



Good Clinical Practice: Understanding the Basics

By the end of each module you'll be able to accomplish the following objectives:

Module 1: Primary Principles of GCP

- Define the term “Good Clinical Practice” and explain why GCPs exist
- List agencies that establish GCP regulations and guidances
- List events that had significant impact on the U.S. federal regulations for the protection of human research subjects

Module 2: FDA Regulation of Clinical Studies

- List FDA regulations specific to drugs and biologics versus devices as well as regulations common to all
- Explain the difference between Significant Risk Devices and Non-Significant Risk Devices
- Explain how FDA regulations treat In Vitro Diagnostic Devices

Module 3: Good Clinical Practice Guidelines

- Relate GCP principles to FDA regulations and international guidances
- Describe the FDA GCP Compliance Program, including regulatory options to address deficiencies found during inspections

Module 4: Lifecycle of a Clinical Trial and the Essential Documents

- List the steps within the lifecycle of a clinical trial
- Identify Essential Documents that are to be collected and where they are to be maintained
- Describe documentation deficiencies commonly identified in Warning Letters issued by the FDA

Module 5: Clinical Study Roles and Responsibilities

- Identify the roles of key parties involved in clinical research
- List Sponsor responsibilities
- List IRB responsibilities
- Define some key terms related to the Sponsor's role
- List Clinical Investigator responsibilities

Module 6: The Informed Consent Process

- Define “informed consent”
- Identify key components of informed consent
- Recognize errors in deficient informed consent forms

Module 7: Safety Reporting

- Define and distinguish important clinical study adverse event safety terms
- List FDA adverse event reporting criteria, including those requiring expedited reporting

Module 8: Investigational Product Accountability

- Define investigational product and state drug and device respective labeling requirements in the U.S.
- List the steps in the investigational product accountability lifecycle
- List important considerations to achieve effective product accountability
- Describe tips for successful audits focused on product accountability

Module 9: Internal Audits

- Explain what a document audit is and what should be examined during this type of internal audit
- Explain what a process audit is and what should be examined during this type of internal audit
- Explain what a system audit is and what should be examined during this type of internal audit

Module 10: Auditing Vendors for GCP Compliance

- List different types of vendor audits and general audit considerations
- Describe ways in which to assess vendor compliance
- Describe auditing standards for computer systems under FDA regulations

Module 11: Clinical Investigator Site Audits

- Identify the reasons for conducting a CI audit
- Properly prepare for an audit
- Properly conduct an audit
- List the follow-up steps that should be performed after conducting a CI audit

Module 12: Hosting Regulatory Inspections

- Describe the FDA Bioresearch Monitoring Program
- Describe how to prepare for, conduct and follow-up on an FDA inspection
- List potential results of an FDA inspection

Module 13: Fraud and Misconduct

- Define and differentiate fraud versus misconduct
- Describe three important cases of clinical investigator fraud in the U.S.
- Uncover fraud and misconduct during the course of an audit

Module 14: ICH E6 Clinical Investigator Responsibilities

- List Clinical Investigator (CI) qualifications required by ICH E6
- List some general responsibilities of the CI as established by ICH E6
- List ICH E6 requirements of the CI as they relate to informed consent
- Describe how source data and all trial-related documents are to be retained in accordance with ICH E6
- Define and distinguish between various adverse event/adverse drug reaction terms as stated in ICH E6