

What Is a Biosimilar?

Biosimilar

A subset of biologics, a **biosimilar** is a biologic that is highly similar to an FDA-approved product, referred to as the reference product. Biosimilars have no clinically meaningful differences compared to a reference product in terms of safety, purity, and potency as demonstrated through human pharmacokinetic and pharmacodynamics studies. Because of their complexity, biosimilars are unlikely to be identical replicates of their comparable reference products.

Related Capabilities

Life Sciences