Clinical Data Management and Quality Assurance 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

The success of modern drug and device development hinges on the unimpeachable integrity and reliability of clinical trial data. Clinical Data Management and Quality Assurance Training Course is meticulously designed to equip professionals with the cutting-edge skills required to navigate the complex and highly regulated landscape of pharmaceutical and biotech research. Data quality is no longer a checklist item but a central, strategic imperative, driven by evolving ICH-GCP guidelines, the shift toward Decentralized Clinical Trials (DCTs), and the increasing reliance on Electronic Data Capture (EDC) systems. Mastering these integrated disciplines ensures that research findings are statistically sound, ethically robust, and fully compliant with global regulatory standards, significantly accelerating the path to patient-benefiting medical innovations.

This program goes beyond foundational principles, focusing on the practical application of Risk-Based Quality Management (RBQM) and the mastery of industry-standard tools and CDISC standards. Participants will develop proficiency in designing efficient Case Report Forms (CRFs), implementing robust Data Validation and Query Management processes, and ensuring meticulous Database Lock procedures. By integrating the perspectives of both CDM and QA, the course prepares specialists to manage the entire data lifecycle, from protocol development to data archival, while consistently upholding the principles of ALCOA-C. This dual focus is essential for career advancement in an industry where data governance and audit readiness are paramount for successful regulatory submission and approval.

Programme Curriculum

Clinical Data Management and Quality Assurance Training Course

Introduction

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Course Objectives

1. Master the complete Clinical Data Management Life Cycle from study startup to data archival and submission.
2. Apply foundational ICH-GCP E6(R2/R3) and 21 CFR Part 11 principles to ensure regulatory compliance in all data handling.
3. Design and implement efficient Electronic Data Capture (EDC) systems and eCRFs optimized for data quality at the source.
4. Develop comprehensive Data Management Plans (DMPs) incorporating Risk-Based Monitoring (RBM) strategies.
5. Execute advanced Data Validation and Discrepancy Management techniques for timely and accurate data cleaning.
6. Perform accurate Medical Coding using standardized dictionaries like MedDRA and WHO Drug Dictionary.
7. Conduct Serious Adverse Event (SAE) Reconciliation between the clinical and safety databases to maintain Pharmacovigilance data integrity.
8. Implement a Quality Management System (QMS) focused on proactive Quality Assurance (QA) and corrective/preventive actions (CAPA).
9. Validate computer systems (CSV) and maintain rigorous Audit Trails to support Inspection Readiness.
10. Utilize CDISC Standards (SDTM and ADaM) for structured data submission to global regulatory authorities.
11. Support Biostatistics and reporting teams by ensuring Database Lock readiness and providing analysis-ready datasets.
12. Address the unique data governance and data privacy challenges associated with Decentralized Clinical Trials (DCTs) and Real-World Data (RWD).

13. Lead and manage multi-functional CDM/QA teams and vendor oversight, applying effective Project Management techniques in a Clinical Research Organization (CRO) or Sponsor setting.

Target Audience

1. Clinical Data Managers and Clinical Data Coordinators.
2. Clinical Research Associates (CRAs) and Study Coordinators.
3. Quality Assurance (QA) Auditors and GCP Inspectors.
4. Database Programmers and Biostatisticians.
5. Professionals from Contract Research Organizations.
6. Health Informatics and Bioinformatics.
7. Project Managers.
8. Recent Life Science or Pharmacy graduates.

Course Modules

Module 1: Introduction to Clinical Data Management (CDM) Fundamentals

- Overview of the CDM Life Cycle and its critical milestones.
- Roles and responsibilities within the CDM team and cross-functional interactions.
- Defining Data Integrity and the ALCOA-C principles.
- The relationship between CDM, ICH-GCP, and the clinical trial protocol.
- FDA, EMA, and the importance of audit trails.
- Case Study: Analyzing a regulatory warning letter related to poor data integrity and identifying the CDM process failures.

Module 2: Good Clinical Practice (GCP) and Regulatory Standards

- Detailed review of ICH-GCP E6(R2) and updates in E6(R3) principles.
- 21 CFR Part 11 for Electronic Records and Electronic Signatures.
- Compliance requirements for data security and data privacy (HIPAA/GDPR).
- Defining Source Data and the process of Source Data Verification (SDV).
- The essential role of Standard Operating Procedures (SOPs) in CDM.
- Case Study: Evaluating an EDC system's compliance features against 21 CFR Part 11 to determine if it ÇÖs fit for regulatory use.

Module 3: Data Management Planning (DMP)

- Creating a comprehensive Data Management Plan (DMP) document structure.
- Developing data flow and transfer specifications for external vendors/labs.
- Strategy for Risk-Based Quality Management (RBQM) and identifying critical data.
- Defining Quality Tolerance Limits (QTLs) and key quality metrics (KPIs).
- Planning for database versioning, security, and access control.
- Case Study: Drafting a DMP for a Phase III oncology trial, prioritizing critical data points for focused RBM.

Module 4: Electronic Data Capture (EDC) System Mastery

- Introduction to leading EDC platforms
- Principles of effective eCRF Design and building user-friendly forms.
- Implementing Edit Checks and Skip Logic to prevent data errors at source.
- System Validation (CSV) and User Acceptance Testing (UAT) methodology.

- Managing User Roles and access privileges in an EDC environment.
- Case Study: Performing UAT on a newly built eCRF for a diabetes study, identifying and documenting system design discrepancies.

