Biosimilars: Design and Analysis of Follow-on Biologics (Chapman Hall/CRC Biostatistics Series)

Shein-Chung Chow
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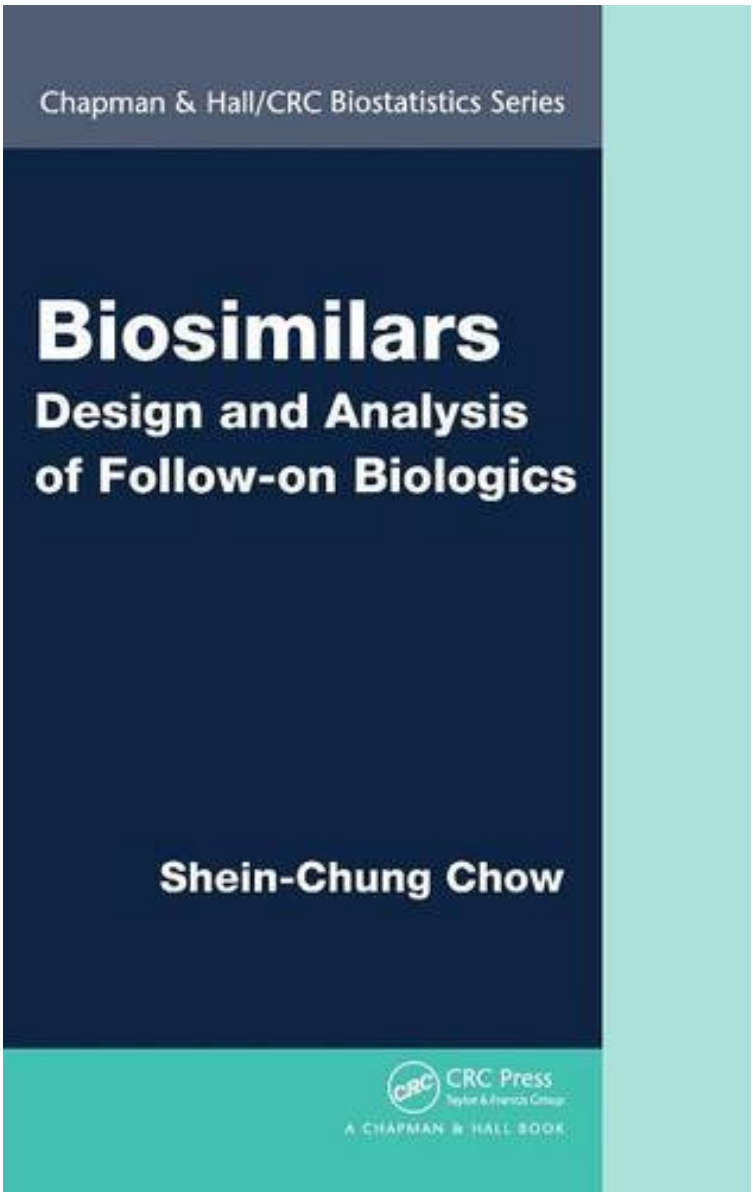

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Shein-Chung Chow : Biosimilars: Design and Analysis of Follow-on Biologics (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Biosimilars: Design and Analysis of Follow-on Biologics (Chapman Hall/CRC Biostatistics Series):

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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 innovators 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.

"This book extensively covers both statistical and regulatory considerations from design to analysis of biosimilarity. it is well presented and comprehensively covers fundamental issues and some of the newly developed methods for biosimilarity studies. The book is very balanced between scientific aspects and regulatory requirements. In addition, the reference lists give readers helpful information. a valuable resource for anyone interested and involved in biosimilarity studies."Biometrics, September 2014 "[Professor] Chows book Biosimilars: Design and Analysis of Follow-On Biologics is the first book ever written on this topic. I commend Professor Chow for his effort to introduce the topic Overall, this is a worthwhile reference book for statisticians interested in understanding biosimilar product development and evaluation." Yi Tsong, PhD, Center for Drug Evaluation and Research, US Food and Drug Administration, USA, in Journal of Biopharmaceutical StatisticsAbout the AuthorShein-Chung Chow is a professor in the Department of Biostatistics and Bioinformatics at Duke University School of Medicine. Dr. Chow is also a professor of clinical sciences at DukeNational University of Singapore Graduate Medical School. He is the editor-in-chief of the Journal of Biopharmaceutical Statistics and editor-in-chief of the Chapman Hall/CRC Biostatistics Series. He has authored or co-authored over 230 papers and 22 books, including Adaptive Design Methods in Clinical Trials, Second Edition, Handbook of Adaptive Designs in Pharmaceutical and Clinical Development, and Controversial Statistical Issues in Clinical Trials. A fellow of the ASA and member of the ISI, Dr. Chow has received the ASA Chapter Service Recognition Award, the DIA Outstanding Service Award, and the ICSA Extraordinary Achievement Award.