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Biologics & Biosimilars Market Forecasts to 2032 – Global Analysis By Product Type (Biologics, Biosimilars), Therapeutic Area (Oncology, Ophthalmology, Autoimmune Disorders, Cardiovascular, Endocrinology, Infectious Diseases, Hematology, and Wound Healing & Regenerative Care), Manufacturing Source, Distribution Channel, End User, and By Geography

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Abstracts

According to Stratistics MRC, the Global Biologics & Biosimilars Market is accounted for $538.20 billion in 2025 and is expected to reach $1219.86 billion by 2032 growing at a CAGR of 12.4% during the forecast period. Biologics are innovative therapies produced using living cells or organisms, such as monoclonal antibodies, proteins, and vaccines, that target chronic and severe diseases. Biosimilars, created after biologics lose patent protection, are close replicas in terms of safety, efficacy, and quality, ensuring similar therapeutic effects. These cost-effective options expand patient access to critical treatments. Together, biologics and biosimilars enhance healthcare by advancing medical solutions, reducing treatment costs, and improving overall clinical outcomes.

Market Dynamics:

Driver:

Rising prevalence of chronic diseases

The increasing global burden of chronic illnesses such as cancer, diabetes, and

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autoimmune disorders is fuelling demand for biologics and biosimilars. Healthcare systems are prioritizing long-term treatment solutions that offer improved efficacy and reduced side effects. Biologics, with their targeted mechanisms, are becoming central to disease management strategies. As patient population's age and diagnostic capabilities improve, the need for biologic therapies continues to rise. Biosimilars are gaining traction as cost-effective alternatives, especially in markets with strained healthcare budgets. This growing demand is accelerating innovation and investment across the biopharmaceutical landscape.

Restraint:

High development and manufacturing costs

Developing biologics and biosimilars involves complex processes, from cell line engineering to purification and validation. These high costs are compounded by stringent regulatory requirements and extended clinical trial timelines. Manufacturing facilities must meet rigorous quality standards, often requiring specialized infrastructure and skilled personnel. The need for cold chain logistics and contamination control further increases operational expenses. Smaller firms face barriers to entry, limiting competition and slowing market expansion. As a result, pricing remains a challenge, especially in emerging economies.

Opportunity:

Technological advancements in R&D and manufacturing

Advanced analytics and AI-driven modelling are enhancing drug discovery and reducing development timelines. Innovations in cell culture media and expression systems are improving yield and product consistency. Automation and digital twins are being adopted to optimize facility operations and reduce human error. These advancements are lowering costs and enabling scalable production of complex biologics. As technology matures, more players can enter the market with competitive biosimilar offerings.

Threat:

Intense competition and pricing pressure

Patent expirations are opening the door to multiple entrants, intensifying pricing battles.

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Regulatory pathways, while evolving, still pose hurdles that delay market access and increase compliance costs. Payers and healthcare providers are demanding lower prices, squeezing margins across the value chain. Brand loyalty and physician hesitancy toward biosimilars also impact adoption rates. Without differentiation and strategic positioning, companies risk losing market share in an increasingly commoditized landscape.

Covid-19 Impact

The pandemic disrupted clinical trials, supply chains, and manufacturing schedules for biologics and biosimilars. Lockdowns and resource reallocation toward vaccines and emergency treatments delayed non-COVID product launches. However, the crisis also highlighted the importance of biologics in managing infectious diseases and immune responses. Biopharma companies accelerated digital transformation, adopting remote monitoring and decentralized trial models. Governments and regulators introduced flexible frameworks to maintain continuity in drug development. Post-pandemic strategies now emphasize resilience, agility, and global collaboration in biologics manufacturing.

The biologics segment is expected to be the largest during the forecast period

The biologics segment is expected to account for the largest market share during the forecast period, its superior therapeutic outcomes and expanding indications. Monoclonal antibodies, recombinant proteins, and gene therapies are gaining widespread clinical acceptance. Increasing prevalence of complex diseases is driving demand for targeted biologic treatments. Regulatory approvals are accelerating, supported by robust clinical data and patient advocacy. Investment in biologics R&D continues to outpace other segments, reinforcing its market leadership. As biologics become more accessible, their share in global pharmaceutical spending is expected to rise steadily.

The biopharma companies segment is expected to have the highest CAGR during the forecast period

Over the forecast period, the biopharma companies segment is predicted to witness the highest growth rate, driven by aggressive innovation and pipeline expansion. These firms are leveraging advanced platforms for biologic synthesis, formulation, and delivery. Strategic collaborations and licensing agreements are enabling faster market entry and broader geographic reach. Biopharma players are also investing in biosimilar

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portfolios to capture post-patent opportunities. Their agility and focus on niche therapies position them well for sustained growth. As demand for personalized medicine increases, biopharma companies are leading the charge in biologics development.

