

Biologics & Biosimilars Manufacturing Market Forecasts to 2034 - Global Analysis By Product Type (Monoclonal Antibodies, Recombinant Proteins, Vaccines, Gene & Cell Therapies and Biosimilars), Manufacturing Type, Expression System, Process, Application, End User and By Geography

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Abstracts

According to Statistics MRC, the Global Biologics & Biosimilars Manufacturing Market is accounted for \$524.2 billion in 2026 and is expected to reach \$1156.7 billion by 2034 growing at a CAGR of 10.4% during the forecast period. Biologics and biosimilars manufacturing covers the production, purification, formulation, characterization, and quality assurance of biologically derived medicines. These products depend on living cells and intricate biological processes, making specialized facilities, advanced bioprocessing systems, and rigorous quality controls essential. Biosimilars replicate the characteristics of established biologics and require detailed analytical assessment, process optimization, comparability studies, and regulatory approval. Rising adoption of biologic therapies, expanding drug pipelines, patent expirations, and healthcare cost-containment initiatives are driving manufacturers to increase capacity, improve production efficiency, and implement innovative manufacturing approaches.

According to the U.S. FDA, biologic medicines accounted for only 5% of prescriptions in the United States but represented 51% of total drug spending in 2024, demonstrating the substantial economic importance of biologic medicines and the need for efficient biologics manufacturing.

Market Dynamics:

Driver:

Rising demand for biologic therapies

Increasing utilization of biologic drugs is significantly supporting growth in the biologics and biosimilars manufacturing market. These therapies are gaining wider application across oncology, autoimmune diseases, diabetes, rare disorders, and other challenging medical conditions. Continuous expansion of therapeutic indications and development of new biological medicines are prompting manufacturers to strengthen production capabilities. Rising interest in targeted and personalized healthcare is further encouraging investment in modern bioprocessing equipment, dedicated production facilities, automation, and stringent quality-assurance systems, thereby contributing to expanding manufacturing capacity and market development.

Restraint:

High manufacturing complexity and costs

The intricate nature of biologics and biosimilars production represents a significant market restraint. Manufacturing depends on living-cell systems, advanced processing equipment, highly controlled facilities, and rigorous quality requirements, resulting in substantial operational expenses. Companies need considerable investments in bioreactors, purification technologies, analytical systems, specialized employees, and contamination prevention. Achieving reliable consistency between batches further increases manufacturing challenges. High initial investments, extended development timelines, and demanding validation procedures can limit participation by smaller manufacturers and slow capacity expansion, especially across price-sensitive markets.

Opportunity:

Expansion of biosimilar manufacturing capacity

Growing biosimilar production capabilities offer substantial opportunities within the biologics and biosimilars manufacturing market. As more established biologics lose patent or exclusivity protection, manufacturers have greater scope to introduce competing biosimilar therapies. Investments in scalable bioreactor systems, sophisticated cell-culture technologies, purification processes, and manufacturing automation can improve production efficiency. Contract development and manufacturing organizations may gain additional business by supporting biosimilar development and commercial production. Increased manufacturing capacity can strengthen supply chains, expand product availability, and enable companies to access pharmaceutical

markets with growing demand.

Threat:

Supply chain disruptions and raw material shortages

Disruptions across pharmaceutical supply chains represent a major threat to biologics and biosimilars manufacturing. Production requires specialized materials, cell-culture inputs, disposable processing components, filtration equipment, and sophisticated manufacturing technologies. Delays or shortages involving these inputs can increase costs and interfere with planned production. Heavy reliance on a small number of qualified suppliers may heighten exposure to supply interruptions. Geopolitical conflicts, trade barriers, extreme weather events, and transportation problems can further disrupt logistics, potentially reducing manufacturing stability, delaying product deliveries, and creating availability challenges for healthcare markets.

