Common Regulatory & Inspection Observations – Good Documentation Practice

WHAT YOU WILL LEARN

Session goals for this training.

By the end of this session, participants will be able to recognize common documentation observations, apply ALCOA+ principles, and take practical steps to prevent inspection findings across all documentation activities.

I **Inspector Expectations**
Understand what regulators look for in documentation quality, data integrity, and adherence to applicable GMP/GDP requirements.

II **ALCOA+ & Observations**
Apply ALCOA+ principles; recognize common non-compliance observations and their impact on product quality and patient safety.

III **Inspection Readiness**
Distinguish Good Documentation Practice from Good Distribution Practice; identify and prevent common documentation errors before inspections.

OVERVIEW

What Inspectors Expect from Documentation

01	**Complete, Accurate, Legible & Contemporaneous**	All records must meet ALCOA+ standards — inspectors verify quality at every entry.
02	**Full Traceability of Activities & Decisions**	Every action and decision must be traceable to a responsible, identified person.
03	**Reconstruction of Processes & Investigations**	Records must enable full reconstruction of any process, batch, or deviation event.
04	**Evidence of Data Integrity & SOP Adherence**	Inspectors look for consistent adherence to site SOPs and validated systems.
05	**Documentation as Primary GMP Evidence**	Documentation is the principal means to verify GMP compliance across all departments.

INSPECTION FOCUS

Why documentation receives close scrutiny.

01 **Tangible Proof of Compliance**
Documentation is the primary tangible evidence that GMP requirements are being met across all operations and departments.

02 **Quality & Patient Safety Link**
Many product quality failures and patient safety incidents trace directly back to inadequate or inaccurate documentation practices.

03 **Consequences of Data Integrity Failures**
Data integrity failures can result in regulatory sanctions, product recalls, or production halts with serious business and safety impact.

04 **Reveals Systemic Weaknesses**
Documentation errors often signal deeper quality management system weaknesses requiring root-cause investigation and corrective action.

05 **Inspection Readiness**
A strong documentation culture supports smoother inspections, faster audits, and demonstrates a site's commitment to quality compliance.

ALCOA+ REFRESHER

The foundational principles of Good Documentation Practice.

A	**Attributable**	Every entry must identify who recorded the data — initials, signature, or unique user ID.
L	**Legible & Original**	Records must be clear and readable; the original observation or first-capture data must be preserved.
C	**Contemporaneous**	Data recorded at the time of the activity — not from memory after the fact.
A	**Accurate**	Entries must be correct, truthful, and free from errors or omissions.
	Complete · Consistent · Enduring · Available	Facilitator prompt: Ask participants to share examples of ALCOA+ breaches they have personally observed.

OBSERVATION CATEGORIES

Where documentation failures most often occur.

01 **Missing or Late Entries**
Records not completed at the time of the activity; data entered retrospectively or omitted entirely from batch and logbook records.

02 **Backdating & Overwriting**
Entries recorded with false dates, or original data obscured by overwriting rather than corrected by approved procedure.

03 **Unjustified Corrections**
Amendments made without a single-line strike-through, reason, initials, and date — obscuring the original entry and breaking traceability.

04 **Illegible or Unsigned Records**
Handwriting that cannot be read, blank fields left without N/A notation, or entries missing required initials and second-person verification.

05 **Uncontrolled & Incomplete Records**
Use of obsolete SOPs, unapproved form copies, missing version details, and incomplete batch or packaging records with reconciliation gaps.

OBSERVATION CLASSIFICATION

How severity is classified by regulators.

01 **Critical**
Immediate risk to product quality or patient safety — requires urgent corrective action.

02 **Major**
Significant non-compliance affecting quality systems, without immediate safety risk.

03 **Minor**
Procedural lapses with no immediate quality impact but requiring timely correction.

04 **Context Matters**
Facilitator: Ask participants to classify examples — what makes a documentation error critical vs. minor?



RISK-BASED CLASSIFICATION

Severity reflects product type, regulator, and inspection context.

CONTEMPORANEOUS RECORDING

Record it now — not later, not from memory.

STEP 01
Perform
Carry out the activity according to the approved SOP or batch record instructions.

STEP 02
Record
Enter data immediately after the activity — never from memory hours later. Example: log critical step completion time at the point of action.

STEP 03
Sign & Date
Initial or sign the entry with the actual date and time. Use time-stamped electronic systems where available.

STEP 04
Spot Check
Supervisors conduct regular spot checks to verify real-time recording. Delayed entries are flagged and investigated.

OBSERVATION — DELAYED DATA ENTRY

Recording later from memory.

01 **Observation**
Batch record shows data entered after shift ended — QC analyst fills test results hours after assay completion.

02 **Expected good practice**
Data must be recorded immediately after observation or test — not reconstructed from memory.

03 **Compliance impact**
Delayed entries breach ALCOA+ contemporaneous requirement and undermine data integrity.

04 **Prevention**
Enforce strict SOPs for data entry timing; supervisor oversight; time-stamped electronic systems.



INSPECTION RED FLAG

Data entered after the shift ended is not contemporaneous.

GOOD DOCUMENTATION PRACTICE

Correcting errors — the right way, every time.

STEP 01
Identify
Identify the error in the record. Never erase, overwrite, or use correction fluid on the original entry.

STEP 02
Strike Through
Draw a single horizontal line through the incorrect entry. The original data must remain clearly legible.

