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Clinical trials audit preparation : a guide for good clinical practice (GCP) inspections / Vera Mihajlovic-Madzarevic

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Abstrak

All clinical investigators, sponsors, and Institutional Review Boards have to comply with the applicable FDA code(s). Good Clinical Practice (GCP) Audit Preparation provides a step-by-step explanation of the FDA audit procedures for clinical trials and how a pharmaceutical company 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.