



GOOD CLINICAL LABORATORY PRACTICES

3DAYS

MODULES TO BE COVERED

1. Organization and Personnel
 - i. Trial Facility Management Responsibilities
 - ii. Analytical Project Manager Responsibilities
 - iii. Trial Staff Responsibilities
2. Facilities
 - i. Trial Facilities
 - ii. Archive Facilities
 - iii. Waste Disposal
3. Equipment, Materials and Reagents
 - i. Equipment
 - ii. Material
 - iii. Reagents
4. Standard Operating Procedures (SOPs)
 - i. General
 - ii. Application
5. Planning of the work
 - i. Analytical Plan
 - ii. Content of the Analytical Plan
6. Sub-Contracting
7. Trial Materials
 - i. Receipt
 - ii. Chain of Custody
 - iii. Logistics
8. Conduct of the Work
 - i. General
 - ii. Computer Systems
 - iii. Method Validation
 - iv. Processing trial materials
9. Reporting Results
 - i. General
 - ii. Analytical Report
 - iii. Content of the Analytical Report
 - iv. Analytical results
10. Quality Control
11. Quality Management
 - i. Introduction to Quality Management
 - ii. Standards for Quality Management
 - iii. Quality Management Plan
 - iv. Internal Audits
 - v. Testing Turnaround Times
 - vi. Laboratory Communication Plan
12. Standards for External Quality Assurance
13. Storage and Retention of Records
14. Confidentiality