

Biosimilars: Are they the same quality?

What are biologics?

Biologics (also called biological products) include a **wide range of products** such as vaccines, monoclonal antibodies, blood components, allergenics, gene therapy, tissues, and proteins.



Biologics are medicines that generally come from **living organisms**, which can include animal cells and microorganisms, such as yeast and bacteria¹.



They are used to treat a variety of diseases and conditions, such as **cancer, kidney diseases, and autoimmune diseases**.

What are biosimilars?

A biosimilar is a biologic that is **highly similar** to another biologic that's already FDA-approved, called a reference product. Biosimilars have **no clinically meaningful differences** from their reference product in terms of **safety, purity, and potency**.

Biosimilars have the same:



Route of administration to patients



Strength and dosage form



Potential side effects

Biosimilars are approved for many biologic reference products², including:

- ▶ Avastin
- ▶ Humira
- ▶ Lucentis
- ▶ Remicade
- ▶ Epogen/Procrit
- ▶ Herceptin
- ▶ Neulasta
- ▶ Rituxan
- ▶ Enbrel
- ▶ Lantus
- ▶ Neupogen

Biosimilars can improve patient access to quality medicines

Biosimilars are versions of brand name biologics that may offer more affordable treatment options to patients, similar to generic drugs.



Understanding the quality of biosimilar products

Biosimilars are:

Rigorously tested by their manufacturers following the same robust quality assessments as their reference products. These assessments are performed in accordance with the Current Good Manufacturing Practice regulations enforced by FDA.



Interchangeable products

An interchangeable biosimilar product is a biosimilar that may be substituted for the reference product without the intervention of the health care professional who prescribed the reference product. This is similar to how generic drugs are substituted for brand name drugs at the pharmacy and is subject to state laws. Interchangeable biosimilars must meet additional requirements related to the potential for automatic substitution. However, both biosimilar and interchangeable biosimilars meet the same high standards for quality and similarity to the reference product.

What steps are involved to help ensure quality biosimilars?



Extensive research and comparative studies by the manufacturer to demonstrate high similarity to the reference product.



Studies directly comparing the biosimilar to the reference product to demonstrate no clinically meaningful differences in safety, purity, and potency.



FDA review of data required for approval of a biosimilar.



FDA inspections of the biosimilar manufacturing facilities.



Post-market drug safety surveillance by FDA and biosimilar manufacturers.

Learn more

www.usp.org/about/convention-membership

www.fda.gov/drugs/biosimilars/patient-materials

References

¹ www.fda.gov/biosimilars

² <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>



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