Multiple Testing Problems in Pharmaceutical Statistics (Chapman & Hall/CRC Biostatistics Series)

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Useful Statistical Approaches for Addressing Multiplicity Issues
Includes practical examples from recent trials

Bringing together leading statisticians, scientists, and clinicians from the pharmaceutical industry, academia, and regulatory agencies, **Multiple Testing Problems in Pharmaceutical Statistics** explores the rapidly growing area of multiple comparison research with an emphasis on pharmaceutical applications. In each chapter, the expert contributors describe important multiplicity problems encountered in pre-clinical and clinical trial settings.

The book begins with a broad introduction from a regulatory perspective to different types of multiplicity problems that commonly arise in confirmatory controlled clinical trials, before giving an overview of the concepts, principles, and procedures of multiple testing. It then presents statistical methods for analyzing clinical dose response studies that compare several dose levels with a control as well as statistical methods for analyzing multiple endpoints in clinical trials. After covering gatekeeping procedures for testing hierarchically ordered hypotheses, the book discusses statistical approaches for the design and analysis of adaptive designs and related confirmatory hypothesis testing problems. The final chapter focuses on the design of pharmacogenomic studies based on established statistical principles. It also describes the analysis of data collected in these studies, taking into account the numerous multiplicity issues that occur.

This volume explains how to solve critical issues in multiple testing encountered in pre-clinical and clinical trial applications. It presents the necessary statistical methodology, along with examples and software code to show how to use the methods in practice.

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