Covid-19 Impact:

The COVID-19 outbreak significantly affected biologics and biosimilars production by creating logistics disruptions, workforce limitations, material shortages, and challenges surrounding conventional facility inspections. Companies experienced difficulties maintaining production continuity while regulatory authorities adopted remote evaluations and other flexible review mechanisms. The crisis also highlighted the importance of strengthening pharmaceutical supply chains and expanding reliable manufacturing capacity. During 2020 and 2021, the FDA's biologics shortages program worked with manufacturers to prevent 34 potential shortages, demonstrating efforts to maintain the availability of biological products throughout the pandemic.

The monoclonal antibodies segment is expected to be the largest during the forecast period

The monoclonal antibodies segment is expected to account for the largest market share during the forecast period due to their broad application in cancer treatment, autoimmune conditions, infectious diseases, and other medical indications. Their ability to precisely target disease-related molecules and their well-established therapeutic performance have encouraged strong utilization. In addition, mature manufacturing platforms allow producers to achieve reliable quality while expanding production efficiently. Increasing development of antibody therapies, wider clinical applications, and rising biosimilar production are supporting continued manufacturing activity. Established production capabilities combined with extensive therapeutic use further strengthen the

segment's position within biologics manufacturing.

The contract research & manufacturing organizations segment is expected to have the highest CAGR during the forecast period

Over the forecast period, the contract research & manufacturing organizations segment is predicted to witness the highest growth rate. Rising outsourcing of biologics research, development, testing, and manufacturing is encouraging pharmaceutical and biotechnology companies to rely on specialized service providers. CROs and CMOs offer technical expertise, scalable facilities, advanced production technologies, and regulatory assistance without requiring companies to establish extensive internal infrastructure. Their capacity to improve operational flexibility, shortens development cycles, and manage complex biologics production is strengthening demand for outsourced manufacturing and development services.

Region with largest share:

During the forecast period, the North America region is expected to hold the largest market share due to its well-developed biotechnology industry, sophisticated production capabilities, and extensive research base. The region hosts major biopharmaceutical manufacturers, contract organizations, and established supply-chain networks that support large-scale production. Supportive regulatory systems and ongoing capacity expansion are strengthening its manufacturing foundation. Increasing utilization of biologic medicines, biosimilar development, cell and gene therapies, and innovative bioprocessing solutions continues to stimulate demand and maintain North America's prominent position in the global market.

Region with highest CAGR:

Over the forecast period, the Asia Pacific region is anticipated to exhibit the highest CAGR, driven by increasing production capacity, greater outsourcing activity, and rising adoption of biological medicines. Major countries such as China, India, South Korea, Japan, and Singapore are developing sophisticated manufacturing ecosystems and attracting international pharmaceutical projects. Investments in modern bioprocessing infrastructure, biosimilars, contract manufacturing, and advanced therapies are strengthening the region's growth prospects. Regulatory improvements and competitive manufacturing costs are additionally motivating global pharmaceutical companies to

expand their operations throughout Asia Pacific.

Key players in the market

Some of the key players in Biologics & Biosimilars Manufacturing Market include AbbVie, Amgen, Biocon, Boehringer Ingelheim, Celltrion, Dr. Reddy's Laboratories, Johnson & Johnson, Lonza, Merck, Novartis, Novo Nordisk, Pfizer, Rsoche, Samsung Biologics, Sanofi, Thermo Fisher Scientific, WuXi Biologics and Zydus Lifesciences.

Key Developments:

In January 2026, AbbVie and RemeGen announced an exclusive licensing agreement for the development, manufacturing and commercialization of RC148, a novel investigational Programmed Cell Death-1 (PD-1)/Vascular Endothelial Growth Factor (VEGF)-targeted bispecific antibody. RC148 is currently being developed by RemeGen as a monotherapy and in combination regimens across multiple advanced solid tumors.

In May 2025, Novartis has signed a strategic agreement with Shanghai Pharma to help sell the Swiss company's mature ophthalmic products in China. Novartis will leverage Shanghai Pharma's omni-channel integrated marketing services and broad market coverage capabilities to accelerate the reach of some Novartis drugs for ocular infections and glaucoma in smaller territories not currently targeted by Novartis.

