

# Insulin Biosimilars Market Set to Double by 2033, Led by Novel Partnerships and Facility Expansions

*Insulin biosimilars will grow at a 8.8% CAGR through 2033, driven by strategic investments in the US and Japan.*

ILLINOIS, IL, UNITED STATES, July 25, 2025 /EINPresswire.com/ -- Diabetes management increasingly relies on affordable, effective [insulin biosimilars](#). According to DataM Intelligence analysis, the global insulin biosimilars market was valued at approximately USD 4.8 billion in 2024 and is projected to reach USD 10.2 billion by 2033, reflecting a CAGR of 8.8%. Key drivers include patent expirations of originator insulins, rising diabetes prevalence, and mounting healthcare cost pressures.



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Insulin biosimilars are biological medical products that are highly similar to an already approved insulin product (known as the reference or originator insulin) and has no clinically meaningful differences in terms of safety, purity, and potency to its originator.

## Market Drivers

### Patent Expirations & Cost Savings

As major insulin analog patents expire, biosimilar developers capitalize on lower-cost manufacturing to offer price reductions of up to 30%, relieving payer and patient burden.

## Growing Diabetes Burden

The global diabetic population is estimated at over 537 million in 2024, and is expanding across both developed and emerging markets, creating sustained demand for accessible insulin therapies.

## Regulatory Alignment

Stringent but clear pathways established by the U.S. FDA's biosimilar framework and Japan's PMDA guidelines are expediting approvals, boosting manufacturer confidence.

## Technological Advances

Process improvements in microbial fermentation, continuous bioprocessing, and purification have reduced production costs and enhanced batch consistency.

## Regional Outlook

### North America

North America dominates with roughly 45% of global revenue, supported by strong biosimilar uptake in the U.S. and Canada. Payer mandates and Medicare reforms are encouraging rapid substitution of originator products with biosimilars.

### Europe

Europe holds the second-largest share, led by Germany, France, and the UK, where early biosimilar adoption patterns set pricing benchmarks. Regional tender systems further drive competitive pricing.

### Asia-Pacific & Japan

The Asia-Pacific market is the fastest-growing segment. Japan is considered as home to a high diabetes prevalence among seniors, the market is witnessing a 10.5% CAGR during the forecast period, the government initiatives and national formulary expansions are key catalysts in the market growth.

## Market Segments Overview

The insulin biosimilars market is segmented by product into long-acting, rapid-acting, and premixed biosimilars, offering diverse options for glycemic control. By indication, these biosimilars address both Type I and Type II diabetes, supporting broader patient needs. Distribution spans hospital, retail, and online pharmacies, reflecting a growing demand for accessible and cost-effective diabetes care solutions.

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## Recent Investments

### United States

- March 2025: Eli Lilly announced a USD 150 million expansion of its Indianapolis facility to produce next-generation insulin biosimilars, increasing annual capacity by 25%.
- April 2025: Biocon and Upjohn (a Pfizer division) signed an USD 80 million distribution and co development agreement to accelerate U.S. approval and commercialization of insulin glargine biosimilars.

### Japan

- February 2025: Takeda committed ¥12 billion (USD 85 million) to upgrade its Osaka biomanufacturing site for long acting insulin biosimilars, targeting domestic and ASEAN markets.
- May 2025: Mitsubishi Tanabe Pharma partnered with the Japan Diabetes Research Foundation on a ¥7 billion grant program to fund early stage biosimilar R&D and clinical studies.

## Industry Collaborations & Pipeline Highlights

- Sanofi & Samsung Biologics: Launched a joint venture in April 2025 to co manufacture rapid acting insulin biosimilars at Samsung's Songdo facility, leveraging advanced single use bioreactors.
- Novo Nordisk & Fujifilm Diosynth Biotechnologies: Expanded a multi year collaboration in May 2025 to scale up insulin aspart biosimilar production, targeting both Japanese and European markets.
- Celltrion & Astellas: Began Phase I trials in Q1 2025 of a concentrated insulin lispro biosimilar designed for pen injector devices in elderly populations.

## Future Outlook

The insulin biosimilars market is positioned for robust expansion, driven by ongoing patent cliffs, rising diabetes rates, and enhanced manufacturing technologies. Strategic investments in manufacturing capacity and distribution partnerships in the U.S. and Japan are setting the stage for accelerated approvals and market penetration.

By 2033, biosimilars are expected to account for more than 60% of global insulin volumes, significantly reducing therapy costs and improving patient access, especially in price sensitive markets.

## Recent Developments

### • Latest News from US (2025)

In June 2025, the U.S. Centers for Medicare & Medicaid Services announced enhanced reimbursement rates for interchangeable insulin biosimilars, effective January 2026, to further incentivize biosimilar prescribing and patient savings.

- Latest News from Japan (2025)

In July 2025, Japan's PMDA granted Sakigake designation to Mitsubishi Tanabe's ultra long acting insulin biosimilar, expediting its review and potential approval by late 2025 under conditional marketing terms.

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