Advanced Good Clinical Practice (GCP) and Auditing Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

This intensive course provides an in-depth, practical exploration of Advanced Good Clinical Practice (GCP) principles, focusing on the critical aspects of clinical trial Auditing and Quality Assurance (QA). In an increasingly complex global Regulatory Landscape, this training is essential for professionals seeking to master ICH E6(R3) compliance, Data Integrity, and the ethical oversight of clinical research. Participants will gain actionable insights into Risk-Based Quality Management (RBQM), advanced auditing techniques, and the latest regulatory expectations, preparing them to confidently lead and conduct audits that ensure the safety and rights of human subjects while upholding the credibility of research data.

Advanced Good Clinical Practice (GCP) and Auditing Training Course is designed to bridge the gap between foundational GCP knowledge and its real-world application in complex clinical environments. Through a blend of theoretical instruction, Interactive Workshops, and extensive Case Studies, attendees will learn to identify and mitigate high-impact Compliance Risks, formulate clear audit findings, and implement effective Corrective and Preventive Actions (CAPA). By focusing on System Audits and Vendor Oversight, the course empowers participants to not only meet but Exceed the stringent requirements of regulatory bodies such as the FDA and EMA, thereby safeguarding their organizations against inspectional findings and ensuring the highest standards of Clinical Research Quality.

Programme Curriculum

Advanced Good Clinical Practice (GCP) and Auditing Training Course

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Course Objectives

1. Master the principles and practical application of the ICH E6(R3) Guideline revisions.
2. Design and execute effective Risk-Based Auditing strategies for clinical sites, systems, and vendors.
3. Evaluate Quality Management Systems (QMS) within a clinical trial framework, aligning with current RBQM approaches.
4. Conduct in-depth audits of the Trial Master File (TMF) and Electronic TMF (eTMF) for completeness and regulatory compliance.
5. Identify, document, and interpret critical GCP Non-Compliance issues and potential Scientific Misconduct.
6. Formulate clear, concise, and defensible Audit Reports that drive actionable change.
7. Develop, implement, and verify the effectiveness of robust CAPA plans derived from audit findings.
8. Analyze and prepare the organization's response to Regulatory Inspection Findings
9. Assess and audit Computerized Systems and Electronic Data Capture (EDC) for Data Integrity and GAMP 5 compliance.
10. Implement effective Vendor Qualification and Oversight strategies for Contract Research Organizations (CROs) and service providers.
11. Apply advanced audit techniques to complex areas such as Investigational Product (IP) Management and Safety Reporting.
12. Navigate the ethical and regulatory challenges of Informed Consent documentation and auditing in vulnerable populations.
13. Lead internal and external audit teams, fostering a culture of Proactive Compliance and continuous quality improvement.

Target Audience

1. Clinical Quality Assurance (CQA) Auditors and Specialists.
2. Clinical Research Associates (CRAs) and Clinical Trial Managers (CTMs).
3. Regulatory Affairs Professionals.

4. Clinical Investigators and Study Coordinators.
5. TMF and Data Management Personnel.
6. Pharmacovigilance and Safety Specialists.
7. Sponsor/CRO Management
8. IT/System Validation personnel.

Course Modules

Module 1: The Evolving Regulatory Landscape and ICH E6(R3)

- Understanding the shift from ICH E6(R2) to the principles-based approach of ICH E6(R3).
- Focus on the new emphasis on Quality by Design (QbD) and Proportionality.
- Review of current FDA and EMA inspectional trends and focus areas.
- Analysis of key differences and harmonization in global GCP regulations
- Case Study: Global Trial Regulatory Compliance. Analyzing discrepancies in consent requirements and reporting between the US, EU, and Asia.

Module 2: Risk-Based Quality Management (RBQM) in Auditing

- Integrating RBQM principles into the audit program lifecycle.
- Techniques for risk Identification, Assessment, and Prioritization in clinical trials.
- Developing a dynamic, Risk-Based Audit Plan that optimizes resource use.
- Establishing Critical Data and Processes for focused auditing efforts.
- Case Study: RBQM Plan Development. Designing an audit strategy for a high-risk decentralized clinical trial (DCT).

Module 3: Advanced Auditing Techniques and Methodology

- Differentiating between routine audits, For-Cause Audits, and system audits.
- Mastering the phases of an audit: Planning, Execution, Reporting, and Follow-up.
- Effective document review and Source Data Verification (SDV)/Source Data Review (SDR) strategies.
- Techniques for conducting effective Investigator Interviews and managing auditor bias.
- Case Study: For-Cause Audit Strategy. Developing an audit plan to uncover suspected fraud at a high-enrolling site.

Module 4: Auditing the Trial Master File

- Deep dive into the Essential Documents required by GCP and regulatory bodies.
- Auditing the TMF/eTMF structure, completeness, timeliness, and accessibility
- Compliance with the TMF Reference Model and sponsor/CRO oversight responsibilities.
- Auditing the use of electronic systems for TMF management and archiving.
- Case Study: eTMF Audit. Auditing a provided eTMF index and identifying missing documents and non-compliance issues.

Module 5: Auditing Clinical Investigator Sites

- Developing a comprehensive Site Audit Checklist focused on high-risk areas.
- In-depth review of Investigator Responsibilities.
- Auditing the Informed Consent Process (ICF), ethics committee/IRB submissions, and communication.
- Assessing Drug Accountability and Investigational Product (IP) management systems.
- Case Study: Site Delegation. Finding that unqualified staff are performing critical procedures; documenting the observation and proposing CAPA.

