

Course Description

Monitoring is a sponsor's regulatory obligation, therefore, the monitoring report and follow up visit letters are the regulatory documents to demonstrate the sponsor's compliance with this obligation. These reports may be audited by the FDA and should be written to cover all monitoring activities in the monitoring plan, in a neutral tone, and document any GCP non-compliance using the concept of (CAPA) Corrective Action and Preventative Action Plan. The documentation using CAPA demonstrates the securing of compliance of that investigator. The participant of this one-day program will be asked to write mock reports covering several GCP non-compliance using CAPA plans as a resolution. In addition, we will learn the limited circumstances of when and how to write a Memo-to-File (Note-to-File).

Course Objectives

1. Identify the key content of a report.
2. Discuss documenting using Corrective Action Plans and Preventative Action Plans for GCP issues.
3. List the key documentation requirements of a monitoring report relating to GCP non-compliance.
4. Recognize the writing style used for a monitoring report, the follow up visit letter, and a Memo to File.

Contact Hours

Florida State Provider #50-11408, Provider approved by the California Board of Registered Nursing, Provider #CEP 13617 for 6 contact hours. Credits can be applied to ACRP certification.

Daily Agenda / Course Topics

Day 1

I. Monitoring Regulatory Obligation and Guidance

- 21 CFR 312 and 21 CFR 812
- FDA Guidelines Drug/Biologic
- ICH GCP Section 5: Sponsor
- Monitoring Reports are a Regulatory Document
 - ICH GCP (E 6) Section 5 (5.18.6a)
 - FDA access to reports
 - FDA monitoring warning letters

II. Monitoring Report Content

- ICH GCP (E 6) Section 5, 5.18.6b-c
- Types of Issues documented in a Monitoring Report
- GCP versus Non-GCP
- GCP issues should have compliance secured by using Corrective Action and Preventative Action Plans (CAPA)
- Issue/Action/Resolution format in reports

III. Report Writing Style

- Check lists vs. Narrative comments
- Third Person vs. First Person
- Neutral wording, Facts and Findings
- Documentation Considerations on Key GCP Areas
Source Documentation, Informed Consent, IRBs, SAEs, Protocol Violations
- Documentation Considerations for Sites that are Transferred to a CRA

IV. Report Writing Drill

- Review Examples of Good vs. Bad Monitoring Reports
- Write a Report using the Concept of CAPA for GCP related issues Identified in the Monitoring Action Items
- When and How to write a Memo to File relating to CAPA Issues

Who Should Take This Course

Anyone in clinical research that writes and/or reviews monitoring reports and follow up visit letters.

- 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:

- October 26, 2011
- March 28, 2012
- October 24, 2012

Fees: \$595.00 (15% discount for 3 or more)

Register by phone at 1-877-633-3322, online, or complete the information below and fax to 954 -346-2791

Name: _____

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Mail to: **Medical Research Management; PO Box 8629; Coral Springs, FL•33075**

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.