

| | |
|-------------------------|---|
| 1. Record Nr. | UNINA9910140166103321 |
| Autore | Mihajlovic-Madzarevic Vera |
| Titolo | Clinical trials audit preparation [[electronic resource]] : a guide for good clinical practice (GCP) inspections // Vera Mihajlovic-Madzarevic |
| Pubbl/distr/stampa | Hoboken, N.J., : John Wiley, 2010 |
| ISBN | 0-470-92088-2 1-283-02484-5 9786613024848 0-470-57275-2 0-470-57274-4 |
| Descrizione fisica | 1 online resource (270 p.) |
| Disciplina | 615.5/80724 |
| Soggetti | Drugs - Testing - Auditing Medical audit |
| Lingua di pubblicazione | Inglese |
| Formato | Materiale a stampa |
| Livello bibliografico | Monografia |
| Note generali | Description based upon print version of record. |
| Nota di bibliografia | Includes bibliographical references and index. |
| Nota di contenuto | CLINICAL TRIALSAUDIT PREPARATION; CONTENTS; PREFACE; INTRODUCTION; Background History on Clinical Research Standards; GLOSSARY; CHAPTER 1 GOOD CLINICAL PRACTICE AND THERAPEUTIC PRODUCT DEVELOPMENT; 1.1 Good Clinical Practice in Clinical Research; 1.1.1 Definition; 1.1.2 GCP Compliance; 1.1.3 GCP Objectives; 1.1.4 Principles of ICH GCP; Clinical Trial Conduct; Risk Assessment; Subject's Rights and Safety; Background Information; Clinical Trial Protocol; Ethics Review and Approval; Medical Care of Trial Subject; Qualifications of Clinical Trial Personnel; Informed Consent Process Data ManagementPatient Confidentiality; Investigational Product Manufacturing, Handling, and Storage; Quality Assurance; 1.1.5 GCP Applicability; 1.2 Role of the Sponsor of a Clinical Investigation; 1.2.1 GCP: Responsibilities of a Sponsor of a Clinical Trial; 1.2.2 Essential Documents for the Clinical Trial; Retention of the Essential Documents for the Clinical Trial; Archiving of the Essential Documents for the Clinical Trial After Discontinuation of Development; Notification; Transfer of Data Ownership; Records Retention; 1.2.3 Investigator |

Selection; Investigator's Qualifications
Resources at the Investigator's Site Protocol and Investigator's Brochure;
Agreement with the Investigator/Institution; 1.2.4 Allocation of
Responsibilities; 1.2.5 Compensation to Subjects and Investigators;
Compensation to Subjects for Trial-Related Injuries; Other types of
Compensation to Trial Subjects; 1.2.6 Financing; 1.2.7
Notification/Submission to Regulatory Authorities; 1.2.8 Confirmation
of Review by IRB/IEC; 1.2.9 Information on Investigational Products;
1.2.10 Manufacturing, Packaging, Labelling, and Coding Investigational
Products
Characterization, Manufacturing, and Labeling of the Investigational
Product Storage Conditions; Packaging of the Investigational Product;
Coding and Decoding of the Investigational Product; Investigational
Product Changes and Bioequivalence Studies; 1.2.11 Supplying and
Handling Investigational Products; Supply; Investigational Product
Records; 1.2.12 Record Access; Verification of Patient Consent to
Record Access; 1.2.13 Safety Information; Safety Issues;
Communication of Safety Issues; 1.2.14 Adverse Drug Reaction
Reporting; Serious Unexpected Adverse Drug Reactions
SAE Reporting Compliance Safety Updates and Periodic Reports; 1.2.15
Monitoring; Purposes; Selection and Qualifications of Monitors;
Monitoring Strategies; Monitor's Responsibilities; Monitoring
Procedures; Monitoring Report; 1.2.16 Audit; Selection and
Qualifications of Auditors; Auditing Procedures; Site Selection Criteria
for Inspection; Reporting of Findings; Audit Certificate; 1.2.17
Noncompliance; 1.2.18 Premature Termination or Suspension of a Trial;
1.2.19 Clinical Trial/Study Reports; 1.2.20 Multicenter Trials
1.3 Role of the Institutional Review Board/Independent Ethics
Committee (IRB/IEC)

Sommario/riassunto

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 investig