Region with largest share:

During the forecast period, the Asia Pacific region is expected to hold the largest market share supported by rising healthcare expenditure and expanding patient populations. Countries like China, India, and South Korea are investing heavily in biologics infrastructure and regulatory modernization. Local manufacturers are scaling up production to meet domestic and export demand. Government initiatives are promoting biosimilar adoption to reduce treatment costs. Clinical trial activity is surging, with Asia Pacific emerging as a hub for biologics research. The region’s demographic and economic dynamics make it a key growth engine for the industry.

Region with highest CAGR:

Over the forecast period, the North America region is anticipated to exhibit the highest CAGR, furled by technological leadership and robust biopharma investment. The U.S. and Canada are advancing biologics innovation through academic-industry partnerships and federal funding. Regulatory agencies are streamlining approval pathways for biosimilars, encouraging market competition. Adoption of precision medicine and biologic therapies is accelerating across therapeutic areas. Digital health integration and AI-driven drug development are enhancing efficiency and outcomes.

Key players in the market

Some of the key players profiled in the Biologics & Biosimilars Market include Amgen, Sanofi, Pfizer, Eli Lilly, Novartis, Viatris, Biocon Biologics, AbbVie, Samsung Bioepis, Teva Pharmaceuticals, Celltrion, Fresenius Kabi, Roche, Boehringer Ingelheim, and Merck KGaA.

Key Developments:

In September 2025, Novartis AG has reached an agreement to purchase the New York-based firm, Tourmaline Bio Inc., in a deal valued at a staggering $1.4 billion. This move is aimed at reducing systemic inflammation, which is termed a major driver of cardiovascular disease. Novartis has been on the lookout for deals that would amplify its sales beyond 2025.

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In August 2025, Sanofi announces the completion of its acquisition of Vigil Neuroscience, Inc. This acquisition strengthens Sanofi's early-stage pipeline in neurology with VG-3927, a novel, oral, small-molecule TREM2 agonist, which will be evaluated in a phase 2 clinical study in patients with Alzheimer's disease. In addition, the acquisition of Vigil's preclinical pipeline will further strengthen Sanofi's research in various neurodegenerative diseases.

Product Types Covered:

- Biologics
- Biosimilars

Therapeutic Areas Covered:

- Oncology
- Ophthalmology
- Autoimmune Disorders
- Cardiovascular
- Endocrinology
- Infectious Diseases
- Hematology
- Wound Healing & Regenerative Care

Manufacturing Sources Covered:

- Mammalian Cell Culture
- Yeast Expression Systems

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- Bacterial Cell Culture
- Transgenic Models

Distribution Channels Covered:

- Hospital Pharmacies
- Specialty Clinics
- Retail Pharmacies
- Online Pharmacies

End Users Covered:

- Hospitals
- Diagnostic Labs
- Research Institutes
- Biopharma Companies
- Other End Users

Regions Covered:

- North America
  - US
  - Canada
  - Mexico

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- Europe
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  - UK
  - Italy
  - France
  - Spain
  - Rest of Europe
- Asia Pacific
  - Japan
  - China
  - India
  - Australia
  - New Zealand
  - South Korea
  - Rest of Asia Pacific
- South America
  - Argentina
  - Brazil
  - Chile

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Rest of South America

Middle East & Africa

Saudi Arabia

UAE

Qatar

South Africa

Rest of Middle East & Africa

What our report offers:

- Market share assessments for the regional and country-level segments
- Strategic recommendations for the new entrants
- Covers Market data for the years 2024, 2025, 2026, 2028, and 2032
- Market Trends (Drivers, Constraints, Opportunities, Threats, Challenges, Investment Opportunities, and recommendations)
- Strategic recommendations in key business segments based on the market estimations
- Competitive landscaping mapping the key common trends
- Company profiling with detailed strategies, financials, and recent developments
- Supply chain trends mapping the latest technological advancements

Free Customization Offerings:

All the customers of this report will be entitled to receive one of the following free customization options:

Company Profiling

Comprehensive profiling of additional market players (up to 3)

SWOT Analysis of key players (up to 3)

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Regional Segmentation

Market estimations, Forecasts and CAGR of any prominent country as per the client's interest (Note: Depends on feasibility check)

Competitive Benchmarking

Benchmarking of key players based on product portfolio, geographical presence, and strategic alliances

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(2024-2032) ($MN)
Table 40 Global Biologics & Biosimilars Market Outlook, By Other End Users (2024-2032) ($MN)
Note: Tables for North America, Europe, APAC, South America, and Middle East & Africa Regions are also represented in the same manner as above.

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