

# **Oral Biologics & Biosimilars Market Outlook 2025-2034: Market Share, and Growth Analysis By Therapy (Lymphocyte Modulators, Interleukin Inhibitors, Tumor Necrosis Factor-Alpha Inhibitors, Immunostimulants, GPCR Modulators, Other Therapies), By Disease (Diabetes, Arthritis and Crohn's Disease, Cancer, Infectious Disease, Other Autoimmune Disease, Other Diseases), By Molecule Type, By Distribution Channel**

<https://marketpublishers.com/r/OE226B803B0EEN.html>

Date: October 2025

Pages: 160

Price: US\$ 3,950.00 (Single User License)

ID: OE226B803B0EEN

## **Abstracts**

The Oral Biologics & Biosimilars Market is valued at USD 7.7 trillion in 2025 and is projected to grow at a CAGR of 16.2% to reach USD 29.8 trillion by 2034. The oral biologics and biosimilars market has emerged as a critical segment in the pharmaceutical industry, as it offers patients an alternative to traditional injection-based biologic treatments. Oral biologics are protein-based drugs that are administered through oral routes, providing enhanced patient convenience and compliance. This market includes biosimilars, which are highly similar versions of original biologic drugs once their patents expire. The growing demand for biologics, driven by the increasing prevalence of chronic diseases such as cancer, autoimmune disorders, and diabetes, has propelled the market for oral biologics and biosimilars. The oral biologics market is expected to expand as advancements in biotechnology and drug delivery systems enable the development of oral formulations for biologics that were previously only injectable. With rising healthcare costs, biosimilars are gaining traction due to their affordability compared to original biologic drugs. This trend is further supported by increasing patient demand for easier, non-injection treatments and the expansion of healthcare access in emerging markets. As more patients seek convenient alternatives

to injections, the oral biologics and biosimilars market is anticipated to grow rapidly over the next decade, with technological innovation continuing to drive progress in this field. The oral biologics and biosimilars market saw significant advancements, particularly in the areas of drug formulation and delivery technologies. Companies focused on improving the stability and bioavailability of biologic drugs in oral forms, utilizing advanced drug delivery methods such as nanoparticles, lipid-based systems, and enteric coatings to protect biologics from degradation in the gastrointestinal tract. The approval of several biosimilar drugs for treatment of diseases like rheumatoid arthritis and certain types of cancer further boosted market growth. In the same year, regulatory bodies such as the U.S. FDA and the European Medicines Agency (EMA) began to streamline their approval processes for oral biologics and biosimilars, accelerating their market entry. Additionally, major pharmaceutical companies increased investments in oral biologics research, making the oral administration of previously injectable biologics more feasible. The development of oral formulations for high-demand biologics, such as monoclonal antibodies and insulin, has also expanded treatment options. With improved patient compliance and fewer challenges associated with injections, oral biologics are beginning to replace their injectable counterparts, especially in chronic conditions that require long-term management. The growing interest in oral delivery systems for biologics is expected to continue to accelerate the market's growth, driving more widespread use of biosimilars in clinical practice. The oral biologics and biosimilars market is expected to experience further innovations, particularly in the development of next-generation drug delivery systems and the expansion of oral biologics to treat a wider array of conditions. Advances in biotechnology and nanotechnology will continue to improve the efficacy and bioavailability of oral biologics, making them viable options for an increasing number of diseases. Additionally, the market will see more oral formulations of biologics for the treatment of oncology, autoimmune diseases, and other chronic conditions, areas that have traditionally relied on injectable biologics. The increasing adoption of biosimilars will drive market competition, leading to lower costs for patients and healthcare systems. Moreover, personalized medicine will play a key role in the development of oral biologics, offering patients more tailored treatments based on their specific genetic profiles. The growing demand for patient-centered care will further fuel the need for convenient, oral alternatives to injectable biologics. The regulatory landscape is also expected to evolve, with governments worldwide implementing policies to support the growth of the oral biologics market, particularly in emerging economies where access to innovative treatments is expanding. Overall, the market will be shaped by the convergence of new technologies, patient demand for easier treatment options, and the need for cost-effective healthcare solutions.

## Key Insights Oral Biologics & Biosimilars Market

**Advancements in Oral Delivery Systems:** Significant advancements in drug delivery technologies, such as nanoparticles, lipid carriers, and enteric coatings, are improving the stability and absorption of biologics in oral forms. These innovations are making it possible to develop oral biologics for diseases previously treated with injectable medications, enhancing patient convenience and compliance.

