

Biosimilars



The availability of high-quality, biosimilar medicines is expected to play a key role in the future of health care, as they have the potential to expand access to important treatments, provide affordable additional options and help address the evolving needs of patients, physicians and payers.

Given the complexity of the development and commercialization of biosimilars, we believe Pfizer's capabilities – which reflect a strong heritage in the development, manufacturing and commercialization of biologic medicines – position us to succeed as the global leader in the biosimilars marketplace.

What are biologics and biosimilars?

A biologic medicine is derived from living organisms that are manufactured through highly complex and stringently controlled biotechnology processes; these medicines have become the standard of care for many serious and chronic diseases, such as rheumatoid arthritis and cancer. Biosimilars are highly similar to a reference biologic, with no clinically meaningful differences in terms of the safety, purity and potency of the product. A biosimilar is not to be confused with a generic medicine; biosimilars are inherently different due to their molecular size and structure. Importantly, biosimilars have higher research and development costs and risks, and are more complex to manufacture and monitor than small molecule generics.

Delivering Excellence in the Development and Manufacturing of Biosimilars

Biosimilar development requires significant expertise to ensure that it is highly similar to the reference biologic drug with only minor differences in the clinically inactive components. State-of-the-art analytical tools and clinical studies are used to ensure each biosimilar matches the reference biologic with a high degree of similarity. This level of control and surveillance is essential because biosimilars and biologics are highly complex molecules created from living cells and any change to the processing conditions – no matter how small – can affect the fundamental properties of the end product.

Pfizer has a long-standing legacy of developing and manufacturing biologics globally for more than 30 years, and nearly 10 years of experience developing and commercializing biosimilars outside the United States. We harness this expertise to continuously improve the process while maintaining a quality product.

How a Biosimilar is Developed

A Step-by-Step Process:

Cell line creation

1 The process begins with establishing the reference biologic's protein structure through reverse engineering



2 The DNA sequence is inserted into a specific cell type

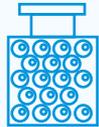


3 The gene instructs the cell to reproduce the desired protein



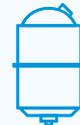
Upscaling

4 Cells are generally grown in cultured bioreactors suspended in a nutrient-rich, liquid environment



3 liter flask

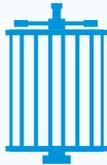
5 After the cells produce the target biologic molecule, the molecules are often released into this environment



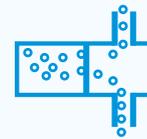
12 liter vat

Purification

6 Purification through chromatography



7 Purification through filtration to ensure that only the medicine is sent on to be packaged for use



Final Product

8 After purification, the completed biosimilar protein is formulated and packaged

