1.

Record Nr.	UNISALENTO991001705169707536
Titolo	Internet.kom : Neue Sprach- und Kommunikationsformen im World Wide Web / Sandro M. Moraldo (Hrsg.)
Pubbl/distr/stampa	Roma : Aracne, 2009-2011
ISBN	9788854829190 (v. 1.) 9788854838796 (v. 2.)
Descrizione fisica	2 v. : ill. ; 21 cm
Altri autori (Persone)	Moraldo, Sandro M.author
Soggetti	Linguaggio e internet Linguaggio elettronico Comunicazione - Linguaggio multimediale Comunicazione interattiva on line
Lingua di pubblicazione	Tedesco
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Contiene riferimenti bibliografici
Nota di contenuto	vol. 1. Kommunikationsplattformen -- vol. 2. Medialität, Hypertext, digitale Literatur

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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 SiteProtocol 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 ProductStorage 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 ComplianceSafety 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