Medical Research Management
Clinical Research Training Specialists

Drug/Biologic GCP & Monitoring

Course Description

This two-day seminar was designed for those who desire an overview of the drug/biologic approval process, the regulations that govern IND studies, the CRA's role in monitoring, and the FDA's role in auditing. It includes a review and discussion on recent monitoring and research site warning letters. It consists of a comprehensive review of the GCP obligations of the sponsor and the investigator, the regulations that protect the rights and safety of human subjects, and a glance at the similarities and differences between the FDA regulations and the ICH GCP (E6) guideline. It also reviews the key documents and elements of the clinical investigation at the site level, including the Investigator Study File and the Sponsor's Trial Master file as well as all the report requirements and the reporting timeframes.

Course Objectives

1. List the sponsor's, investigator's and IRB's responsibilities with investigational drug/biologic studies.
2. Discuss an overview of the monitoring activities performed for an investigational drug/biologic study.
3. Identify adverse and serious adverse event assessments, documentation, and reporting requirements.
4. Discuss the differences between the IND Application versus the NDA and BLA.
5. Recognize the purpose of the FDA BIMO Inspection program.

Contact Hours

Florida State Provider #50--1140, Provider approved by the California Board of Registered Nursing, Provider #CEP 13617 for 11 contact hours. Credits can be applied to ACRP certification.

Daily Agenda / Course Topics

Day 1

I. Overview of the Drug/Biologic approval Process
- IND Submission and Key Content
- Phases of Research
- NDA Submission and Key Content
- BLA Submission and Key Content

II. FDA GCP & ICH GCP
- FDA Guidance: Investigator Supervisory Role, Oct 2009
- FDA GCP: Sponsor Obligations 21CFR312
- ICH GCP (E6) Section 5: Sponsor
- FDA GCP: Investigator Obligations 21CFR312
- ICH GCP (E6) Section 4: Investigator
- Financial Disclosure by Clinical Investigators
- Electronic Records and Signatures
- FDA Form 1572 "Statement of the Investigator"
- Essential Documents: TMF and the ISF
- Study Drug Accountability
- Protocol and the Investigator Brochure

Day 2

III. Adverse Events
- Serious Adverse Events vs. Non-Serious Adverse Events: Recognizing and Reporting
- IND Safety Reports and SUSARS
- AE Drill Exercise

IV. Protection of Human Subjects
- Data Safety Monitoring Board
- IRB/IEC
- Informed Consent
- HIPAA: Research Authorization

V. Monitor Role and Responsibilities
- Monitoring Visit types & Strategies for Effectivene Visits
- Monitoring Responsibilities and Techniques
- MRM Step Monitoring Method, the 8 R's to Consent GCP Compliance Verification, the 5 R's to HIPAA Compliance Verification
- Monitoring Plan Content and Documentation

V. FDA's Bioresearch Monitoring Program (BIMO)
- BIMO program Objective and Function
- What happens during an audit?
- Typical FDA Audit Findings & their Classification
- Recent Monitoring Warning letters
- What is Fraud and Misconduct?

Who Should Take This Course

CRA's and other Drug/Biologic Industry professionals who want to gain knowledge about the drug/biologic approval process, GCP governing IND studies and the monitoring role.
- Course hours are from 9 AM - 4 PM
- Continental breakfast (8:30 AM) and lunch are provided

Fees / Registration

Location: ***MRM Headquarters, Coral Springs, FL***

Select a date:

☐ **Call 877-633-3322 for more information**

Fees: $995.00 (15% discount for 3 or more)

Register by phone at 1-877-633-3322, online, or complete the information below and fax to 800-763-4103

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Mail to: **Medical Research Mgt; 11555 Heron Bay Blvd, Ste 102 Coral Springs, FL 33076**

Cancellations and Substitutions

Cancellations by registrants must be provided in writing prior to the start date of the seminar, such registrants shall receive a credit voucher toward a future MRM seminar. Companies may substitute someone registered with another participant at any time. MRM reserves the right to cancel a seminar due to poor enrollment or acts of nature and shall not be responsible for any airfare, hotel, or other costs. MRM shall offer a credit voucher to a future seminar or a complete refund for MRM Seminar cancellations. Seminar topics and speakers may be subject to change without any prior notice.