GCP Training Course for Sponsors and Investigators

Module 1 – General (for Sponsors and Investigators) *1.5 h*

1. Types of Clinical Trials (Phase I – IV), Randomized, Blinded, etc.
2. GCP History
3. The Principles of ICH GCP
4. Institutional Review Boards - Responsibilities, Composition, Function and Operation

Module 2 – Investigator (for Investigators) *6 h*

1. Investigator's Qualifications & Agreements
2. Adequate Resources
3. Medical Care of Trial Subjects
4. Communication with IRB
5. Compliance with Protocol
6. Investigational Product(s)
7. Randomization Procedures and Unblinding
8. Informed Consent of Trial Subjects
9. Records and Reports (Source Data Management and CRF Completion)
10. Progress Reports
11. Safety Reporting
12. Premature Termination or Suspension of Trial
13. Final Report(s) by Investigator

Module 3 – Sponsor (for Sponsors)

1. Quality Assurance and Quality Control
2. Contract Research Organization
3. Medical Expertise
4. Trial Design
5. Trial Management, Data Handling and Record Keeping
6. Investigator Selection
7. Allocation of Responsibilities
8. Compensation to Subjects and Investigators
9. Financing
10. Notification of Competent Authorities

11. Confirmation of Review by IRB
12. Information on Investigational Product(s)
13. Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)
14. Supplying and Handling Investigational Product(s)
15. Record Access
16. Safety Information
17. Adverse Drug Reaction Reporting
18. Monitoring
19. Audit
20. Noncompliance
21. Premature Termination or Suspension of a Trial
22. Clinical Trial/Study Reports
23. Multicenter Studies

Module 5 - Clinical Trial Protocol and Protocol Amendments (for Sponsors)

1. Clinical Trial Protocol and Protocol Amendments
2. Background Information
3. Trial Objectives and Purposes
4. Trial Design
5. Selection and Withdrawal of Subjects
6. Treatment of Subjects
7. Assessment of Efficacy
8. Assessment of Safety
9. Statistics
10. Direct Access to Source Data/Documents
11. Quality Control and Quality Assurance
12. Ethics and Informed Consent Content
13. Data Handling and Record Keeping
14. Financing and Insurance
15. Publication Policy
16. Supplements

Module 6 - Investigator's Brochure (IB) (for Sponsors)

1. Investigator's Brochure
2. General Considerations
3. Contents of the IB

Module 7 - Essential Documents for the Conduct of a Trial (for Sponsors and Investigators) *1 h*

1. Essential Documents for the Conduct of a Trial
2. Before the Clinical Phase of the Trial
3. During the Clinical Conduct of the Trial
4. After the Completion or Termination of the Trial