Module 6: System and Process Audits

- Defining and scoping a System Audit across multiple trials and departments.
- Techniques for Process Mapping and gap analysis in a QMS context.
- Auditing standard operating procedures (SOPs) and internal quality controls.
- Focus on auditing the Monitoring Process and the effectiveness of CRAs.
- Case Study: Monitoring Process Audit. Auditing the sponsor's monitoring department, finding inconsistent report quality, and recommending system-level improvements.

Module 7: Vendor Qualification and Oversight Audits

- Regulatory expectations for Sponsor Oversight of Contract Research Organizations (CROs) and vendors.
- Developing a Vendor Qualification Audit framework and checklist.
- Auditing specialized vendors.
- Managing audit findings and CAPA implementation across multiple contract organizations.
- Case Study: CRO Oversight Failure. Auditing a sponsor and finding they relied solely on the CRO's QA plan; developing a risk-based oversight plan.

Module 8: Data Integrity and Computerized Systems Validation

- Applying the ALCOA+ principles to clinical trial data management.
- Auditing Computerized Systems Validation (CSV) documentation
- Assessing the audit trail, electronic signatures, and system access controls
- Focus on auditing EDC systems and the process of data lock/transfer.
- Case Study: EDC Audit Trail. Auditing an EDC system and uncovering unexplainable data changes from a non-validated user role; documenting the data integrity breach.

Module 9: Auditing Safety Reporting and Pharmacovigilance

- GCP and regulatory requirements for Serious Adverse Event (SAE) reporting timelines and documentation.
- Auditing the investigator site's and sponsor's safety reporting SOPs and processes.
- Verifying consistency between Source Documents, CRFs, and the Safety Database.
- Auditing the ongoing safety evaluation and DSMB/IDMC interactions.
- Case Study: Safety Reporting Lag. Auditing a trial and finding a significant lag in SAE reporting to the sponsor/regulatory bodies; formulating a critical finding and CAPA.

Module 10: Non-Compliance, Fraud, and Scientific Misconduct

- Defining and differentiating between Non-Compliance, Serious Breaches, and willful misconduct.
- Techniques for detecting Data Falsification and fabrication during an audit.
- The auditor's role in Whistleblower reports and investigating for-cause issues.
- Procedural requirements for reporting misconduct to the sponsor and regulatory bodies.
- Case Study: Image Duplication. A site's pre-clinical images appear duplicated; developing an investigative audit plan to determine the scope of fraud.

Module 11: Audit Report Writing and Communication

- Structuring an effective, objective, and non-confrontational Audit Report.
- Techniques for writing clear, evidence-based Audit Observations and Deficiencies.
- Assigning severity and classifying audit findings based on Risk to Human Subjects and Data Integrity.

- Best practices for presenting and communicating critical findings to auditees and management.
- Case Study: Drafting a Critical Finding. Rewriting a subjective observation into a professional, factual, and defensible critical finding.

Module 12: CAPA Development and Follow-up

- Principles of effective Corrective and Preventive Action (CAPA) planning.
- Conducting Root Cause Analysis (RCA) for significant audit observations.
- Auditing the adequacy and timeliness of the auditee's CAPA Response.
- Techniques for verifying CAPA Effectiveness checks and closure.
- Case Study: RCA and CAPA. A critical finding on consent issues; performing an RCA and designing a robust, preventive CAPA plan.

Module 13: Regulatory Inspection Readiness and Support

- Developing a comprehensive Inspection Readiness plan for sponsors and sites.
- The auditor's role during a Regulatory Inspection
- Strategies for managing inspectors' requests and handling challenging inspection questions.
- Preparing and submitting the formal response to FDA Form 483 and other official findings.
- Case Study: Inspection Simulation. Role-playing a regulatory inspection where the auditor is the subject matter expert on TMF compliance.

Module 14: Auditing Special Trial Types and Technologies

- Auditing Decentralized Clinical Trials (DCTs) and the use of wearables/telemedicine.
- GCP considerations and audit points for Adaptive Trial Designs and Master Protocols.
- Auditing biospecimen handling and compliance with GCLP at labs.
- Focus on Electronic Health Record (EHR)-to-EDC data flow and reconciliation.
- Case Study: DCT Audit. Auditing a DCT for consent verification and remote monitoring effectiveness.

Module 15: Professional Skills for the GCP Auditor

- Developing effective Interviewing and Listening skills for complex audit scenarios.
- Techniques for Conflict Resolution and maintaining professionalism during difficult audits.
- Strategies for managing Time and Logistics for multi-site or global audit travel.
- Maintaining Auditor Independence and ethical conduct in a QA role.
- Case Study: Challenging Interview. Role-playing an interview with a defensive Investigator and maintaining control while obtaining necessary information.

Training Methodology

The course utilizes a highly Interactive and Practical approach:

1. Expert-Led Lectures.
2. Interactive Workshops.
3. Hands-on Case Studies.
4. Role-Playing Exercises.
5. Resource Toolkit.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.com or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to FINESKILL TRAINING CENTER account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
07 Sep 2026	18 Sep 2026	Online	$4,000
14 Sep 2026	25 Sep 2026	Online	$4,000
21 Sep 2026	02 Oct 2026	Online	$4,000
28 Sep 2026	09 Oct 2026	Online	$4,000
05 Oct 2026	16 Oct 2026	Online	$4,000
12 Oct 2026	23 Oct 2026	Online	$4,000
19 Oct 2026	30 Oct 2026	Online	$4,000
26 Oct 2026	06 Nov 2026	Online	$4,000

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