microbial systems to produce large quantities of proteins makes them an attractive option for the mass production of vaccines and insulin. Moreover, advancements in microbial fermentation technologies are making it easier to produce complex proteins. Furthermore, a wide range of approved microbial-based products and a robust pipeline of microbial-based therapies are contributing to the growth of this segment.

On the other hand, the mammalian cell culture segment is particularly suited for the production of complex biologics that require post-translational modifications. Though costlier and more time-consuming than microbial systems, mammalian cell culture remains critical for certain high-value biologics, like monoclonal antibodies. Advances in cell line development and culture methods are contributing to increased yields and efficiency. Given the specific advantages, the mammalian segment continues to maintain a substantial share in the market.

Breakup by Product:

Monoclonal Antibodies
Vaccines
Recombinant Proteins
Antisense, RNAi and Molecular Therapy
Others

Monoclonal antibodies represents the largest market segment

The report has provided a detailed breakup and analysis of the market based on the product. This includes monoclonal antibodies, vaccines, recombinant proteins, antisense, RNAi and molecular therapy, and others. According to the report, monoclonal antibodies represented the largest segment.

The monoclonal antibodies (mAbs) segment is increasingly prominent due to their specificity in targeting a wide array of diseases including cancers, autoimmune disorders, and infections. Technological advancements in antibody engineering and hybridoma technologies have allowed for the development of highly specific and potent mAbs. Additionally, the growing number of FDA approvals for monoclonal antibodies further fuels this segment. The capacity for personalized treatment options using monoclonal antibodies also adds to its robust market potential.

On the other hand, the segments comprising vaccines, recombinant proteins, antisense

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RNAi, and molecular therapy, is primarily fueled by advances in genetic engineering and biotechnology. These approaches offer new avenues for treating a variety of diseases that are not adequately addressed by existing therapies. Investments in R&D are contributing to the growth of this segment, along with a growing understanding of the mechanisms behind these therapies. A robust pipeline of products in clinical trials indicates promising future prospects for these segments.

Breakup by Disease:

Oncology
Immunological Disorders
Cardiovascular Disorders
Hematological Disorders
Others

Oncology accounts for the majority of the market share

The report has provided a detailed breakup and analysis of the market based on the disease. This includes oncology, immunological disorders, cardiovascular disorders, hematological disorders, and others. According to the report, oncology represented the largest segment.

The oncology segment in the global market is driven by the high prevalence of cancer worldwide and an aging population more susceptible to this disease. Advancements in genomics have facilitated the development of targeted therapies for various types of cancer. The growing awareness about personalized medicine and targeted therapy in cancer treatment is also propelling this segment forward. Moreover, a strong pipeline of oncology biologics in clinical trials indicates future market growth.

On the other hand, the minor segments consisting of immunological, cardiovascular, and hematological disorders is driven by increasing incidence rates and a lack of effective treatments in some cases. Emerging biologics offer novel methods for treating these conditions, including monoclonal antibodies and recombinant proteins. The growing awareness of these innovative treatments among healthcare professionals and patients is also contributing to these segments. A strong pipeline of therapies targeting these disorders is indicative of potential growth.

Breakup by Manufacturing:

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Outsourced
In-House

In-house represents the largest market segment

The report has provided a detailed breakup and analysis of the market based on the manufacturing. This includes outsourced and in-house. According to the report, in-house represented the largest segment.

The in-house segment benefits from complete control over the research, development, and manufacturing processes. Organizations are increasingly preferring in-house production to protect intellectual property rights and proprietary technologies. In-house facilities also allow for quicker adaptations to market changes and more effective implementation of quality controls. The capacity for more integrated and streamlined operations contributes to the growth of the in-house segment in the global biologics market.

On the other hand, outsourcing is an increasingly common practice due to the high costs and complexities associated with biologics production. Organizations are utilizing contract manufacturing organizations (CMOs) to lower operational costs and accelerate time-to-market. Outsourcing also allows companies to focus on core competencies like R&D while leaving production to specialized firms. Thus, the outsourced segment is seeing consistent growth in the biologics market.

