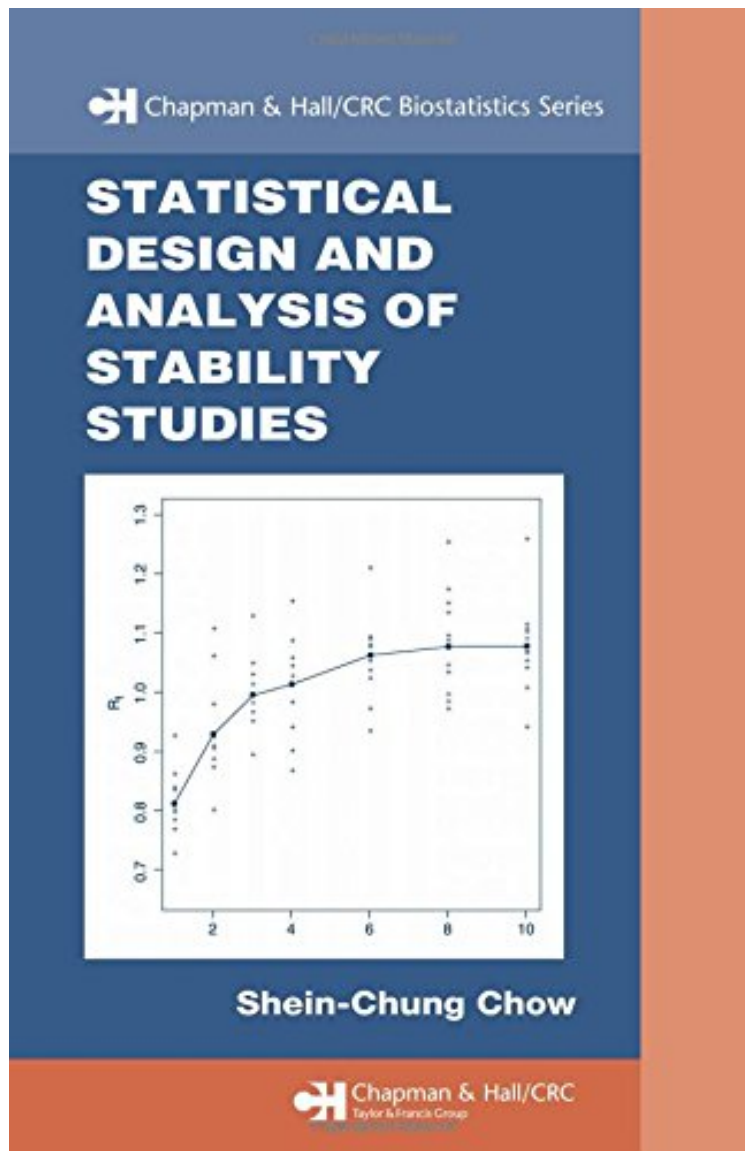


Statistical Design and Analysis of Stability Studies (Chapman Hall/CRC Biostatistics Series)

Shein-Chung Chow

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

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informative. have not finished reading the whole book but. compact and to the point kind of book in my opinion. (I am in pharmaceutical industry)29 of 29 people found the following review helpful. first and excellent treatment of a key topic in pharmaceuticalsBy Michael R. ChernickWhen the expiration date on a drug passes, the pharmacist must destroy the items that exceed their shelf life. In a clinical trial, drugs stored for use in the trial can exceed their shelf life and then must be destroyed. Since the late 1980s the FDA requires that stability testing be conducted to establish the shelf life of a drug. Products discovered to be unstable have been taken off the market. Therefore, stability testing is an important part of the early phase statistical analysis of a new drug. Yet in my nearly five years of experience as a clinical trials statistician in the pharmaceutical industry I was only once (and only just recently) confronted with the issue. We had a drug that started phase III but in the course of the trial some of the stored samples became unstable and the trial was put on hold. As the manufacturer of the product we had to make changes to ensure that moisture did not get into the vials to ruin the mixture. We were motivated to fix the problem quickly and get the trial restarted. However bioavailability and stability needed to be reestablished. I learned that we used very rudimentary and inaccurate tools to estimate the stability from the test batches. This meant that during the trial we could only claim a minimal shelf-life and the drug could be wasted because of the need to destroy it before it "really" expired. So it was with pleasure and excitement that I bought this book.Professor Chow has authored, co-authored and edited books on every aspect of the statistics of drug development. As usual he is very thorough in his presentation of the topic, the FDA and ICH rules and guidelines and the development of the various options for statistical analysis. This is another in the long series of publications by Dr. Chow and his colleagues. He is always at the forefront being the first or one of the first to present new statistical methods or applications to the biopharmaceutical community. A book that is a must for the bookshelf of any biopharmaceutical statistician!

The US Food and Drug Administration's Report to the Nation in 2004 and 2005 indicated that one of the top reasons for drug recall was that stability data did not support existing expiration dates. Pharmaceutical companies conduct stability studies to characterize the degradation of drug products and to estimate drug shelf life. Illustrating how stability studies play an important role in drug safety and quality assurance, *Statistical Design and Analysis of Stability Studies* presents the principles and methodologies in the design and analysis of stability studies. After introducing the basic concepts of stability testing, the book focuses on short-term stability studies and reviews several methods for estimating drug expiration dating periods. It then compares some commonly employed study designs and discusses both fixed and random batch statistical analyses. Following a chapter on the statistical methods for stability analysis under a linear mixed effects model, the book examines stability analyses with discrete responses, multiple components, and frozen drug products. In addition, the author provides statistical methods for dissolution testing and explores current issues and recent developments in stability studies. To ensure the safety of consumers, professionals in the field must carry out stability studies to determine the reliability of drug products during their expiration period. This book provides the material necessary for you to perform stability designs and analyses in pharmaceutical research and development.

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