Product Types Covered:

Monoclonal Antibodies

Recombinant Proteins

Vaccines

Gene & Cell Therapies

Biosimilars

Manufacturing Types Covered:

In-house Manufacturing

Contract Manufacturing Organizations (CMOs)

Expression Systems Covered:

Mammalian Cell Culture

Microbial Cell Culture

Yeast Expression Systems

Other Expression Systems

Processes Covered:

Upstream Processing

Downstream Processing

Fill-Finish Operations

Applications Covered:

Oncology

Autoimmune Diseases

Infectious Diseases

Rare Diseases

Other Therapeutic Areas

End Users Covered:

Biopharmaceutical Companies

Contract Research & Manufacturing Organizations

Academic & Research Institutes

Regions Covered:

North America

United States

Canada

Mexico

Europe

United Kingdom

Germany

France

Italy

Spain

Netherlands

Belgium

Sweden

Switzerland

Poland

Rest of Europe

Asia Pacific

China

Japan

India

South Korea

Australia

Indonesia

Thailand

Malaysia

Singapore

Vietnam

Rest of Asia Pacific

South America

Brazil

Argentina

Colombia

Chile

Peru

Rest of South America

Rest of the World (RoW)

Middle East

Saudi Arabia

United Arab Emirates

Qatar

Israel

Rest of Middle East

Africa

South Africa

Egypt

Morocco

Rest of 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 2023, 2024, 2025, 2026, 2027, 2028, 2030, 2032 and 2034

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)

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

Contents

1 EXECUTIVE SUMMARY

- 1.1 Market Snapshot and Key Highlights
- 1.2 Growth Drivers, Challenges, and Opportunities
- 1.3 Competitive Landscape Overview
- 1.4 Strategic Insights and Recommendations

2 RESEARCH FRAMEWORK

- 2.1 Study Objectives and Scope
- 2.2 Stakeholder Analysis
- 2.3 Research Assumptions and Limitations
- 2.4 Research Methodology
 - 2.4.1 Data Collection (Primary and Secondary)
 - 2.4.2 Data Modeling and Estimation Techniques
 - 2.4.3 Data Validation and Triangulation
 - 2.4.4 Analytical and Forecasting Approach

3 MARKET DYNAMICS AND TREND ANALYSIS

- 3.1 Market Definition and Structure
- 3.2 Key Market Drivers
- 3.3 Market Restraints and Challenges
- 3.4 Growth Opportunities and Investment Hotspots
- 3.5 Industry Threats and Risk Assessment
- 3.6 Technology and Innovation Landscape
- 3.7 Emerging and High-Growth Markets
- 3.8 Regulatory and Policy Environment
- 3.9 Impact of COVID-19 and Recovery Outlook

4 COMPETITIVE AND STRATEGIC ASSESSMENT

- 4.1 Porter's Five Forces Analysis
 - 4.1.1 Supplier Bargaining Power
 - 4.1.2 Buyer Bargaining Power
 - 4.1.3 Threat of Substitutes
 - 4.1.4 Threat of New Entrants

- 4.1.5 Competitive Rivalry
- 4.2 Market Share Analysis of Key Players
- 4.3 Product Benchmarking and Performance Comparison

5 GLOBAL BIOLOGICS & BIOSIMILARS MANUFACTURING MARKET, BY PRODUCT TYPE

- 5.1 Monoclonal Antibodies
- 5.2 Recombinant Proteins
- 5.3 Vaccines
- 5.4 Gene & Cell Therapies
- 5.5 Biosimilars

6 GLOBAL BIOLOGICS & BIOSIMILARS MANUFACTURING MARKET, BY MANUFACTURING TYPE

- 6.1 In-house Manufacturing
- 6.2 Contract Manufacturing Organizations (CMOs)

7 GLOBAL BIOLOGICS & BIOSIMILARS MANUFACTURING MARKET, BY EXPRESSION SYSTEM

- 7.1 Mammalian Cell Culture
- 7.2 Microbial Cell Culture
- 7.3 Yeast Expression Systems
- 7.4 Other Expression Systems

