AUDITING CLINICAL TRIALS

Medical Research Management
Clinical Research Training Specialists

Course Description:

Auditing is an essential part of clinical research quality management. Auditing requires a thorough comprehension of the application of GCP to apply as a standard to any observations identified. This class focuses on a systematic approach to auditing, using audit tools, applying standards to observations, and the corrective action plan recommendations. A repository of audit observations and recommendations are reviewed to enhance the learning experience and expand knowledge. Simulated case studies are used along with key line item data to develop the auditing skill set. This 3-day course is designed for new auditors or for experienced research professionals who want to add auditing to their skill set. The course is applicable to drug, biologic, and medical device studies.

LEARNING OBJECTIVES

- Describe the GCP audit process for Investigators and Sponsors/CRO.
- Discuss the application of relevant GCP standards to audit observations/findings.
- Implement the MRM Auditing techniques and tools to applying standards to observations.
- Identify the different pathways for observations/findings resolution based on type of findings.
- Develop and write audit reports
- Identify root causes of deficiencies and develop and implement corrective and preventative action (CAPA) plans

COURSE AGENDA & TOPICS

Day 1

- Overview of Investigation Product Development, FDA and ICH GCP obligations.
- The Types of Clinical Research Audits
- The Auditing System and the Audit Plan

Day 2

- Identifying and Writing Audit Observations
- Classifying Audit Observations
- Observations and Recommendation and/or CAPA Plans
- Audit Drills to Develop Skills

Day 3

- Hands On-Application of Auditing via Case Study Scenarios
- Includes selecting observation standards and recommendations

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

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**

Select a date: ❑ May 1-3, 2019

Name: _____

Address: _____

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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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