

What Is the Approval Process for Biosimilar Drugs?

Biosimilar Approval Process

Biosimilars are evaluated and approved according to the Biologics Price Competition and Innovation Act (BPCIA), which provides an abbreviated approval pathway. The BPCIA provides the framework for an applicant to demonstrate that its proposed medicine is similar to a reference product in terms of safety, purity, and potency as demonstrated through human pharmacokinetic and pharmacodynamics studies.

Related Capabilities

Life Sciences