8 GLOBAL BIOLOGICS & BIOSIMILARS MANUFACTURING MARKET, BY PROCESS

- 8.1 Upstream Processing
- 8.2 Downstream Processing
- 8.3 Fill-Finish Operations

9 GLOBAL BIOLOGICS & BIOSIMILARS MANUFACTURING MARKET, BY APPLICATION

- 9.1 Oncology
- 9.2 Autoimmune Diseases

9.3 Infectious Diseases

9.4 Rare Diseases

9.5 Other Therapeutic Areas

10 GLOBAL BIOLOGICS & BIOSIMILARS MANUFACTURING MARKET, BY END USER

10.1 Biopharmaceutical Companies

10.2 Contract Research & Manufacturing Organizations

10.3 Academic & Research Institutes

11 GLOBAL BIOLOGICS & BIOSIMILARS MANUFACTURING MARKET, BY GEOGRAPHY

11.1 North America

11.1.1 United States

11.1.2 Canada

11.1.3 Mexico

11.2 Europe

11.2.1 United Kingdom

11.2.2 Germany

11.2.3 France

11.2.4 Italy

11.2.5 Spain

11.2.6 Netherlands

11.2.7 Belgium

11.2.8 Sweden

11.2.9 Switzerland

11.2.10 Poland

11.2.11 Rest of Europe

11.3 Asia Pacific

11.3.1 China

11.3.2 Japan

11.3.3 India

11.3.4 South Korea

11.3.5 Australia

11.3.6 Indonesia

11.3.7 Thailand

11.3.8 Malaysia

- 11.3.9 Singapore
- 11.3.10 Vietnam
- 11.3.11 Rest of Asia Pacific
- 11.4 South America
 - 11.4.1 Brazil
 - 11.4.2 Argentina
 - 11.4.3 Colombia
 - 11.4.4 Chile
 - 11.4.5 Peru
 - 11.4.6 Rest of South America
- 11.5 Rest of the World (RoW)
 - 11.5.1 Middle East
 - 11.5.1.1 Saudi Arabia
 - 11.5.1.2 United Arab Emirates
 - 11.5.1.3 Qatar
 - 11.5.1.4 Israel
 - 11.5.1.5 Rest of Middle East
 - 11.5.2 Africa
 - 11.5.2.1 South Africa
 - 11.5.2.2 Egypt
 - 11.5.2.3 Morocco
 - 11.5.2.4 Rest of Africa

12 STRATEGIC MARKET INTELLIGENCE

- 12.1 Industry Value Network and Supply Chain Assessment
- 12.2 White-Space and Opportunity Mapping
- 12.3 Product Evolution and Market Life Cycle Analysis
- 12.4 Channel, Distributor, and Go-to-Market Assessment

13 INDUSTRY DEVELOPMENTS AND STRATEGIC INITIATIVES

- 13.1 Mergers and Acquisitions
- 13.2 Partnerships, Alliances, and Joint Ventures
- 13.3 New Product Launches and Certifications
- 13.4 Capacity Expansion and Investments
- 13.5 Other Strategic Initiatives

14 COMPANY PROFILES

- 14.1 AbbVie
- 14.2 Amgen
- 14.3 Biocon
- 14.4 Boehringer Ingelheim
- 14.5 Celltrion
- 14.6 Dr. Reddy's Laboratories
- 14.7 Johnson & Johnson
- 14.8 Lonza
- 14.9 Merck
- 14.10 Novartis
- 14.11 Novo Nordisk
- 14.12 Pfizer
- 14.13 Roche
- 14.14 Samsung Biologics
- 14.15 Sanofi
- 14.16 Thermo Fisher Scientific
- 14.17 WuXi Biologics
- 14.18 Zydus Lifesciences

List of Tables

Table 1 Global Biologics & Biosimilars Manufacturing Market Outlook, By Region (2023-2034) (\$MN)

