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COURSE BROCHURE

Data Integrity and Document Management Essentials Training Course

jupiterprime.uk

info@jupiterprime.uk

Registered in the United Kingdom and Saudi Arabia

Data Integrity and Document Management Essentials Training Course

Data Integrity and Document Management Essentials is a 1-week training course for quality, laboratory and records staff, in which each participant builds a data integrity checklist for one document process. Inspectors and auditors now test whether batch records, test results and controlled procedures are attributable, legible and complete, so weak entries can halt release decisions. Jupiter Prime Training delivers this course for practitioners who create and check regulated records.

Why Data Integrity and Document Management Matters Now

Three forces push data integrity up the agenda. Laboratories and plants have moved from paper logbooks to hybrid and electronic systems, where a missing audit trail or shared login can undermine a whole data set. Inspectors increasingly review raw data and metadata rather than printed summaries. Organisations with sound practice release products and reports with confidence; those with gaps face rework, rejected submissions and lost trust. The course rests on ISO 15489-1 for the authenticity, reliability, integrity and usability of records.

Who Gains Most from Data Integrity and Document Management

- Analysts who record observations, calculations and instrument results
- Quality reviewers who check entries before a batch or report is approved
- Document coordinators who issue, revise and withdraw controlled procedures and forms
- Records officers who keep original and certified copies for their retention periods
- System owners who configure user access, audit trails and electronic signatures

A quality unit and its partner laboratory or production area gain most when reviewers and the people who make entries attend together.

Data Integrity and Document Management Capabilities

Each capability links a recording or review habit to the person who relies on the record later.

- Apply attributable, legible, contemporaneous, original and accurate principles to paper and electronic entries — analysts and supervisors
- Assess a controlled document lifecycle from draft to withdrawal for gaps in approval and issue — document coordinators
- Specify audit trail review steps for laboratory and production systems — quality reviewers and system owners
- Design correction, true copy and late entry rules for logbooks and worksheets — quality heads
- Test a hybrid record set for missing metadata and orphan data — internal auditors
- Build a data integrity checklist for one document process — the quality unit and process owners

Key Data Integrity and Document Management Terms

- Data integrity — the extent to which data stays complete, consistent and accurate across its whole lifecycle.
- Contemporaneous recording — writing an entry at the time the activity takes place, not later from memory.
- Audit trail — a secure, time-stamped log of who created, changed or deleted an electronic record and why.
- True copy — a verified copy of an original record that keeps its content, context and meaning.
- Hybrid record — a record made of linked paper and electronic parts, such as a printout with a signed cover sheet.
- Controlled document — a procedure, form or specification issued under approval, version control and distribution rules.

Data Integrity and Document Management Day by Day

Day 1: Records That Must Be Trusted

- Data Lifecycle Mapping — From Creation to Archive and Destruction
- Attributable and Legible Entries — Who Did What and When
- Contemporaneous and Original Records — Avoiding Transcription and Backdating
- Accurate and Complete Records — Calculations, Units and Blank Spaces
- Records Characteristics From ISO 15489-1 — Authenticity, Reliability and Usability

Day 2: Controlled Documents and Forms

- Document Hierarchy — Policies, Procedures, Work Instructions and Forms
- Draft, Review and Approval Routes — Signatories and Effective Dates
- Issue and Reconciliation of Logbooks — Numbered Pages and Accountability
- Revision and Withdrawal — Removing Superseded Copies From Use
- Change Requests — Linking Document Edits to Their Reasons

Day 3: Electronic Systems and Audit Trails

- User Accounts and Access Levels — Ending Shared Logins
- Audit Trail Configuration — Which Events Must Be Captured
- Electronic Signatures — Meaning, Linking and Ownership of Signing
- Audit Trail Review — Frequency, Scope and Escalation of Findings
- Backup and Archive of Raw Data — Readable for the Retention Period

Day 4: Good Documentation Practice and Investigation

- Correction Rules — Single Line, Initials, Date and Reason
- Late Entries and True Copies — Controlled Exceptions
- Hybrid Record Control — Linking Printouts to Electronic Sources
- Integrity Red Flags — Repeated Values, Gaps and Unexplained Reruns
- Deviation Handling — Root Cause and Corrective Action for Record Failures

Day 5: Practising the Data Integrity Checklist

- Laboratory Scenario — Applying Day Three Audit Trail Review to Test Results
- Production Scenario — Applying Day Two Logbook Controls to Batch Records
- Records Room Scenario — Applying Day Four Correction Rules to Archived Files
- Peer Challenge — Testing Another Participant's Draft Against Red Flags
- Data Integrity Checklist — Lifecycle Map, Controls, Review Steps and Owners

Applying Data Integrity and Document Management After the Course

- Map the lifecycle of one regulated record set and mark where each integrity principle could fail.
- Run a first audit trail review on one laboratory or production system and log findings with owners.

Data Integrity and Document Management Questions FAQ

What is data integrity and document management and why does it matter now?

Data integrity and document management is the set of controls that keeps records complete, accurate and traceable from creation to archive. It matters now because inspectors and customers review raw data and metadata, not only printed summaries.

Which roles gain most from data integrity and document management training?

Analysts, quality reviewers, document coordinators, records officers and system owners gain most.

How does a data integrity and document management essentials course differ from a records retention course?

A data integrity and document management essentials course focuses on how entries are made, checked and corrected. A records retention course focuses on how long records are kept and how they are disposed of.

What do you bring back from data integrity and document management training?

You bring back a checklist for one document process covering lifecycle risks, controls, audit trail review steps and owners, ready for your quality unit to adopt.

Data Integrity and Document Management: The Way Forward

The data integrity checklist sets out lifecycle risks, controls, review steps and owners for one document process. Its first use is deciding which system or logbook receives an audit trail or entry review first, led by the quality reviewer with the process owner. Revisit it after the first internal audit, when real findings show which controls hold.