Medical Research Management
Clinical Research Training Specialists

ADVANCED QUALITY MONITORING

Course Description:

This three-day seminar is the starting point for quality monitoring. MRM's 3-step monitoring method 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. This course is enhanced by the hands-on training that utilizes simulated case studies, and an investigator study file. These techniques can be applied to all studies whether they are drug, device, or biologic.

This course is designed for individuals with a minimum of 6 months clinical research experience. CRAs that do not have formal training, but are interested in learning skills that will enhance their monitoring activities and those who are transitioning into a CRA position will benefit from this course.

- Course hours are from **9 AM - 4 PM**
- Continental breakfast (8:30 AM) and lunch are provided

COURSE AGENDA & TOPICS

Day 1

- The 2016 ICH GCP Addendum and how it affects monitoring practice
- Verifying informed consent GCP compliance and medical record audit using the MRM Step Method™.
- Current industry practice on the use of source worksheets and applying the ALCOA standard.
- Using monitoring tools for systematic review of AEs/SAEs, deviations and action items
- Developing CAPA plans to address GCP non-compliance and determining when escalation is required

Day 2

II. Case Study # 1:

- Applying Monitoring Technique and Tools
- Monitor SV1, SV2, V1, AEs, and CC meds
- Case Study # 1 – Review and Discussion of Deficiencies, Remedies, and Prevention (CAPA)

III. Case Study # 2 – Applying Monitoring Technique and Tools

- Monitor SV1, SV2, V1, AEs, and CC meds
- Case Study #2 – Review and Discussion of Deficiencies,Remedies, and Prevention (CAPA)
- Potential Issue/Problem Exercise

Day 3

IV. Investigator Study File Review including the Regulatory reason and different SOP requirements

- ISF Case Study – Monitoring
- ISF Case Study – Review and Discussion of Deficiencies,Remedies, and Prevention

V. Queries and Action Items

- Writing effective queries and action items

REGISTRATION

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

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

Mail to: Medical Research Mgt; 11555 Heron Bay Blvd, Ste 102; 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**

Select a date: ❑ October 10-12, 2018 ❑ TBA, 2018

Name: _____

Address: _____

City/State _____ Zip _____

Tel: _____ Fax: _____

Email: _____

Company Name: _____

Method of Payment:
❑ Company Check ❑ MasterCard ❑ VISA ❑ Amex ❑ Discover

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Security Code: _____ Expiration Date: _____

Signature _____

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. In the event that MRM cancels the seminar, MRM will provide a complete refund or offer a credit voucher that can be used for a future seminar.

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