GOOD CLINICAL PRACTICES 2 DAYS

MODULES TO BE COVERED

1. Introduction to ICH - GCP & The principles of ICH-GCP
2. Key Players in Clinical Trials
3. Regulatory Authorities & Ethics Committees
4. Informed Decision making for health research
5. The Drug Development Process
6. The Study Protocol & Protocol Compliance
7. Investigational Product Management
8. Adverse Events and Safety Reporting
9. Principles of Documentation
10. Essential Documents & Site Organization
11. Monitoring, Audits & Inspections