Data Integrity and GxP Compliance Training Course Outline

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

Data Integrity is the cornerstone of GxP compliance and a non-negotiable requirement for ensuring product quality and patient safety across the life sciences industry. In a world of accelerating digital transformation, the industry faces unprecedented challenges from electronic data management, cybersecurity threats, and the integration of technologies like AI/ML and Cloud Computing. Data Integrity and GxP Compliance Training Course Outline provides a comprehensive framework to master ALCOA+ principles, implement robust data governance policies, and navigate the latest global regulatory expectations from the FDA (21 CFR Part 11), EMA (Annex 11), and MHRA. Investing in this training directly mitigates the severe regulatory risk, financial penalties, and reputational damage associated with data integrity failures.

This program goes beyond basic compliance by embedding a culture of quality and accountability. Participants will gain practical, hands-on expertise in audit trail review, computer system validation (CSV/CSA), managing hybrid systems, and securing data across its entire life cycle. We emphasize a risk-based approach (ICH Q9), providing the tools to proactively identify and remediate vulnerabilities in GMP, GLP, GCP, and GDP environments. By equipping your workforce with trending knowledge in areas like Real-World Data (RWD) and Decentralized Clinical Trials (DCTs), this training ensures your organization achieves and maintains a state of inspection readiness in the complex regulatory landscape of 2025 and beyond.

Programme Curriculum

Data Integrity and GxP Compliance Training Course Outline

Introduction

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Course Duration

10 days

Course Objectives

1. Master the ALCOA+ Principles for all GxP data.
2. Interpret and apply global Regulatory Frameworks.
3. Design and implement a robust Data Governance structure, defining clear roles and data ownership throughout the organization.
4. Execute effective, risk-based Audit Trail Review strategies to detect anomalies and prevent data manipulation.
5. Apply the principles of Computer System Validation (CSV) and Computer Software Assurance (CSA) to new and legacy systems.
6. Understand and manage data integrity risks associated with Cloud Computing, IoT Sensors, and mobile devices.
7. Differentiate between and securely manage Data and Metadata across the entire Data Life Cycle.
8. Implement compliant controls for Paper and Hybrid Records following Good Documentation Practices (GDocP).
9. Integrate Quality Risk Management (ICH Q9) methodologies, such as FMEA, to assess data integrity vulnerabilities.
10. Navigate the unique DI challenges posed by Decentralized Clinical Trials (DCTs) and the use of Real-World Data (RWD).
11. Develop and execute a comprehensive Data Integrity Remediation Plan based on regulatory findings
12. Foster a Quality Culture where personnel are empowered to report discrepancies without fear of retribution
13. Prepare the organization for successful Regulatory Inspections by demonstrating Data Integrity Maturity.

Target Audience

1. Quality Assurance (QA) and Quality Control (QC) Personnel
2. IT and Computer System Validation (CSV) Specialists
3. Laboratory Analysts and Managers

4. Manufacturing and Production Operators/Supervisors
5. Data Scientists and Clinical Data Managers
6. Regulatory Affairs Professionals and Compliance Officers
7. Senior Management and Data/System Owners
8. Internal Auditors and Supplier Auditors

15 Modules with 5 Key Bullet Points & Case Study

Module 1: The Foundation of Data Integrity and GxP

- Defining Data Integrity, GxP, and the core purpose of reliable data.
- Consequences of DI failures.
- Overview of GMP, GLP, GCP, and GDP and where DI applies in each.
- The essential distinction between Data and Metadata.
- The concept of the Data Life Cycle.
- Case Study: Analyzing a manufacturing plant shutdown due to falsified raw material testing data.

Module 2: Mastering the ALCOA+ Principles

- Detailed breakdown of the five core ALCOA attributes.
- The critical "Plus" criteria.
- Practical examples of non-compliance for each ALCOA+ attribute.
- Integrating ALCOA+ into SOPs and daily operational practice.
- Measuring and monitoring ALCOA+ compliance maturity.
- Case Study: Reviewing an inspection finding on inconsistent data dating and missing metadata in laboratory notebooks.

Module 3: Global Regulatory Landscape (FDA, EMA, MHRA)

- In-depth analysis of FDA 21 CFR Part 11
- Understanding EudraLex Volume 4, Annex 11
- Key takeaways from MHRA, PIC/S, and WHO DI guidance documents.
- Recent DI focus areas from global regulatory body inspections
- The concept of Global Convergence in DI expectations.
- Case Study: Comparing an FDA 483 and an EMA inspection finding for a similar DI lapse in an overseas facility.

Module 4: Data Governance and Quality Culture

- Establishing a formal Data Governance Policy and framework.
- Defining clear Data Ownership and accountability across departments.
- Roles and responsibilities for DI oversight
- Fostering a proactive Quality Culture and "Speak Up" environment.
- The role of management in setting the "tone at the top" for data ethics.
- Case Study: How a company resolved conflicts over data ownership using a dedicated Data Governance Committee after a major audit.

Module 5: Good Documentation Practices (GDocP)

- Core principles for creating Attributable and Legible records.
- Ensuring Contemporaneous recording of all GxP activities.
- Proper handling of corrections, changes, and deviations in documentation.

