CONCEPT

Data Integrity and Good Documentation Practice: ALCOA+, Audit Trails and Records

12 – 16 July 2027
Amsterdam - Zuidas business district hotel



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Introduction:

Data integrity failures in regulated laboratories rarely start with fraud; they start with a result written on a scrap of paper, a shared login, an unreviewed audit trail or a corrected entry with no reason recorded. Each weakens the evidence that a batch or test result can be trusted and exposes the site at inspection. This Core Concept course trains quality assurance, QC laboratory, production and validation staff to apply ALCOA+ and good documentation practice to paper, electronic and hybrid records. Participants build a Data Integrity Risk Assessment and Remediation Plan for a case QC laboratory.

Course Objectives:

- Apply ALCOA+ attributes to judge whether laboratory, production and validation records are trustworthy evidence
- Record, correct and review paper entries, logbooks and controlled forms to good documentation practice rules
- Review audit trails, electronic signatures and user access profiles to detect unauthorised or unexplained data changes
- Control hybrid records and document versions so printed outputs stay linked to their electronic source data
- Investigate data integrity breaches, assess product impact and define corrective and preventive actions
- Produce a Data Integrity Risk Assessment and Remediation Plan for a QC laboratory

Target Audience:

- Laboratory staff who generate, calculate and second-check analytical and microbiological results
- Quality assurance staff who review batch records, approve deviations and host inspections
- Production staff who complete batch manufacturing records, equipment logbooks and in-process checks
- Validation and computerised system staff who configure, qualify and periodically review GxP systems
- Document control staff who issue forms, manage procedure versions and archive records
- Team supervisors in medical device, food and testing laboratory settings who sign off records produced by their teams

Course Outline:

Day 1: Data Integrity Foundations and Regulated Record Expectations

- ALCOA and ALCOA+ Attributes: Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available
- Raw Data, Metadata and True Copy Definitions for Laboratory and Batch Records
- Data Lifecycle Map: Creation, Processing, Review, Reporting, Archiving, Retrieval and Destruction
- Data Integrity Versus Data Security: Accidental Error, Poor Practice and Deliberate Falsification
- Site Data Integrity Gap Assessment Checklist for Paper, Electronic and Hybrid Records

Day 2: Good Documentation Practice and Document Control

- Contemporaneous Entries in Indelible Ink, Blank Space Handling and N/A Conventions
- Single-Line Correction Rules With Signature, Date and Reason for Change
- Equipment Use, Instrument Calibration and Cleaning Logbook Design and Review
- Controlled Forms, Issuance Registers and Reconciliation of Blank Worksheets
- Document Control Lifecycle: Drafting, Approval, Version Numbering, Distribution and Retirement of Procedures

Day 3: Electronic Records, Audit Trails and Computerised Systems

- Electronic Record and Electronic Signature Principles: Individual User Identity, Signature Manifestation and Record Linking
- Audit Trail Content Configuration: Who, What, When and Why of Each Change
- Risk-Based Audit Trail Review Procedure for Chromatography Data Systems and LIMS
- User Access Matrix, Role Profiles and Segregation of Duties Between Analysts and Administrators
- Computerised System Validation Touchpoints: User Requirements, Configuration Records and Periodic Review

Day 4: Hybrid Systems, Red Flags, Culture and Breach Investigation

- Hybrid System Controls: Linking Printouts, Handwritten Signatures and Electronic Source Data
- Red Flag Patterns: Trial Injections, Orphan Data, Reprocessing, Time Stamp Anomalies and Shared Logins
- Data Integrity Culture: Speak-Up Channels, Management Behaviours and Workload Pressure Indicators
- Data Integrity Breach Investigation: Scope Determination, Impact on Released Batches and Root Cause
- CAPA Design for Behavioural, Procedural and Technical Data Integrity Gaps

Day 5: Case QC Laboratory Risk Assessment and Remediation Plan

- Case QC Laboratory Brief: Chromatography, Dissolution and Microbiology Records From Pharma and Food Sites
- Data Flow Mapping and Criticality Ranking for the Case Laboratory Systems
- Data Integrity Risk Assessment Using Severity, Likelihood and Detectability Scoring
- Remediation Plan Drafting: Interim Controls, Long-Term Fixes, Owners and Culture Measures
- Inspection Readiness Mock Interview and Plan Defence Before a Quality Review Panel

Skills You Will Gain:

- ALCOA+ Record Assessment
- Good Documentation Practice
- Logbook and Form Control
- Audit Trail Review
- Access Privilege Review
- Hybrid Record Control
- Data Integrity Investigation
- Data Integrity Risk Scoring

Why Attend This Course:

- Leave with a Data Integrity Risk Assessment and Remediation Plan for a case QC laboratory, defended before a quality review panel
- Spot red flags such as trial injections, orphan data and shared logins before an inspector does
- Answer inspection questions on audit trails, corrections and raw data with evidence already in order
- Compare record practices with peers from pharmaceutical, medical device, food and testing laboratory operations

Conclusion:

Trustworthy data is built one entry, one signature and one audit trail at a time. The week moves from ALCOA+ attributes, raw data definitions and the data lifecycle, through paper entries, corrections, logbooks and document control, to electronic records, electronic signatures, audit trail review, access control and validation touchpoints. It then covers hybrid systems, red flags, culture, breach investigation and CAPA, and closes with a Data Integrity Risk Assessment and Remediation Plan for a case QC laboratory, tested in a mock inspection interview.