**Regulatory Support for Biosimilars:** Regulatory bodies are increasingly facilitating the approval of biosimilars, streamlining the approval process, and promoting competition in the biologics market. With biosimilars becoming more widely accepted, patients now have access to more affordable alternatives, which is driving their adoption in the treatment of various diseases.

**Personalized Medicine Integration:** The integration of personalized medicine with oral biologics is gaining momentum, allowing for more customized treatment options for patients based on their genetic and molecular profiles. This trend is expected to drive demand for oral biologics in oncology, autoimmune disorders, and other complex diseases, ensuring more effective and targeted therapies.

**Increased Focus on Chronic Disease Management:** With the growing prevalence of chronic diseases such as diabetes, arthritis, and cardiovascular disorders, there is a greater demand for oral biologics. These biologics offer patients long-term treatment options that are more convenient and less invasive than injectable alternatives, which is driving their development and adoption in chronic disease management.

**Expansion of Biosimilars in Emerging Markets:** As healthcare access improves in emerging markets, the adoption of biosimilars is increasing, driven by the need for cost-effective treatment options. This trend is particularly prominent in regions such as Asia-Pacific, Latin America, and Africa, where access to biologic therapies has been historically limited due to high costs.

**Cost-Effectiveness of Biosimilars:** Biosimilars offer a significant cost advantage over original biologic drugs, making them more affordable for both patients and healthcare systems. This cost-effectiveness is driving the widespread adoption of biosimilars and helping reduce overall healthcare expenditures, particularly in oncology and autoimmune disease treatments.

**Demand for Non-Injection Treatment Options:** The growing demand for non-injection treatments is one of the primary drivers for oral biologics. Patients prefer oral medications for their convenience, ease of use, and comfort. As a result, the market for oral biologics is expanding as more pharmaceutical companies develop oral versions of biologic therapies.

**Advances in Drug Delivery and Formulation Technologies:** Breakthroughs in drug delivery systems, such as improved absorption techniques and more effective protective coatings, are making oral biologics more feasible. These advancements allow for the development of oral versions of biologics that were previously only available as injections, expanding treatment options for patients.

**Growing Prevalence of Chronic Diseases:** The increasing global prevalence of

chronic diseases such as diabetes, arthritis, and cancer is driving the demand for biologic therapies. Oral biologics provide an attractive alternative to injectable drugs, offering greater convenience for patients who require long-term treatments for these chronic conditions. **Stability and Absorption Challenges:** One of the main challenges for oral biologics is ensuring the stability and absorption of biologic molecules in the gastrointestinal tract. These molecules are often unstable and may degrade before reaching the bloodstream, requiring advanced drug delivery systems to protect them and ensure their effective absorption.

## Oral Biologics & Biosimilars Market Segmentation

### By Therapy

Lymphocyte Modulators

Interleukin Inhibitors

Tumor Necrosis Factor-Alpha Inhibitors

Immunostimulants

GPCR Modulators

Other Therapies

### By Disease

Diabetes

Arthritis and Crohn's Disease

Cancer

Infectious Disease

Other Autoimmune Disease

Other Diseases

## By Molecule Type

Vaccines

Proteins and Peptides

Monoclonal Antibodies

Other Molecule Types

## By Distribution Channel

Hospital Pharmacies

Retail Pharmacies

Online Pharmacies

## Key Companies Analysed

Merck & Co. Inc.

GlaxoSmithKline

Novo Nordisk

ALK-Abell?

Aimmune Therapeutics Inc.

VIVUS Inc

Materia Medica Holding

VECTOR-MEDICA

Henlius

Innovent Biologics

Bio-Thera

Hisun Pharma

3SBio

Beijing ShuangLu Pharmaceuticals

Qilu Pharmaceutical

Shanghai Fosun Pharmaceuticals

Biocon

Dr.Reddy's

Mylan

Kyowa Hakko Kirin

Takeda

Mitsubishi Tanabe

AGC Biologics

BiosanaPharma

AstraZeneca

Bayer

Merck

Boehringer Ingelheim

Sanofi

Microgen

Geropharm

Valenta

NovaMedica

SynBio

Roche

Rani Therapeutics

Eli Lilly and Company

Emisphere Technologies Inc.