- Management and protection of Source Data and true copies.
- Controlling and reconciling Paper and Hybrid Records.
- Case Study: A citation for "backdating" entries in a paper logbook and the corrective action plan.

Module 6: Electronic Records and Audit Trails

- Technical controls for Electronic Records compliant with 21 CFR Part 11.
- Requirements for a secure, computer-generated Audit Trail.
- Configuration and validation of audit trails in common GxP systems.
- Effective and Risk-Based Audit Trail Review methodologies.
- Management of electronic signatures and user access controls.
- Case Study: A chromatography system found to have a disabled audit trail and the resulting data qualification investigation.

Module 7: Computer System Validation (CSV) & Assurance (CSA)

- The importance of system validation in ensuring DI
- Transitioning from traditional CSV to the new CSA framework.
- Defining and validating the system?ÇÖs Intended Use.
- Managing DI in Legacy Systems
- Change Control and Periodic Review to maintain a validated state.
- Case Study: Using a risk assessment to justify the validation approach for a critical legacy system lacking modern DI features.

Module 8: Data Integrity in the Laboratory (GLP/QC)

- DI requirements for Lab Information Management Systems and Chromatography Data Systems
- Managing Raw Data from analytical instruments
- Controls for manual and automated data entry
- The process of Review by Exception in high-volume lab data.
- Ensuring DI in analytical method validation and transfer.
- Case Study: An investigation into laboratory data where repeat injections/tests were performed but only the passing data was reported.

Module 9: Data Integrity in Manufacturing (GMP)

- DI requirements for Manufacturing Execution Systems and SCADA.
- Ensuring contemporaneous data capture for **Electronic Batch Records**.
- Process automation and data integration challenges.
- Data verification for **Batch Release** decisions.
- DI considerations for equipment calibration and maintenance logs.
- Case Study: Analysis of a failed batch due to an uninvestigated data deviation in the MES that affected critical process parameters.

Module 10: Data Integrity in Clinical Trials (GCP)

- DI principles for Electronic Data Capture systems.
- Source Data Verification and its role in DI assurance.
- Compliance with ICH E6(R2) and emerging ICH E8 principles.
- Managing DI challenges in Decentralized Clinical Trials and remote monitoring.
- Handling and ensuring the integrity of Patient-Reported Outcomes

- Case Study: A clinical trial halted due to inconsistent data between the EDC and the patient's source medical records at the investigator site.

Module 11: Quality Risk Management (QRM) and DI

- Applying ICH Q9 principles to identify DI risks.
- Using risk assessment tools to assess data flow vulnerabilities.
- Developing a risk-based approach to data review frequency and depth.
- Implementing Corrective and Preventive Actions for DI gaps.
- The relationship between DI risk and overall product quality risk.
- Case Study: Conducting a risk assessment on an unvalidated excel spreadsheet used for calculation, leading to a CAPA for system validation.

Module 12: Advanced Technologies and Data Integrity

- Addressing DI and security challenges in Cloud Computing environments.
- Managing data from Mobile Devices, Wearables, and IoT Sensors.
- The potential and pitfalls of AI/ML in GxP compliance and data analysis.
- Fundamentals of Data Security and Cybersecurity to protect GxP data.
- Blockchain technology for enhanced data traceability.
- Case Study: A company's migration to a cloud-based ERP system that revealed data integrity vulnerabilities related to vendor access and data segregation.

Module 13: Vendor, Supplier, and Third-Party Oversight

- DI expectations for Third-Party Management and CMOs
- Conducting Supplier Audits focused on GxP data integrity controls.
- Establishing Quality Agreements with service providers for DI responsibilities.
- Managing hosted GxP systems and vendor access controls.
- Ensuring DI for outsourced laboratory and clinical trial activities.
- Case Study: A regulatory observation at a CMO traced back to a failure in the sponsor's oversight of the CMO's audit trail review procedures.

Module 14: Inspection Readiness and Response

- Developing a DI-focused Inspection Readiness Plan.
- Handling regulatory questions about Data Governance and audit trails.
- Strategies for a successful defense of electronic and hybrid systems.
- Best practices for Root Cause Analysis of DI findings.
- Formulating and managing responses to FDA 483s and Warning Letters.
- Case Study: Reviewing a company's successful response to a major Part 11 observation during an FDA inspection, focusing on the quality of their RCA.

Module 15: Practical Tools and DI Program Implementation

- Developing a Data Integrity Master Plan and Remediation Program.
- Creating effective Data Integrity Checklists for self-assessment.
- Techniques for creating a Data Flow Map for critical processes.
- Establishing metrics for continuous DI Monitoring and Improvement.
- Practical tips for conducting an internal DI audit.

- Case Study: A template-driven exercise where participants create a risk-based audit plan for a new analytical method validation process.

Training Methodology

The course utilizes a Blended Learning approach, focusing on maximum engagement and practical application:

- Interactive Workshops.
- Case Study Deep Dives.
- Role-Playing.
- Microlearning Modules.
- Hands-on Tools.

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

Start Date	End Date	Location	Price
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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