

## 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 also 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. MRM provides each participant with a CD-ROM Regulatory Reference.

## Course Objectives

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

### Contact Hours

Florida State Provider #50-11408, Provider approved by the California Board of Registered Nursing, Provider #CEP 13617 for 11 contact hours. Credits can be applied to ACRP certification.

## Daily Agenda / Course 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

## Who Should Take This Course

CRA's and other Device Industry professionals who want to gain knowledge about the device approval process, GCP governing IDE studies, and the monitoring role.

- 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:**

- January 12-13, 2012     March 22-23, 2012 .....  
 July 19-20, 2012         October 18-19, 2012

**Fees:** \$995.00 (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

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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.