



*Third Program
In The Series*

Ensuring Subject Protection and Scientific Integrity

Course Introduction

Monitoring of Clinical Studies

- Introduction
- Site Initiation Visit: Initiation Visit Planning
- Site Initiation Visit: Conducting the Initiation Visit
- Site Initiation Visit: Initiation Visit Follow-up
- Routine Monitoring Visits
- How Much Data Needs To Be Monitored?
- Final Monitoring Visit
- Changing Data in Case Report Forms
- Monitoring Reporting Requirements

Clinical Quality Assurance (CQA)

- Introduction
- Typical CQA Group
- CQA Audits
- GCP Audits
- Data Evaluation
- Investigator Site Audit

FDA Inspections

- Clinical Trial Monitoring
- Noncompliance Issues
- Regulations Guiding Inspections
- Non-US Inspections
- What FDA Will Inspect
- Common Deficiencies
- Inspection Results
- Managing FDA Inspections
- IRB/EC and CRO Inspections

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