Module 5: Data Validation and Discrepancy Management

- Types of data checks.
- The life cycle of a Data Query.
- Developing Edit Check Specifications and validation programming rules.
- Using Central Monitoring tools to identify systematic data issues and trends.
- Documentation of all query activities and the audit trail.
- Case Study: Simulating a query resolution workflow, from generating a discrepancy report to site response and final database update.

Module 6: Medical Coding and External Data Integration

- The necessity of Medical Coding for Adverse Events (AEs) and Concomitant Medications.
- Practical application of Medical Dictionary for Regulatory Activities and WHO Drug Dictionary.
- Process for receiving, validating, and reconciling External Data
- Programming data transfer and reconciliation checks.
- Ensuring data traceability and mapping to internal and CDISC standards.
- Case Study: Reconciling central lab data with EDC entries, focusing on identifying out-of-range values and managing lab data transfers.

Module 7: Quality Assurance (QA) Principles and Auditing

- Distinction between Quality Control (QC), Quality Assurance (QA), and Auditing.
- Developing a risk-based QA Audit Plan for a clinical trial.
- Conducting internal and external GCP Audits of clinical sites and CDM processes.
- Managing Audit Findings and implementing Corrective and Preventive Actions
- Preparing the organization and the data for Regulatory Inspections
- Case Study: Analyzing a mock QA audit report, prioritizing CAPA implementation based on risk to participant safety and data integrity.

Module 8: Risk-Based Monitoring (RBM) and Quality Management

- Integrating RBM principles into the CDM and Monitoring Plan.
- Defining and tracking Key Risk Indicators and Key Performance Indicators
- Using Statistical Monitoring to detect anomalies and fraud at the site level.
- Implementation of Targeted Source Data Verification (TSDV) and 100% SDV.
- Documenting RBM rationale and activities for regulatory review.
- Case Study: Interpreting KRI reports for a multi-site trial and recommending a revised monitoring strategy

Module 9: Safety Data Management and Reconciliation

- Understanding Adverse Events (AEs) and Serious Adverse Events (SAEs) in the data context.
- Workflow for expedited reporting of SAEs to regulatory authorities.
- The critical process of SAE Reconciliation between the EDC/Clinical database and the Safety/Pharmacovigilance database.
- Creating a SAE Reconciliation Plan and tracking discrepancies.

- Ensuring consistency in Medical Coding for safety data.
- Case Study: Performing a mock SAE reconciliation exercise, identifying a critical data discrepancy and documenting the resolution process.

Module 10: CDISC Standards and Data Submission

- Introduction to the Clinical Data Interchange Standards Consortium (CDISC).
- Mastering the Study Data Tabulation Model (SDTM) for organizing submission data.
- Understanding the Analysis Data Model for statistical analysis datasets.
- Preparing the required metadata and supporting documentation
- Impact of CDISC on accelerating Regulatory Review
- Case Study: Mapping raw eCRF data fields for a primary endpoint to the appropriate SDTM domain variables.

Module 11: Database Lock and Archival

- Defining the process and criteria for Data Freeze and Database Lock.
- Zero Open Queries, Complete Coding, And Reconciliation Sign-Offs.
- Procedures for handling a post-lock Database Unlock and re-lock
- Preparing the final, clean dataset for Biostatistics and regulatory submission.
- Strategies for long-term Data Archival and retrieval in a regulatory compliant manner.
- Case Study: Developing a final database lock checklist and simulating the stakeholder sign-off process.

Module 12: Advanced Data Handling in Decentralized Trials (DCTs)

- Managing data from eSource, Wearable Devices, and Mobile Health apps.
- Implementing data capture and quality checks for Patient-Reported Outcomes
- Strategies for integrating and standardizing diverse, high-volume DCT data streams.
- Addressing unique data privacy and cybersecurity concerns in DCTs.
- Ensuring Source Data verification and traceability in a remote setting.
- Case Study: Designing a data flow diagram for a hybrid trial incorporating wearable device data and an eConsent process.

Module 13: Clinical System Validation and IT Infrastructure

- Principles of Computer System Validation and validation documentation.
- The role of the IT Infrastructure and data center compliance in CDM.
- Disaster recovery, backup procedures, and business continuity planning.
- Managing system upgrades, changes, and revalidation.
- Encryption, Access Control, And Vulnerability Testing.
- Case Study: Reviewing a validation summary report for a new EDC system upgrade, focusing on impact assessment and revalidation needs.

Module 14: Data Governance and Data Privacy

- Establishing Data Governance structures, policies, and ownership.
- Detailed review of HIPAA and GDPR requirements for clinical data.
- Techniques for Data Anonymization and Pseudonymization.
- Cross-border data transfer regulations and compliance.
- Managing data sharing agreements and external vendor contracts.

- Case Study: Developing a protocol for handling a simulated minor data breach, ensuring all GDPR reporting requirements are met.

Module 15: Professional Development and Career Paths

- Essential Soft Skills for CDM/QA.
- Navigating career opportunities as a Clinical Data Manager, QA Auditor, or Data Analyst.
- Vendor oversight and management for Contract Research Organizations (CROs).
- Metrics and Performance Management for data management teams.
- AI/Machine Learning in data validation and coding.
- Case Study: Creating a career development plan, mapping current skills to required competencies for a Senior CDM role.

Training Methodology

The training employs a highly interactive, practical, and blended learning approach to ensure deep understanding and skill retention:

1. Instructor-Led Sessions
2. Hands-on Workshops
3. Real-World Case Studies
4. Group Projects & Simulations
5. Role-Playing
6. Guest Speakers

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	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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