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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.

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