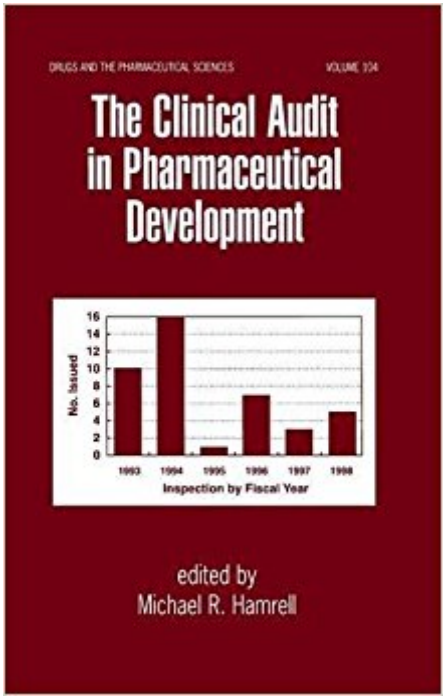
The Clinical Audit In Pharmaceutical Development (Drugs And The Pharmaceutical Sciences)



Synopsis

This blue-chip guide adds quality to the pharmaceutical clinical development process by detailing the need for, and stressing the importance of, an independent audit of clinical data to protect participants and validate study results.Examines the use of personal computers, the Internet, and third-party organizations to assist in data validation!Positioning the audit as the only reliable tool to verify that a drug has been shown to be safe and effective in clinical trials, The Clinical Audit in Pharmaceutical Development recommends establishing auditing and quality assurance at the beginning of a clinical study describes Good Clinical Practices (GCPs) and the role of regulatory agencies in the review, validation, and auditing processes outlines the clinical process, from trial design through report writing compares and contrasts United States and international regulatory statutes identifies monitoring as the key to guaranteeing high-quality data focuses on the role of the clinical audit in achieving unity in a multinational study discusses the worldwide influence of the US Food and Drug Administration audit analyzes findings from previous FDA clinical audits to reveal trends and future directions provides guidelines for fraud detection and considers the ramifications of falsified data and more!Confirming that all clinical information has been properly collected and reported, The Clinical Audit in Pharmaceutical Development is a crucial reference for clinical and research pharmacists and pharmacologists; biostatisticians; clinical research associates, coordinators, and investigators; quality control, quality assurance, and regulatory compliance managers; and upper-level undergraduate and graduate students in these disciplines.

Book Information

Series: Drugs and the Pharmaceutical Sciences (Book 104)
Hardcover: 216 pages
Publisher: CRC Press; 1 edition (November 5, 1999)
Language: English
ISBN-10: 082470309X
ISBN-13: 978-0824703097
Product Dimensions: 6.1 x 0.6 x 9.2 inches
Shipping Weight: 1.1 pounds (View shipping rates and policies)
Average Customer Review: 5.0 out of 5 stars 1 customer review
Best Sellers Rank: #2,647,294 in Books (See Top 100 in Books) #51 inÃ Â Books > Medical Books > Pharmacology > Product Development #499 inÃ Â Books > Textbooks > Medicine & Health Sciences > Medicine > Clinical > Pulmonary & Thoracic Medicine #775 inÃ Â Books >

Customer Reviews

The individual responded through email in a timely fashion. Book appeared to be brand new when I received it; however, I thought I would have receieved it much quicker than I did.

The Clinical Audit in Pharmaceutical Development (Drugs and the Pharmaceutical Sciences) Percutaneous Absorption: Drugs--Cosmetics--Mechanisms--Methodology: Drugs--Cosmetics--Mechanisms--Methodology, Third Edition, (Drugs and the Pharmaceutical Sciences) Audit Guide: Government Auditing Standards and Single Audits 2017 (AICPA Audit Guide) Automation and Validation of Information in Pharmaceutical Processing (Drugs and the Pharmaceutical Sciences) Transport Processes in Pharmaceutical Systems (Drugs and the Pharmaceutical Sciences) Pharmaceutical Skin Penetration Enhancement (Drugs and the Pharmaceutical Sciences) Pharmaceutical Particulate Carriers: Therapeutic Applications (Drugs and the Pharmaceutical Sciences) Polymorphism in Pharmaceutical Solids (Drugs and the Pharmaceutical Sciences) Pharmaceutical Process Validation, Second Edition (Drugs and the Pharmaceutical Sciences) Introduction to the Pharmaceutical Sciences: An Integrated Approach (Pandit, Introduction to the Pharmaceutical Sciences) Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and Development (Drugs and the Pharmaceutical Sciences) Clinical Drug Trials and Tribulations, Revised and Expanded, Second Edition (Drugs and the Pharmaceutical Sciences) Simulation for Designing Clinical Trials: A Pharmacokinetic-Pharmacodynamic Modeling Perspective (Drugs and the Pharmaceutical Sciences) Transdermal Drug Delivery Systems: Revised and Expanded (Drugs and the Pharmaceutical Sciences) Controlled Drug Delivery: Fundamentals and Applications, Second Edition (Drugs and the Pharmaceutical Sciences) Drug Permeation Enhancement: Theory and Applications (Drugs and the Pharmaceutical Sciences) Microencapsulation: Methods and Industrial Applications (Drugs and the Pharmaceutical Sciences) Protein Formulation and Delivery (Drugs and the Pharmaceutical Sciences) Microparticulate Systems for the Delivery of Proteins and Vaccines (Drugs and the Pharmaceutical Sciences) Prodrugs: Topical and Ocular Drug Delivery (Drugs and the Pharmaceutical Sciences)

Privacy

FAQ & Help