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Biosimilar Drug Development and Approval Process

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Abstract

Emphasis will be placed on a stepwise approach to provide analytical studies, biological characterization, preclinical and clinical testing of the proposed biosimilar product presented in the premarket applications.The sponsors of premarket applications must present analytical characterization, pharmacokinetic (PK), pharmacodynamic (PD) and comparative clinical studies to demonstrate that a proposed biosimilar product is highly similar to a licensed reference product.Discussions will be presented on Quality Systems approach to c-GMP's for Biosimilar Applications (Design Controls, validation and verification studies, analytical similarity, manufacturing and effective total product life-cycle CMC strategy).Discussions will be presented on clinical aspects of proposed biosimilar product (Immunogenicity Assessment, Extrapolations & Interchangeability in conformance with specific recommendations described in the FDA's guidance on biosimilar labeling) .Emphasis will be placed on Quality Risk Management approach to design of studies by providing oversight and objective review of risk-benefit analysis that guides the clinical use of the new biosimilar drug product by providing patients organized data and appropriate labeling information in support of the new drug's intended clinical use

13th European Biosimilars Congress; August 26-27, 2020 Webinar.

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