Preamble
This book was the 36th in a series of statistics textbooks and monographs edited by DB Owen (Department of Statistics, Southern Methodist University, Dallas, Texas, USA) and RG Cornell (School of Public Health, University of Michigan, Ann Arbor, Michigan, USA, for the publisher Marcel Dekker. A second edition was published in 1994 and a third in 2006.

Aims
This is the first book that we know of devoted to applied statistics in the pharmaceutical industry. The principal audience for this book is the graduate student in statistics or biostatistics. A second audience is statistics faculty members who have had little or no acquaintance with the pharmaceutical industry. A third audience consists of other persons interested in the pharmaceutical industry who are not statisticians. Finally we believe that the pharmaceutical industry currently documents its statistical and other evidence better than any other segment of our society. As more and more comparable problems become a greater problem for industry and regulatory agencies, we foresee that parts of industry and government other than the pharmaceutical industry and the Food and Drug Administration will be doing the same extensive work and documentation that has been pioneered in the pharmaceutical industry. We think that those other industrial / governmental interfaces will profit by learning the lessons of the pharmaceutical industry and applying them in their own spheres as appropriate (Preface, pages iii to v).

Contents (x+465 pages)
[Sub-headings omitted]
Preface (C Ralph Buncher)
Contributors
1. Introduction to the evolution of pharmaceutical products (C Ralph Buncher, Jia-Yeong Tsay)
2. Screening products for clinically active drugs (Charles E Redman)
3. Uses of bioassay in drug development: dose-response relationships (Chiao Yeh)
4. Clinical trial designs (C Ralph Buncher, Jia-Yeong Tsay)
5. The role of FDA statisticians in the efficacy and safety evaluation of new drugs (Satya D Dubey)
6. Selection of patients participating in a clinical trial:
   Part A: The inpatient (José F Calimlim)
   Part B: The outpatient (Michael Weintraub)
7. Crossover designs in medical research (Alan C Fisher, Sylvan Wallenstein)
8. Design and analysis of clinical trials of psychoactive drugs (Carl M Metzler, Gordon L Schooley)
9. Design and analysis of clinical trials of analgesic drugs (Jack W Green)
10. Design and analysis of bioavailability studies (Daniel L Weiner)
11. The wonders of placebo (Roy L Sanford, Thomas H Schmitz)
12. Documenting the results of a study (Joseph R Assenzo, Kathleen R Lamborn).
13. Data quality assurance (Kenneth H Falter)
14. Quality control of the manufacturing process (Charles B Sampson)
15. Stability of drugs: accelerated storage tests (Owen L Davies, Harry E Hudson)
16. When and how to do multiple comparisons (Charles Dunnett, Charles Goldsmith)
17. Jackknife techniques in practice (James N Arvesen, Maxwell W Layard)
18. A survey of pharmaceutical managers (Christine Trautwein)

Index

Authors
The editors are Charles Ralph Buncher ScD (Professor and Director of the Division of Biostatistics and Epidemiology, University of Cincinnati Center of Medicine, Cincinnati, Ohio, USA, and Jia-Yeong Tsay PhD, (Statistician, Division of Biometrics, Bureau of Drugs, Food and Drug Administration, Rockville, Maryland, USA). The other contributors are James N Arvesen PhD (President, Princeton Analytical Services Corporation, Princeton, New Jersey, USA); Joseph R Assenzo PhD (Group Manager, Biostatistical and Clinical Information Systems, The Upjohn Company, Kalamazoo, Michigan, USA); José F Calimlim MD (Department of Anesthesiology, and Pharmacology and Toxicology, School of Medicine and Dentistry, University of Rochester, Rochester, New York, USA); Owen L Davies PhD (Professor Emeritus, Department of Statistics, University College of Wales, Aberystwyth, Wales); Satya D Dubey (Chief, Statistical Evaluation Branch, Bureau of Drugs, Food and Drug Administration, Rockville, Maryland, USA; Charles Dunnett DSc (Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada); Kenneth H Falter PhD (Director, Scientific Evaluation, GD Searle and Company, Skokie, Illinois, USA), Alan C Fisher MS (Senior Statistician, Hoechst-Roussel Pharmaceuticals Inc, Somerville, New Jersey, USA); Charles Goldsmith PhD (Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada); Jack W Green PhD (Director, Biostatistics, Adria Laboratories, Inc, Columbus, Ohio, USA); Harry E Hudson PhD (Head of Drug Stability Studies, Pharmaceutical Department, Imperial Chemical Industries Ltd, Macclesfield, Cheshire, England); Kathleen R Lamborn PhD (Research Head, Biostatistics, The Upjohn Company, Kalamazoo, Michigan, USA); Maxwell W Layard PhD (Cooperative Studies Program Coordinating Center, Veterans Administration Medical Center, Palo Alto, California, USA); Carl M Metzler PhD (Senior Statistician, The Upjohn Company, Kalamazoo, USA); Charles E Redman PhD (Director, Medical Information Systems, Lilly Research Laboratories, Indianapolis, Indiana, USA); Charles B Sampson PhD (Head, Statistical and Mathematical Services, Lilly Research Laboratories, Indianapolis, Indiana, USA); Roy L Sanford PhD (Associate Director, Statistical Services, Travenol Laboratories Inc, Deerfield, Illinois, USA); Thomas H Schmitz PhD (Corporate Director, Regulatory Affairs, Travenol Laboratories Inc, Deerfield, Illinois, USA); Gordon L Schooley PhD (Associate Director Research, Biostatistics, Allergan Pharmaceuticals, Irvine, California, USA); Christine Trautwein MPH (Senior Biostatistician, Warner-Lambert Co, Ann Arbor, Michigan, USA); Sylvan Wallenstein PhD (School of Public Health, Columbia University, New York, USA); Daniel L Weiner PhD (Senior Statistician, Merrell Dow Pharmaceutical Inc, Cincinnati, Ohio, USA); Michael Weintraub MD (Department of Pharmacology and Toxicology, School of Medicine and Dentistry, University of Rochester, Rochester, New Year, USA); and, Chiao Yeh PhD (Senior Biomathematician, ICI Americas Inc, Wilmington, Delaware, USA).