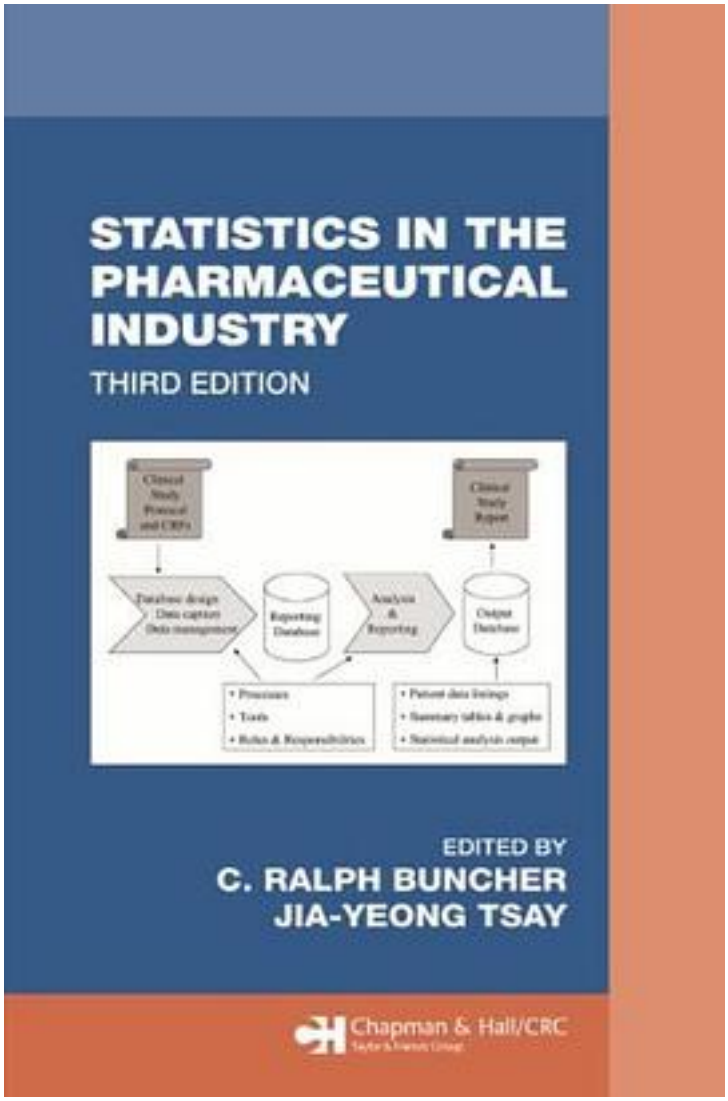
Statistics in the Pharmaceutical Industry



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出版者:Marcel Dekker Inc

出版时间:2005-9

装帧:HRD

isbn:9780824754693

The growth of the pharmaceutical industry over the past decade is astounding, but the impact of this growth on statistics is somewhat confusing. While software has made analysis easier and more efficient, regulatory bodies now demand deeper and more complex analyses, and pharmacogenetic/genomic studies serve up an entirely new set of challenges. For more than two decades, "Statistics in the Pharmaceutical Industry" has been the definitive guide to sorting through the challenges in the industry, and this Third Edition continues that tradition. Updated and expanded to reflect the most recent trends and developments in the field, "Statistics in the Pharmaceutical Industry, Third Edition" presents chapters written by experts from both regulatory agencies and pharmaceutical companies who discuss everything from experimental design to post-marketing studies. This approach sheds light on what regulators consider acceptable methodologies and what methods have proven successful for industrial statisticians. Both new and revised chapters reflect the increasingly global nature of the industry as represented by authors from Japan and Europe, the increasing trend toward non-inferiority/equivalence testing, adaptive design in clinical trials, global harmonization of regulatory standards, and multiple comparison studies. The book also examines the latest considerations in anti-cancer studies. "Statistics in the Pharmaceutical Industry, Third Edition" demystifies the approval process by combining regulatory and industrial points of view, making it a must-read for anyone performing statistical analysis at any point in the drug approval process.

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