Table 2 Global Biologics & Biosimilars Manufacturing Market Outlook, By Product Type (2023-2034) (\$MN)

Table 3 Global Biologics & Biosimilars Manufacturing Market Outlook, By Monoclonal Antibodies (2023-2034) (\$MN)

Table 4 Global Biologics & Biosimilars Manufacturing Market Outlook, By Recombinant Proteins (2023-2034) (\$MN)

Table 5 Global Biologics & Biosimilars Manufacturing Market Outlook, By Vaccines (2023-2034) (\$MN)

Table 6 Global Biologics & Biosimilars Manufacturing Market Outlook, By Gene & Cell Therapies (2023-2034) (\$MN)

Table 7 Global Biologics & Biosimilars Manufacturing Market Outlook, By Biosimilars (2023-2034) (\$MN)

Table 8 Global Biologics & Biosimilars Manufacturing Market Outlook, By Manufacturing Type (2023-2034) (\$MN)

Table 9 Global Biologics & Biosimilars Manufacturing Market Outlook, By In-house Manufacturing (2023-2034) (\$MN)

Table 10 Global Biologics & Biosimilars Manufacturing Market Outlook, By Contract

Manufacturing Organizations (CMOs) (2023-2034) (\$MN)

Table 11 Global Biologics & Biosimilars Manufacturing Market Outlook, By Expression System (2023-2034) (\$MN)

Table 12 Global Biologics & Biosimilars Manufacturing Market Outlook, By Mammalian Cell Culture (2023-2034) (\$MN)

Table 13 Global Biologics & Biosimilars Manufacturing Market Outlook, By Microbial Cell Culture (2023-2034) (\$MN)

Table 14 Global Biologics & Biosimilars Manufacturing Market Outlook, By Yeast Expression Systems (2023-2034) (\$MN)

Table 15 Global Biologics & Biosimilars Manufacturing Market Outlook, By Other Expression Systems (2023-2034) (\$MN)

Table 16 Global Biologics & Biosimilars Manufacturing Market Outlook, By Process (2023-2034) (\$MN)

Table 17 Global Biologics & Biosimilars Manufacturing Market Outlook, By Upstream Processing (2023-2034) (\$MN)

Table 18 Global Biologics & Biosimilars Manufacturing Market Outlook, By Downstream Processing (2023-2034) (\$MN)

Table 19 Global Biologics & Biosimilars Manufacturing Market Outlook, By Fill-Finish Operations (2023-2034) (\$MN)

Table 20 Global Biologics & Biosimilars Manufacturing Market Outlook, By Application (2023-2034) (\$MN)

Table 21 Global Biologics & Biosimilars Manufacturing Market Outlook, By Oncology (2023-2034) (\$MN)

Table 22 Global Biologics & Biosimilars Manufacturing Market Outlook, By Autoimmune Diseases (2023-2034) (\$MN)

Table 23 Global Biologics & Biosimilars Manufacturing Market Outlook, By Infectious Diseases (2023-2034) (\$MN)

Table 24 Global Biologics & Biosimilars Manufacturing Market Outlook, By Rare Diseases (2023-2034) (\$MN)

Table 25 Global Biologics & Biosimilars Manufacturing Market Outlook, By Other Therapeutic Areas (2023-2034) (\$MN)

Table 26 Global Biologics & Biosimilars Manufacturing Market Outlook, By End User (2023-2034) (\$MN)

Table 27 Global Biologics & Biosimilars Manufacturing Market Outlook, By Biopharmaceutical Companies (2023-2034) (\$MN)

Table 28 Global Biologics & Biosimilars Manufacturing Market Outlook, By Contract Research & Manufacturing Organizations (2023-2034) (\$MN)

Table 29 Global Biologics & Biosimilars Manufacturing Market Outlook, By Academic & Research Institutes (2023-2034) (\$MN)

Note: Tables for North America, Europe, APAC, South America, and Rest of the World (RoW) Regions are also represented in the same manner as above.

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