Data Integrity in Laboratories Training Course

Professional Development Training Course Outline

Category	General Training	**Duration**	5 Days
Base Fee	$1,500 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

In today’s highly regulated scientific and pharmaceutical environment, Data Integrity, Laboratory Compliance, GxP Standards, and Regulatory Data Governance have become critical pillars for ensuring trustworthy laboratory outcomes. Laboratories are expected to generate ALCOA+ compliant data (Attributable, Legible, Contemporaneous, Original, Accurate) while adhering to global standards such as FDA 21 CFR Part 11, EU GMP Annex 11, ISO 17025, and WHO Data Integrity Guidelines. Any compromise in data integrity can lead to regulatory penalties, product recalls, compromised patient safety, and loss of organizational credibility.

Data Integrity in Laboratories Training Course is designed to strengthen competencies in audit readiness, electronic records management, laboratory information systems (LIMS), risk-based compliance, and quality assurance frameworks. Participants will gain practical skills to identify data integrity gaps, implement robust controls, and foster a culture of quality assurance, regulatory compliance, and digital data governance in laboratory operations.

Programme Curriculum

Data Integrity in Laboratories Training Course

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Course Duration

5 days

Course Objectives

1. Understand Data Integrity principles (ALCOA+) in regulated laboratory environments
2. Apply GxP compliance standards in daily laboratory operations
3. Interpret FDA 21 CFR Part 11 and EU Annex 11 requirements effectively
4. Strengthen laboratory quality management systems (QMS)
5. Identify and mitigate data integrity risks and vulnerabilities
6. Implement audit trail review and electronic record controls
7. Enhance LIMS (Laboratory Information Management System) governance
8. Develop skills in regulatory inspection readiness and compliance audits
9. Ensure proper data lifecycle management and traceability
10. Promote data governance and cybersecurity in laboratory systems
11. Detect and prevent data falsification, manipulation, and breaches
12. Strengthen SOP compliance and documentation control systems
13. Build a culture of ethical data management and continuous improvement

Target Audience

1. Laboratory Managers and Supervisors
2. Quality Assurance (QA) and Quality Control (QC) Officers
3. Compliance and Regulatory Affairs Professionals
4. Pharmaceutical and Biotech Scientists
5. Clinical Laboratory Technicians
6. Data Integrity and Validation Specialists
7. Internal and External Auditors
8. IT/LIMS System Administrators in regulated environments

Course Modules

Module 1: Fundamentals of Data Integrity in Laboratories

- Overview of ALCOA+ principles and data lifecycle
- Importance of regulatory compliance in laboratories
- Types of laboratory data
- Introduction to data governance frameworks
- Case Study: FDA warning letter due to missing raw data traceability

Module 2: Global Regulatory Requirements

- Overview of FDA 21 CFR Part 11 compliance
- Understanding EU GMP Annex 11 requirements
- ISO 17025 data integrity expectations

- WHO guidelines on laboratory data integrity
- Case Study: EU GMP audit failure due to incomplete audit trails

Module 3: Laboratory Data Lifecycle Management

- Data creation, processing, storage, and archival
- Ensuring data traceability and authenticity
- Data retention policies and regulatory timelines
- Data migration and system validation
- Case Study: Data loss during system migration in a QC laboratory

Module 4: Electronic Records and LIMS Compliance

- Role of Laboratory Information Management Systems (LIMS)
- User access control and role-based permissions
- Electronic signatures and audit trails
- System validation and lifecycle management
- Case Study: Unauthorized data modification in LIMS environment

Module 5: Audit Trails and Risk Management

- Importance of audit trail review processes
- Risk-based approach to data integrity
- Identifying high-risk laboratory processes
- Corrective and Preventive Actions (CAPA)
- Case Study: Failure to detect manipulated chromatographic data

Module 6: Data Integrity Breaches and Investigation

- Types of data integrity breaches
- Root cause analysis techniques
- Investigation workflows in laboratories
- Regulatory reporting requirements
- Case Study: Intentional data falsification in stability testing

Module 7: Laboratory Quality Systems and SOP Compliance

- Development of robust SOP frameworks
- Document control and version management
- Training and competency management
- Internal audit systems and compliance checks
- Case Study: Repeated SOP violations leading to GMP non-compliance

Module 8: Cybersecurity and Digital Data Governance

- Cybersecurity threats in laboratory environments
- Data protection and backup strategies
- Cloud-based laboratory systems compliance
- Integration of AI and automation in labs
- Case Study: Ransomware attack affecting laboratory data integrity

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
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$3,000

Start Date	End Date	Location	Price
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:

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