Compliance in Clinical Trials Training Course

Professional Development Training Course Outline

Category	Research and Data Analysis	**Duration**	5 Days
Base Fee	$1,500 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Compliance in clinical trials is a critical pillar that ensures the integrity, safety, and efficacy of medical research. As regulatory landscapes evolve globally, understanding and adhering to compliance standards such as Good Clinical Practice (GCP), FDA regulations, and EMA guidelines is more important than ever. Compliance in Clinical Trials Training Course delves into the essential frameworks, ethical considerations, and operational best practices that safeguard participant rights and data quality, fostering trust between sponsors, regulators, and healthcare professionals.

With rapid advancements in clinical research methodologies, digital data capture, and decentralized trials, the course emphasizes emerging trends in regulatory compliance, risk-based monitoring, and adaptive trial designs. Participants will gain hands-on experience through case studies addressing real-world challenges such as audit readiness, data privacy, and protocol deviations, empowering them to navigate complex compliance requirements confidently and contribute to the success of clinical research endeavors.

Programme Curriculum

Compliance in Clinical Trials Training Course

Introduction

Compliance in clinical trials is a critical pillar that ensures the integrity, safety, and efficacy of medical research. As regulatory landscapes evolve globally, understanding and adhering to compliance standards such as Good Clinical Practice (GCP), FDA regulations, and EMA guidelines is more important than ever. Compliance in Clinical Trials Training Course delves into the essential frameworks, ethical considerations, and operational best practices that safeguard participant rights and data quality, fostering trust between sponsors, regulators, and healthcare professionals.

With rapid advancements in clinical research methodologies, digital data capture, and decentralized trials, the course emphasizes emerging trends in regulatory compliance, risk-based monitoring, and adaptive trial designs. Participants will gain hands-on experience through case studies addressing real-world challenges such as audit readiness, data privacy, and protocol deviations, empowering them to navigate complex compliance requirements confidently and contribute to the success of clinical research endeavors.

Course Duration

5 days

Course Objectives

1. Master Good Clinical Practice (GCP) principles and global regulatory frameworks.
2. Understand FDA, EMA, and ICH compliance requirements for clinical trials.
3. Implement risk-based monitoring (RBM) strategies for efficient oversight.
4. Ensure data integrity and patient safety in clinical trial conduct.
5. Navigate ethical considerations and informed consent processes.
6. Manage audit readiness and inspection preparedness.
7. Address protocol deviations and non-compliance issues effectively.
8. Leverage electronic data capture (EDC) and clinical trial management systems (CTMS).
9. Apply privacy laws and GDPR compliance in clinical data handling.
10. Adapt to decentralized and hybrid clinical trial models.
11. Utilize quality management systems (QMS) for continuous improvement.
12. Analyze case studies of compliance failures and remediation strategies.
13. Develop skills for regulatory submissions and documentation management.

Target Audience

1. Clinical Research Associates (CRAs)
2. Clinical Trial Managers
3. Regulatory Affairs Professionals
4. Quality Assurance Specialists
5. Data Managers and Biostatisticians
6. Medical Monitors and Investigators
7. Pharmacovigilance Officers
8. Compliance and Audit Professionals

Course Modules

Module 1: Introduction to Clinical Trial Compliance

- Overview of Clinical Trial Phases
- Regulatory Bodies and Guidelines
- Good Clinical Practice (GCP) Fundamentals
- Roles and Responsibilities in Compliance
- Case Study: GCP Violations and Lessons Learned

Module 2: Regulatory Frameworks and Guidelines

- Global and Regional Regulatory Requirements
- IND and NDA Processes
- Regulatory Submissions and Documentation

- Impact of FDA and EMA Inspections
- Case Study: Regulatory Non-Compliance Consequences

Module 3: Risk-Based Monitoring and Quality Management

- Principles of Risk-Based Monitoring (RBM)
- Quality Management Systems (QMS) in Trials
- Risk Assessment Tools and Techniques
- Monitoring Plans and Reporting
- Case Study: RBM Implementation Success Story

Module 4: Data Integrity and Electronic Systems

- Data Management Principles
- Electronic Data Capture (EDC) Systems
- Clinical Trial Management Systems (CTMS)
- Ensuring Data Accuracy and Security
- Case Study: Data Breach and Remediation

Module 5: Patient Safety and Ethics in Clinical Trials

- Informed Consent Process
- Ethical Review Boards and Approvals
- Adverse Event Reporting
- Protecting Vulnerable Populations
- Case Study: Ethical Breach and Regulatory Response

Module 6: Handling Protocol Deviations and Non-Compliance

- Identifying and Reporting Deviations
- Corrective and Preventive Actions (CAPA)
- Impact on Trial Outcomes and Integrity
- Documentation and Communication Strategies
- Case Study: Protocol Deviation Management

Module 7: Audits, Inspections, and Compliance Management

- Preparing for Audits and Inspections
- Audit Types and Processes
- Responding to Findings and Observations
- Continuous Compliance Monitoring
- Case Study: Successful Audit Preparation

Module 8: Emerging Trends in Clinical Trial Compliance

- Decentralized and Hybrid Clinical Trials
- Regulatory Changes and Digital Health Innovations
- Use of Artificial Intelligence and Machine Learning
- Data Privacy and GDPR Updates
- Case Study: Compliance in a Decentralized Trial

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org 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
23 Nov 2026	27 Nov 2026	Online	$1,000
23 Nov 2026	27 Nov 2026	Physical	$1,500

Start Date	End Date	Location	Price
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$6,000
23 Nov 2026	27 Nov 2026	Physical	$4,500
23 Nov 2026	27 Nov 2026	Physical	$6,000
23 Nov 2026	27 Nov 2026	Physical	$6,000

Ready to enroll or request a customized program? Book online or contact us:

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com