

Seminars

Advanced Quality Monitoring

Course Description:

The starting point for quality monitoring is a systematic approach that includes the CRA's organization and application of methods to facilitate standardization and assessment, complying with GCP, ICH, and HIPAA. Developing monitoring skills involves learning valuable time management tips and acquiring tools that facilitate consistency in performing the responsibilities of a CRA. The student will learn how to write professional and effective monitoring reports and follow-up visit correspondence. This 3-day course is enhanced by the hands-on training that utilizes simulated case studies, an investigator study file, and report writing exercises. These techniques can be applied to all studies whether they are drug, device, or biologic.

Course Fee: \$1,195

16.5* CE Hours

Coordinating a Clinical Trial

Course Description:

This two-day course is designed to provide a brief overview of clinical research with a comprehensive review of FDA GCP and ICH GCP (E6) and the fundamental elements involved in coordinating a clinical trial. It provides practical tips and suggestions that can be applied to promote a GCP and HIPAA compliant clinical trial, including preventative measures and problem solving techniques of some of the most common GCP non-compliance issues.

Course Fee: \$995

11* CE Hours

Drug/Biologic GCP and Monitoring

Course Description:

This 2-day seminar is designed for those who desire an understanding of the drug/biologic approval process, the regulations that govern IND studies, and the CRA's role in monitoring these studies. The course provides a solid overview of the drug/biologic development process, presenting GCP obligations of the sponsor, investigator, and IRB together with a review of the regulatory documents, study documents, and drug accountability. A comprehensive review of the roles and responsibilities of the monitor and the types of site visits will be discussed along with an example of FDA audit findings.

Course Fee: \$995

11* CE Hours

Medical Device GCP and Monitoring

Course Description:

This 2-day seminar is designed for those who desire an understanding of the device approval process, the regulations that govern IDE studies and the CRA's role in monitoring. The course consists of a comprehensive overview of the medical device development process and the GCP obligations of the sponsor, investigator, and IRB; including the regulatory documents, study documents, and device accountability. A comprehensive review of the role and responsibilities of the monitor, the type of site visits, and a discussion on example FDA audit findings.

Course Fee: \$995

11* CE Hours

Writing Professional Monitoring Reports

Course Description:

Monitoring is a sponsor's regulatory obligation therefore the monitoring report and follow up visit letter 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 how to write Memo-to-Files that are left at the site to explain an issue or provide clarification.

Course Fee: \$595

6* CE Hours

Florida State Provider # NCE 3423 / California State Provider # CEP 13617

*Continuing education credits are available for RN's and may be applied to ACRP / SoCRA certification.



SEMINAR REGISTRATION APPLICATION

Coordinating a Clinical Trial:

- Jan 8-9, 2009
- Apr 16-17, 2009
- Jun 25-26, 2009
- Aug 13-14, 2009
- Oct 15-16, 2009
- Dec 10-11, 2009

Writing Professional Monitoring Reports:

- Jan 14, 2009
- Apr 29, 2009
- Sep 9, 2009

Advanced Quality Monitoring:

- Jan 15-17, 2009
- Apr 30-May 2, 2009
- Sep 10-12, 2009

Drug/Biologic GCP and Monitoring:

- Feb 12-13, 2009
- Jun 18-19, 2009
- Oct 1-2, 2009

Medical Device GCP and Monitoring:

- Mar 12-13, 2009
- Aug 20-21, 2009
- Dec 3-4, 2009

Location:

Coral Springs, Florida

Hotel Info:

Marriot Coral Springs Hotel

2009 MRM Student nightly rate:

January 1 - March 31, 2009 - \$149.00

April 1 - December 31, 2009 - \$109.00

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

Name: _____

Address: _____

City: _____ State: _____ Zip _____

Phone: _____

Email: _____

Company Name: _____

Method of Payment:

Company Check MasterCard VISA Amex Discover

Credit Card # _____

Name on card _____

Billing Address: (Same as above) _____

City: _____ State: _____ Zip _____

Expiration Date: _____

Signature _____

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

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.