Breakup by Region:
North America
United States
Canada
Asia-Pacific
China
Japan
India
South Korea
Australia
Indonesia
Others
Europe
Germany
France

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United Kingdom
Italy
Spain
Russia
Others
Latin America
Brazil
Mexico
Others
Middle East and Africa

North America exhibits a clear dominance, accounting for the largest biologics market share

The market research report has also provided a comprehensive analysis of all the major regional markets, which include North America (the United States and Canada); Asia Pacific (China, Japan, India, South Korea, Australia, Indonesia, and others); Europe (Germany, France, the United Kingdom, Italy, Spain, Russia, and others); Latin America (Brazil, Mexico, and others); and the Middle East and Africa. According to the report, North America accounted for the largest market share.

North America dominates the global biologics market, primarily due to the presence of a well-established healthcare infrastructure and significant investments in biopharmaceutical research. The region is home to numerous leading biopharmaceutical companies and research institutions that drive innovation, which is creating a positive outlook for the market.

In addition to this, favorable regulatory support in the form of fast-track approvals for biologics and various financial incentives for extensive research and development (R&D) activities are also contributing to the market growth. Moreover, rising patient awareness and willingness to adopt new therapies are further fueling the demand for biologics in North America.

Furthermore, the U.S. is the largest market within the region, which is majorly buoyed by high healthcare spending, broad insurance coverage, and an increase in chronic and lifestyle-related diseases.

Competitive Landscape:
Key players in the global biologics market are aggressively focusing on innovation and

research & development (R&D) activities. They are continually expanding their product pipelines to include advanced therapies in oncology, immunology, and other therapeutic areas. To meet stringent regulatory requirements, companies are investing significantly in state-of-the-art manufacturing facilities that adhere to good manufacturing practices. Collaborative agreements with academic institutions are being initiated for acquiring novel technologies. Through mergers and acquisitions, these organizations are consolidating their market presence. Strategic partnerships with smaller biotech companies are enabling the leveraging of unique skill sets and technologies. Furthermore, market leaders are engaging in patient access programs to facilitate the affordability of biologics.

The report has provided a comprehensive analysis of the competitive landscape in the market. Detailed profiles of all major companies have also been provided. Some of the key players in the market include:

AbbVie Inc.
Amgen Inc.
AstraZeneca plc
F. Hoffmann-La Roche Ltd
GlaxoSmithKline plc
Johnson & Johnson
Merck KGaA
Novartis AG
Pfizer Inc.
Sanofi

Recent Developments:
In August 2023, AbbVie Inc. announced that the European Commission has approved AQUIPTA (atogepant) for the prophylaxis of migraine in adults who have four or more migraine days per month. The approval makes AQUIPTA the first and only once-daily oral calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) treatment in the European Union for the preventive treatment of both chronic and episodic migraine.
In September 2023, Amgen announced that it has reached a consent order agreement with the Federal Trade Commission, resolving a pending lawsuit and paving the way for its acquisition of Horizon Therapeutics. The companies anticipate finalizing the acquisition in early Q4 2023, focusing on serving patients with rare diseases.
In August 2023, AstraZeneca plc announced that Japan's Ministry of Health, Labour and Welfare has approved the expanded use of Soliris (eculizumab) for treating pediatric patients with generalized myasthenia gravis who are resistant to other

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therapies. The approval follows positive outcomes from a Phase III trial, making Soliris the first targeted therapy for this condition in children and adolescents in Japan.

Key Questions Answered in This Report

1. What was the size of the global biologics market in 2023?
2. What is the expected growth rate of the global biologics market during 2024-2032?
3. What are the key factors driving the global biologics market?
4. What has been the impact of COVID-19 on the global biologics market?
5. What is the breakup of the global biologics market based on the source?
6. What is the breakup of the global biologics market based on the product?
7. What is the breakup of the global biologics market based on the disease?
8. What is the breakup of the global biologics market based on the manufacturing?
9. What are the key regions in the global biologics market?
10. Who are the key players/companies in the global biologics market?

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