Medical Research Management
Clinical Research Training Specialists

Course Description:

This seminar was designed for medical device professionals including those in the In-Vitro Diagnostics Industry. It provides an overview of the device approval pathway for class 1, 2, 3 medical devices as well as IVD/LDT devices. It provides key clinical trial elements and an overview of monitoring including the FDA Guidance on a Risk-based monitoring approach to clinical research.

This seminar also provides a solid review of monitoring activities using a focused quality approach and resolving GCP issues using CAPA plans. It consists of a comprehensive review of the GCP obligations of the sponsor and the investigator, the FDA Guidance: Investigator Supervisory Role, the regulations that protect the rights and safety of human subjects. A glance at the similarities and differences between the FDA regulations and the ICH GCP (E6) guideline, and a review of some key safety definitions from ISO 14155-1:2011. It additionally reviews the key documents and elements of the clinical investigation at the site level, including the Investigator Study File and the Sponsor's Trial Master File, as well as all the report requirements and the reporting timeframes. Informed Consent, CAPA and AE Exercises are performed to enhance learning.

COURSE AGENDA & TOPICS

Day 1

I. Overview of the Medical Device Approval Process

- History/Legislation
- Device Classification (Class 1,2, and 3)
- IDE Submission
- Overview of the Marketing Clearance, including De Novo
- 510 k (Traditional, Special, Abbreviated, de novo)
- PMA, HDE and PDP
- Overview of In-Vitro Diagnostics including Analytic Special Reagents, General Purpose Reagents, and Laboratory Developed Tests.

II. FDA GCP and ICH GCP

- FDA GCP: Sponsor and Investigator Obligations 21 CFR 812
- FDA Guidance: Investigator Supervisory Role, October 2009
- Overview of ICH GCP (E6) Section 5: Sponsor
- FDA GCP: Investigator Obligations 21 CFR 812
- Overview of ICH GCP (E6) Section 4: Investigator
- Financial Disclosure by Clinical Investigators (21 CFR 54) and the recent FDA Guidance.

Day 2

III. Key Clinical Trial Elements

- Investigator Agreement
- Regulatory Documents: Investigator File versus the Sponsor's Trial Master File
- Clinical Investigational Plan Content
- Study Device Accountability
- Adverse Event definitions (ICH GCP E2A, and ISO 14155-1:2011): Adverse Device Effects, Serious Adverse Device Effects, & Serious Adverse Events
- Unanticipated Adverse Device Effects
- AE Drill Exercise

IV. Protection of Human Subjects

- IRB Role and Responsibility
- Informed Consent Requirements, the use of Exceptions, & Documentation
- ICH GCP (E6) Consent Similarities and Differences
- HIPAA: Research Authorization Requirements
- Informed Consent Compliance Exercise

V. Monitor Role and Responsibilities

- Risk Based Monitoring – FDA Guidance
- Monitoring Visit Types & strategies for Effective Visits
- Monitoring Responsibilities and Techniques including CAPA plan usage
- MRM Step Monitoring Method, the 8 R's to Consent GCP Compliance Verification, the 5 R's to HIPAA Compliance Verification
- Monitoring Plan Content and Documentation

VI. Fraud and Misconduct

- What is Fraud and Misconduct?
- Fraud prevention

LEARNING OBJECTIVES

- List the sponsor's, investigator's and IRB's responsibilities in medical device studies and human subject protections.
- Discuss the monitoring activities performed for an investigational device study.
- Identify adverse device effects and their reporting requirements.
- Discuss the differences between the IDE Application versus the 510K and the PMA.
- Recognize the differences in the regulatory pathway for In-Vitro Diagnostics including Laboratory Developed Tests.
- List common GCP issues and methods of securing compliance.

REGISTRATION

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

Fees: $995.00 (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: ❑ March 8-9, 2018 ❑ TBA, 2018

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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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