Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections

Vera Mihajlovic-Madzarevic

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A must-have guide for any professional in the drug manufacturing industry

The Good Clinical Practice (GCP) audit is a tedious but necessary exercise that assures that all parties do their job properly and in compliance with the applicable FDA code. *Clinical Trials Audit Preparation* demystifies the audit process for all parties involved, including clinical research sponsors, clinical investigators, and institutional review boards.

This book provides a step-by-step explanation of the FDA audit procedures for clinical trials and of how pharmaceutical companies, clinical investigators, and institutional review boards should prepare for regulatory audits. The book emphasizes the processes and procedures that should be implemented before a clinical audit occurs, making this an imperative guide to any professional in the drug manufacturing industry, including drug manufacturing companies, regulatory affairs personnel, clinical investigators, and quality assurance professionals.

Among the topics discussed:

- Good Clinical Practices and therapeutic product development in clinical research
- The roles of the sponsor of a clinical investigation, the IRB, or independent ethics committee
- The roles and responsibilities of the clinical trial investigator
- The inspection preparation
- The Audit Report and the Form 483
- Warning letters issued to clinical investigators and clinical trial sponsors and their impact on product development

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