

GCP and Essential Guidelines

Duration:15 -20 Days

Course Content

- Background
- History of Clinical Trial Legislation
 - Code of Federal Regulations
 - ICH GCP
- Overview of ICH GCP
 - Roles and Responsibilities
 - IRB/IEC
 - Investigator
 - Sponsor
 - Monitor
 - Protocol and amendments
 - Investigators Brochure
 - Essential Documents
 - Ultimate responsibilities under ICH
- Europe
 - EU Clinical Trials Directive
 - EU GCP Directive
 - GMP Directive and Annexe 13
- The USA
 - FDA Code of Federal Regulations Title 21 Part 312
 - FDA 21 CFR part 11