

# Statistics in Drug Research: Methodologies and Recent Developments (Chapman & Hall/CRC Biostatistics Series)

Shein-Chung Chow, Jun Shao



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Emphasizing the role of good statistical practices (GSP) in drug research and formulation, this book outlines important statistics applications for each stage of pharmaceutical development to ensure the valid design, analysis, and assessment of drug products under investigation and establish the safety and efficacy of pharmaceutical compounds. Coverage include statistical techniques for assay validation and evaluation of drug performance characteristics, testing population/individual bioequivalence and in vitro bioequivalence according to the most recent FDA guidelines, basic considerations for the design and analysis of therapeutic equivalence and noninferiority trials.

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