Enteris BioPharma

Allena Pharmaceuticals

Abbvie

Johnson & Johnson

Pfizer Inc.

Biogen Inc.

Ach?

Eurofarma

Teva Pharmaceuticals

Oramed Pharmaceuticals

Entera Bio

Julphar

Hikma Pharmaceuticals

Altis Biologics

Cipla Medpro South Africa

Genzyme

## Oral Biologics & Biosimilars Market Analytics

The report employs rigorous tools, including Porter's Five Forces, value chain mapping, and scenario-based modeling, to assess supply–demand dynamics. Cross-sector influences from parent, derived, and substitute markets are evaluated to identify risks and opportunities. Trade and pricing analytics provide an up-to-date view of international flows, including leading exporters, importers, and regional price trends.

Macroeconomic indicators, policy frameworks such as carbon pricing and energy security strategies, and evolving consumer behavior are considered in forecasting scenarios. Recent deal flows, partnerships, and technology innovations are incorporated to assess their impact on future market performance.

## Oral Biologics & Biosimilars Market Competitive Intelligence

The competitive landscape is mapped through OG Analysis' proprietary frameworks, profiling leading companies with details on business models, product portfolios, financial performance, and strategic initiatives. Key developments such as mergers & acquisitions, technology collaborations, investment inflows, and regional expansions are analyzed for their competitive impact. The report also identifies emerging players and innovative startups contributing to market disruption.

Regional insights highlight the most promising investment destinations, regulatory

landscapes, and evolving partnerships across energy and industrial corridors.

## Countries Covered

North America — Oral Biologics & Biosimilars market data and outlook to 2034

United States

Canada

Mexico

Europe — Oral Biologics & Biosimilars market data and outlook to 2034

Germany

United Kingdom

France

Italy

Spain

BeNeLux

Russia

Sweden

Asia-Pacific — Oral Biologics & Biosimilars market data and outlook to 2034

China

Japan

India

South Korea

Australia

Indonesia

Malaysia

Vietnam

Middle East and Africa — Oral Biologics & Biosimilars market data and outlook to 2034

Saudi Arabia

South Africa

Iran

UAE

Egypt

South and Central America — Oral Biologics & Biosimilars market data and outlook to 2034

Brazil

Argentina

Chile

Peru

*\* We can include data and analysis of additional countries on demand.*

Research Methodology

This study combines primary inputs from industry experts across the Oral Biologics &

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Biosimilars value chain with secondary data from associations, government publications, trade databases, and company disclosures. Proprietary modeling techniques, including data triangulation, statistical correlation, and scenario planning, are applied to deliver reliable market sizing and forecasting.

### Key Questions Addressed

What is the current and forecast market size of the Oral Biologics & Biosimilars industry at global, regional, and country levels?

Which types, applications, and technologies present the highest growth potential?

How are supply chains adapting to geopolitical and economic shocks?

What role do policy frameworks, trade flows, and sustainability targets play in shaping demand?

Who are the leading players, and how are their strategies evolving in the face of global uncertainty?

Which regional “hotspots” and customer segments will outpace the market, and what go-to-market and partnership models best support entry and expansion?

Where are the most investable opportunities—across technology roadmaps, sustainability-linked innovation, and M&A—and what is the best segment to invest over the next 3–5 years?

### Your Key Takeaways from the Oral Biologics & Biosimilars Market Report

Global Oral Biologics & Biosimilars market size and growth projections (CAGR), 2024-2034

Impact of Russia-Ukraine, Israel-Palestine, and Hamas conflicts on Oral Biologics & Biosimilars trade, costs, and supply chains

Oral Biologics & Biosimilars market size, share, and outlook across 5 regions and 27 countries, 2023-2034

Oral Biologics & Biosimilars market size, CAGR, and market share of key products, applications, and end-user verticals, 2023-2034

Short- and long-term Oral Biologics & Biosimilars market trends, drivers, restraints, and opportunities

Porter's Five Forces analysis, technological developments, and Oral Biologics & Biosimilars supply chain analysis

Oral Biologics & Biosimilars trade analysis, Oral Biologics & Biosimilars market price analysis, and Oral Biologics & Biosimilars supply/demand dynamics

Profiles of 5 leading companies—overview, key strategies, financials, and products

Latest Oral Biologics & Biosimilars market news and developments

### Additional Support

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