

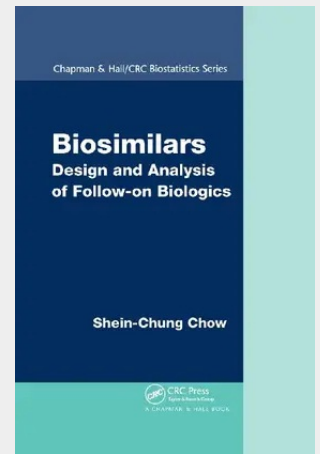
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Biosimilars

Design and Analysis of Follow-on Biologics

As many biological products face losing their patents in the next decade, the pharmaceutical industry needs an abbreviated regulatory pathway for approval of biosimilar drug products, which are cost-effective, follow-on/subsequent versions of the innovator's biologic products. But scientific challenges remain due to the complexity of both the manufacturing process and the structures of biosimilar products. Written by a top biostatistics researcher, *Biosimilars: Design and Analysis of Follow-on Biologics* is the first book entirely devoted to the statistical design and analysis of biosimilarity and interchangeability of biosimilar products. It includes comparability tests of important quality attributes at critical stages of the manufacturing processes of biologic products. Connecting the pharmaceutical/biotechnology industry, government regulatory agencies, and academia, this state-of-the-art book focuses on the scientific factors and practical issues related to the design and analysis of biosimilar studies. It covers most of the statistical questions encountered in various study designs at different stages of research and development of biological products.

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