

MAKING

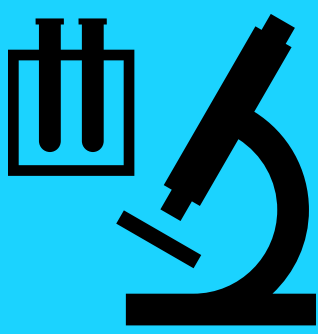
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BIOSIMILAR

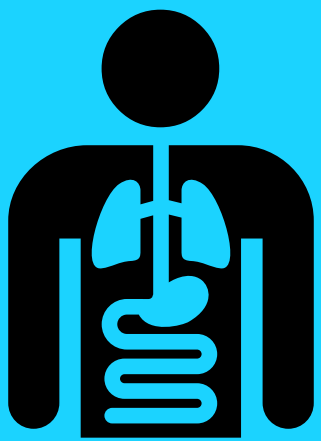
HOW DO BIOSIMILAR POLICIES ENSURE PATIENTS GET SAFE BIOSIMILAR MEDICINES



Make a biologic medicine that is similar to, but not an identical copy of an existing medicine



Show in a laboratory that the two medicines have no important differences in structure



Carry out tests to make sure the two medicines behave in the same way

Show that the two medicines act the same in patients



Decide how the biosimilar will be manufactured, labelled, & used



Follow requirements for **Concept of Biosimilarity, Reference Product Formulation, Route & Dosage Form**

Quality & Analytical Tests Required

General Considerations

Isolation of drug substance

Physiochemical

Stability

Specifications

Non-Clinical Tests Required

General Considerations

Pharmacology

Pharmacokinetics

Toxicology

Clinical Tests Required

General Considerations

Pharmacokinetics

Pharmacodynamics

Efficacy & Safety

Immunology

Review guidance for:

Extrapolation

Pharmacovigilance

Interchangeability

Naming & Labeling

Manufacturing