FDA BIMO INSPECTION PREPARATION

Medical Research Management
Clinical Research Training Specialists

Course Description:

The FDA's Bioresearch Monitoring (BIMO) Program is an agency-wide system of inspections and data audits designed to monitor the conduct and quality of clinical studies at all levels - investigator sites, sponsors, pre-clinical laboratories and IRBs. Inspections may be planned or unannounced, so it is important to maintain inspection readiness at all times. This course is designed to guide monitors/auditors and investigator site personnel through the process of preparing for a BIMO inspection.

COURSE OBJECTIVES

- Recognize the FDA Bioresearch Monitoring (BIMO) Program purpose
- Discuss type of inspections and what occurs at the investigator site versus sponsor level.
- Describe the techniques and planning for BIMO inspection preparation.
- Examine GCP issues and its management during BIMO inspection.

COURSE AGENDA & TOPICS

Day 1

- The Bioresearch Monitoring Program-Objectives and Regulatory Background
- Types of Inspections
- Compliance Program Guidance Manuals
- What to expect during a Sponsor/CRO and Investigator Inspection

Day 2

- Developing a Preparation Plan and Tools/Techniques
- GCP issues and their management during the inspection.
- Preparing for an Investigator Site Inspection
  - ✓ Safety
  - ✓ Deviations
  - ✓ Investigator Product Accountability
  - ✓ Regulatory Binder
- Preparing for Sponsor/CRO Inspection
  - ✓ Safety
  - ✓ Deviations
  - ✓ Investigator Product Accountability
  - ✓ Trial Master File

REGISTRATION

Fees: $1,195.00 (15% discount for 3 or more)

Make checks payable to: **Medical Research Management**

Mail to: Medical Research Mgt; 6250 Coral Ridge Drive; Coral Springs, FL 33076
Register by phone at **1-877-633-3322,** Online at **CRA-Training.com,**
or complete and digitally sign this form and email to **info@CRA-Training.com**

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

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