Practical Clinical Trial Design

Course Objective: Discuss current issues and problems in the implementation of GCP regulations. Apply principles of GCP to the conduct of clinical trials in the US and other countries. Manage GCP documentation to ensure regulatory compliance. Strategically plan, prepare for, and organize an FDA GCP inspection. Recognize the various types of clinical trial fraud and misconduct and the ramifications, and describe the quality assurance audit process.

In addition, participants will learn the current status of the requirements in the European Union, Japan, the United States, and Canada. Insights into the procedures for achieving compliance will be gained.

Course Description: The efficacy and safety of a new drug are demonstrated by phase I to IV clinical trials. GCP is an ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. In order to use clinical data internationally and for registration purposes all clinical trials must conform to GCP standard.

This course provides in detail the principles and practices in the conduct of a clinical trial and is designed to provide the attendee with thorough knowledge of the following topics:

- How drugs are discovered and developed for marketing approval
- The four different study phases of clinical research
- What constitutes Good Clinical Practices (GCP)
- The principles of ICH GCP
- The IRB/IEC’s composition and role/responsibilities
- The IRB study review & approval process
- The role and responsibilities of the investigator & study site
staff

- The role and responsibility of the sponsor
- The history of the FDA and their role & responsibilities
- Which sections of 21 CFR govern conduct of clinical studies
- The purpose for an IND and its composition
- How INDs are filed, reviewed, approved & amended
- The IND reporting requirements
- The requirements for Informed Consent
- How to review an Informed Consent form for compliance
- The process for Informed Consent review & approval
- The administration of subjects Informed Consent
- The different types of study Monitoring visits & tasks for each
- Adverse Events - the types and reporting requirements
- How to perform Drug Accountability & compliance
- How to manage study supplies
- How to detect and deal with Fraud
- The purpose and composition of the NDA
- How NDAs are filed, reviewed and approved
- Sponsor responsibilities after approval
- How to review study documents & determine compliance
- How to review Case Report Forms and determine adherence to protocol
- How to perform Source Document Verification

**Course Outline:**

- The Principles of Good Clinical Practices (GCP)
- Role of GCP in clinical research
- Regulatory requirements specific to GCP
- Data requirements specific to GCP
- GCP audits/inspections
- Quality Control and Quality Assurance process as a method of ensuring data quality
- The Conduct of a clinical trial
  - Site initiation
  - Site monitoring
  - Site closure