



## Good Clinical Practices (GCP)

**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.

**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