

Biologics Market Will Estimated to Reach 1,140.2 Bn by 2035, Driven by Precision Medicine and Chronic Disease Prevalence

The Global Biologics Market Size is Estimated to reach US\$ 1,140.2 Bn and Expanding at a CAGR of 8.8% by 2035 | Transparency Market Research Inc.

WILMINGTON, DE, UNITED STATES, August 13, 2025 /EINPresswire.com/ -- The global [Biologics Market](#), valued at US\$ 448.8 billion in 2024, is projected to grow at a compound annual growth rate (CAGR) of 8.8% from 2025 to 2035, reaching US\$ 1,140.2 billion by 2035. Biologics, complex drugs derived from living organisms, include monoclonal antibodies, vaccines, recombinant proteins, and gene therapies,

addressing diseases like cancer, autoimmune disorders, and rare genetic conditions. The market is driven by rising chronic disease prevalence, advancements in precision medicine, and supportive regulatory frameworks. However, challenges such as high development costs, stringent regulations, and biosimilar competition pose barriers. This comprehensive report

analyzes the market's overview, key drivers, challenges, regional insights, competitive landscape, and future opportunities, providing a detailed outlook through 2035.

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Transparency Market Research



Biologics Market

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Market Overview

The Biologics Market encompasses a wide range of products, including monoclonal antibodies (mAbs),

vaccines, recombinant proteins, cell and gene therapies, and others, used in oncology, immunology, infectious diseases, and rare disorders. Valued at US\$ 448.8 billion in 2024, it is expected to reach US\$ 1,140.2 billion by 2035 at a CAGR of 8.8%. The market is segmented by product type (monoclonal antibodies, vaccines, recombinant proteins, gene therapies, others), application (oncology, immunology, infectious diseases, rare diseases, others), manufacturing type (in-house, outsourced), end-user (hospitals, specialty clinics, research institutes), distribution channel (hospital pharmacies, retail pharmacies, online), and region (North America, Europe, Asia-Pacific, Latin America, Middle East & Africa). Monoclonal antibodies dominate with a 40% share in 2024, driven by drugs like Keytruda and Humira, while oncology leads applications with a 35% share.

Key Drivers of Growth

Several factors are fueling the robust growth of the Biologics Market:

Rising Chronic Disease Prevalence: Globally, chronic diseases like cancer (19.3 million new cases in 2020) and diabetes (537 million cases in 2021) are increasing, driving demand for biologics. Monoclonal antibodies and cell therapies are critical for targeted cancer treatment, with 60% of new oncology drugs in 2024 being biologics.

Advancements in Precision Medicine: Technologies like CRISPR-Cas9 and next-generation sequencing enable personalized biologics, improving efficacy for diseases like rheumatoid arthritis and rare genetic disorders (7,000+ conditions affecting 400 million people).

Regulatory Support: Fast-track designations, such as the FDA's Breakthrough Therapy and EMA's PRIME, have accelerated approvals for biologics like Zolgensma (2019) and Yescarta (2017), with 25% of FDA approvals in 2023 being biologics.

Growing Geriatric Population: The global population aged 65+ is projected to reach 1.5 billion by 2030, increasing demand for biologics targeting age-related conditions like Alzheimer's and cardiovascular diseases.

Investment in R&D: Global biopharma R&D spending reached US\$ 230 billion in 2023, with companies like Roche and Pfizer investing heavily in biologics for oncology and immunology.

Emerging Gene and Cell Therapies: Approvals of therapies like Casgevy (2023) for sickle cell disease and beta-thalassemia highlight the growing role of gene therapies, with the segment expected to grow at a CAGR of 15% through 2035.

Challenges and Barriers

Despite its promising outlook, the Biologics Market faces significant challenges:

High Development Costs: Developing a biologic costs US\$ 1–2 billion and takes 10–12 years, deterring smaller firms and straining budgets.

Stringent Regulatory Requirements: Complex approval processes, like the FDA's BLA and EMA's MAA, increase costs and delay market entry, with only 30% of biologics in Phase III trials gaining approval.

Biosimilar Competition: Biosimilars, priced 20–30% lower than originator biologics, are eroding market share, with 40 biosimilars approved in the U.S. by 2024.

Manufacturing Complexities: Producing biologics requires specialized facilities and stringent quality control, leading to supply chain bottlenecks and high costs (e.g., US\$ 500 million for a single facility).

Limited Access in Developing Regions: High costs, ranging from US\$ 10,000–\$500,000 per treatment, and inadequate healthcare infrastructure in Africa and parts of Asia-Pacific restrict market penetration.

Side Effect Risks: Biologics like monoclonal antibodies can cause immunogenicity or infusion reactions, impacting patient compliance and market adoption.

Regional Insights

The Biologics Market exhibits distinct regional dynamics:

North America: Dominates with a 45% share in 2024, driven by advanced healthcare infrastructure, high R&D investment (US\$ 100 billion in 2023), and key players like Amgen and Gilead Sciences. The U.S. leads with 60% of global biologic approvals.

Europe: Holds a 30% share, with Germany, France, and the UK benefiting from robust regulatory frameworks and growing demand for biosimilars. The region's market is projected to grow at a CAGR of 8.5%.

Asia-Pacific: Fastest-growing region with a projected CAGR of 10.2%, fueled by rising healthcare expenditure, increasing cancer prevalence, and biopharma hubs in China and India. China's biologics market alone is expected to reach US\$ 150 billion by 2035.

Latin America: Moderate growth, with Brazil and Mexico leading due to improving healthcare systems. High costs and regulatory delays limit broader adoption.

Middle East & Africa: Smallest share at 5% in 2024, constrained by limited infrastructure. Growth potential exists in Gulf countries like UAE due to healthcare investments.

Competitive Landscape

The Biologics Market is highly competitive, with key players driving innovation and market share:

Roche: Leads with monoclonal antibodies like Rituxan and Avastin, with US\$ 20 billion in biologics revenue in 2023.

Amgen: Dominates in recombinant proteins and biosimilars, with Enbrel generating US\$ 4 billion annually.

Novartis: Strong in gene therapies (e.g., Zolgensma) and CAR T-cell therapies, with a US\$ 10 billion biologics portfolio.

Pfizer: Expands in vaccines and oncology biologics, with BioNTech-partnered Comirnaty generating US\$ 15 billion in 2023.

Emerging Players: Companies like Biocon (India) and Samsung Biologics (South Korea) are scaling biosimilar production, capturing emerging market share.

Recent developments include Merck's 2024 launch of a new mAb for lung cancer and Sanofi's US\$ 1 billion investment in a biologics manufacturing facility in Asia-Pacific.

Future Opportunities

The Biologics Market offers numerous avenues for growth and innovation:

Next-Generation Therapies: Advances in bispecific antibodies and CAR T-cell therapies for solid tumors could unlock a US\$ 100 billion opportunity by 2035.

Biosimilar Expansion: Developing affordable biosimilars for drugs like Humira, with patents expiring in 2023–2025, can capture cost-sensitive markets.

Emerging Markets: Scaling biologics access in India, China, and Africa, with CKD and cancer prevalence rising, presents untapped potential.

AI and Automation: AI-driven drug discovery and automated manufacturing, like Amgen's AI platform (2023), can reduce costs and development timelines.

Personalized Vaccines: mRNA-based vaccines for cancer and infectious diseases, building on COVID-19 successes, are projected to grow at a 20% CAGR.

Collaborations: Partnerships, like Bristol Myers Squibb's 2024 deal with Century Therapeutics for

iPSC-based therapies, can accelerate innovation.

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