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Strategy for biosimilar development

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Abstract

Biosimilar is gaining great traction in the world as it offers expanded accessibility of life-saving biopharmaceuticals, as well as the potential of a lucrative business opportunity. However, unlike the generic pharmaceuticals for small molecules, development of biosimilar is ever challenging and expensive. The presentations will overview the landscape, the general strategy, the workflow, the pitfalls of biosimilar development, with a focus on the analytical tools for protein characterization. Case studies from Laureate's experience with biosimilar development will be presented.

Biography

Jay Kang is the Director of Analytical and Formulation Development in Laureate Biopharmaceutical Services, Inc. He holds a Ph.D. in Pharmaceutics from Peking University (China) and had his postdoctoral training in University of Michigan. He has been working on characterization, method development, and formulation for proteins since 1995, and is the author of 15 peer-reviewed journal articles and book chapters, and several patents. He has extensive hands-on experience in antibodies, cytokines, enzymes, and protein conjugates. He is an instructor in IBC Training Academy since 2010, teaching a two-day professional training course on "Analytical Method Development and Validation for Therapeutic Proteins".