Good Clinical Practice (GCP) for Clinical Trials Training Course

Professional Development Training Course Outline

Category	Quality Assurance and ISO standards	**Duration**	5 Days
Base Fee	$1,500 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Good Clinical Practice (GCP) is the globally recognized ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials involving human subjects. Good Clinical Practice (GCP) for Clinical Trials Training Course equips clinical researchers, trial coordinators, ethics committees, and healthcare professionals with the critical knowledge and skills required to ensure compliance with regulatory guidelines, safeguard patient safety, and maintain data integrity. With the increasing globalization of clinical research, GCP training ensures that trials meet international regulatory standards while advancing medical innovation responsibly.

Through interactive modules, case studies, and real-world applications, this course bridges the gap between theoretical frameworks and practical clinical trial implementation. Participants will gain a strong understanding of essential elements such as informed consent, safety reporting, trial monitoring, sponsor responsibilities, and investigator obligations. By mastering these principles, participants will strengthen their ability to ensure compliance, manage trial complexities, and contribute to high-quality clinical research outcomes.

Programme Curriculum

Good Clinical Practice (GCP) for Clinical Trials Training Course

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Course Objectives

1. Understand the fundamental principles of Good Clinical Practice in clinical trials
2. Apply international regulatory guidelines to trial design and conduct
3. Ensure ethical protection of human subjects through informed consent processes
4. Implement effective trial monitoring and quality assurance measures
5. Manage clinical trial documentation and essential records accurately
6. Strengthen compliance with ICH-GCP E6 (R2) standards
7. Identify investigator and sponsor roles and responsibilities
8. Enhance participant safety through adverse event reporting and risk management
9. Integrate digital technologies and electronic records in GCP compliance
10. Improve trial management efficiency through practical tools and templates
11. Develop effective strategies for clinical site management and monitoring
12. Apply GCP in multi-site, global, and remote clinical trial settings
13. Analyze real-world GCP case studies for applied learning and best practices

Organizational Benefits

1. Strengthens organizational compliance with global regulatory requirements
2. Enhances credibility and reliability of clinical trial outcomes
3. Improves efficiency in trial operations and monitoring processes
4. Reduces risks of regulatory non-compliance and penalties
5. Builds staff capacity and professional competence in GCP standards
6. Fosters ethical research practices that prioritize participant safety
7. Improves sponsor-investigator collaboration and communication
8. Enhances data accuracy, quality, and transparency
9. Supports readiness for audits and inspections
10. Boosts organizational reputation in clinical research excellence

Target Audiences

1. Clinical Research Associates
2. Clinical Trial Investigators
3. Study Coordinators and Site Managers
4. Ethics Committee Members
5. Regulatory Affairs Professionals
6. Data Managers and Biostatisticians
7. Pharmacovigilance and Safety Reporting Teams
8. Healthcare Professionals involved in clinical research

Course Duration: 5 days

Course Modules

Module 1: Introduction to Good Clinical Practice

- Principles and history of GCP
- Ethical foundations of human subject research
- Overview of ICH-GCP guidelines
- Role of GCP in clinical trial success
- Importance of global harmonization
- Case Study: Historical unethical trials and lessons learned

Module 2: Regulatory Frameworks and Guidelines

- ICH E6 (R2) and related guidelines
- FDA, EMA, and global regulatory bodies
- Local regulatory compliance requirements
- Harmonization across international sites
- Legal implications of non-compliance
- Case Study: International multi-site compliance challenges

Module 3: Roles and Responsibilities in Clinical Trials

- Investigator responsibilities
- Sponsor obligations
- Contract Research Organization (CRO) functions
- Ethics committees and institutional review boards
- Responsibilities of site staff
- Case Study: Investigator vs sponsor accountability

Module 4: Informed Consent Process

- Principles of informed consent
- Elements of consent documentation
- Ensuring participant understanding
- Vulnerable populations in clinical research
- Electronic informed consent (eConsent)
- Case Study: Informed consent violations and corrective actions

Module 5: Clinical Trial Design and Protocol Development

- Key elements of clinical trial protocols
- Study design considerations
- Protocol amendments and compliance
- Feasibility assessments
- Importance of standard operating procedures (SOPs)
- Case Study: Protocol deviations and consequences

Module 6: Safety Reporting and Risk Management

- Adverse event reporting requirements
- Serious adverse event (SAE) documentation
- Risk-benefit analysis in clinical trials

- Pharmacovigilance integration
- Risk-based monitoring approaches
- Case Study: Safety reporting delays and regulatory impact

Module 7: Data Integrity and Record Keeping

- Essential documents in clinical trials
- Source data verification
- Electronic records and e-signatures compliance
- Maintaining data confidentiality
- Archiving and retention policies
- Case Study: Data falsification detection and resolution

Module 8: Monitoring, Audits, and Inspections

- Monitoring methods and strategies
- Preparing for regulatory audits
- Inspection readiness checklists
- Identifying and managing non-compliance
- Corrective and preventive action plans (CAPA)
- Case Study: Regulatory audit findings and organizational response

Training Methodology

- Interactive instructor-led sessions
- Real-world case study analysis
- Group discussions and role-plays
- Practical exercises and document reviews
- Online and blended learning options

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	11 Sep 2026	Online	$1,100
14 Sep 2026	18 Sep 2026	Online	$1,100
21 Sep 2026	25 Sep 2026	Online	$1,100
28 Sep 2026	02 Oct 2026	Online	$1,100
05 Oct 2026	09 Oct 2026	Online	$1,100
12 Oct 2026	16 Oct 2026	Online	$1,100
19 Oct 2026	23 Oct 2026	Online	$1,100
26 Oct 2026	30 Oct 2026	Online	$1,100

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