STEP 03
Enter Correct Data
Write the correct value adjacent to or above the struck-through entry using permanent, non-erasable ink.

STEP 04
Reason, Date & Sign
Add a brief reason for the correction, the date of correction, and your initials or signature. No exceptions.

OBSERVATION: PENCIL / ERASABLE ENTRIES

Use only permanent, non-erasable ink in all controlled records.

STEP 01
Approve Ink
Only permanent, non-erasable ink pens are approved for use in official batch records, logbooks, and controlled forms.

STEP 02
Remove Prohibited Items
Remove pencils, erasable pens, and correction fluid from all controlled work areas. Restrict stationery per site SOP.

STEP 03
Record at the Time
Entries must be made contemporaneously in permanent ink. No transcription from pencil notes or scratch pads.

STEP 04
Periodic Checks
Supervisors perform regular stationery audits. Findings are documented and retraining initiated where pencil use is detected.

OBSERVATION & CONTROL

Pencil entries found in equipment logbooks.

01 **Remove pencils from controlled areas**
Conduct immediate sweep of all GMP areas; confiscate pencils and erasable pens from workstations and logbook stations.

02 **Supply correct stationery**
Issue only approved permanent, non-erasable black or blue ballpoint pens; maintain a controlled stationery log for GMP areas.

03 **Retrain all affected personnel**
Deliver targeted GDP retraining on approved writing instruments; document attendance and competency assessment per site SOP.

04 **Implement periodic inspection checks**
Schedule routine area walk-throughs to verify compliance; log findings and escalate repeat non-conformances to QA for CAPA.



CORRECTIVE CONTROLS

Remove pencils; enforce permanent ink across all controlled areas.

OBSERVATION: BLANK FIELDS

Never leave unexplained blank fields in controlled records.

01	**Use "N/A" for Non-Applicable Fields**	If a field does not apply to the activity, write "N/A" — never leave it blank.
02	**Use "Not Done" Where Applicable**	Where a step was intentionally omitted, record "Not Done" with justification per site SOP.
03	**Follow SOP Definitions for Field Completion**	Site SOPs must define acceptable entries for each field type; staff must follow these consistently.
04	**Train Personnel on Blank-Field Risks**	Blank fields may be interpreted as missed activities or missing data during inspections — train all staff.
05	**Review Records for Completeness at Issuance**	QA or supervisors must verify all fields are completed or appropriately marked before batch record closure.

ILLEGIBLE HANDWRITING — GOOD PRACTICE

A clear, legible record — step by step.

STEP 01

Write Clearly

Print entries in block letters. Avoid cursive in critical fields. Legibility is a regulatory requirement, not a preference.

STEP 02

Verify Entries

Reviewer confirms all entries are readable before sign-off. Flag and resolve any unclear data immediately.

STEP 03

Use Electronic Records

Where validated systems are available, prefer electronic entry. Audit trails support traceability and data integrity.

STEP 04

Resolve Before Review

Do not advance unclear records to QA review. Clarify with the originator, document the resolution, and re-sign.

ATTRIBUTION REQUIREMENTS

Every entry must be attributable to the person who made it.

01	**Every Entry Must Be Attributable**	All data entries require initials or a full signature to identify the responsible person.
02	**Approved Initials & Signature List**	Maintain a current, approved reference list of authorised personnel signatures and initials on file.
03	**Operator & Reviewer Accountability**	Both the operator performing the task and the reviewer checking the record must sign and date independently.
04	**Missing-Signature Observation (Red Flag)**	Unsigned entries on critical QC test sheets or batch records are a common inspection finding — no accountability, no traceability.
05	**Periodic Audits & Verification**	Schedule regular record audits to identify unsigned or incorrectly attributed entries; address gaps through retraining and corrective action.

MISSING SECOND-PERSON VERIFICATION

Independent verification: a four-step process.

STEP 01

Complete Entry

The primary operator records all required data fields, signs, and dates the entry before passing for review.

STEP 02

Independent Review

A second qualified person independently checks the entry for accuracy, completeness, and compliance with the SOP.

STEP 03

Second Signature

The reviewer records their initials, signature, and date to confirm the independent check has been performed.

STEP 04

Resolve & Approve

Any discrepancies are raised and resolved before approval. Unresolved issues must not proceed to the next stage.

MISSING SECOND-PERSON VERIFICATION

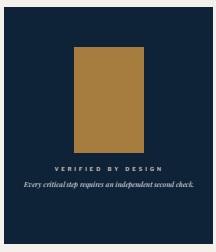
Controls to close the verification gap.

01 **Observation**
Production log found missing the required supervisor review signature on batch record verification.

02 **Root cause**
No systematic prompt to enforce dual-sign requirements; supervisor oversight gap not detected in time.

03 **Corrective action: checklist implementation**
Introduce mandatory completion checklists requiring second-person sign-off before batch record closure.

04 **Preventive action: electronic sign-off alerts**
Configure validated systems to block batch record submission until independent verification signature is captured.



OBSERVATION: UNCONTROLLED COPIES & FORMS

Risks of uncontrolled documents in operations.

01	**Use Only Approved, Current Documents**	All documents in use must be the current approved version per the document management system.
02	**Control Document Distribution**	Issue controlled copies only; maintain a distribution log to track all recipients and locations.
03	**Remove Photocopies & Obsolete Forms**	Withdraw and destroy uncontrolled photocopies promptly; prevent re-introduction of obsolete forms.
04	**Maintain Document Management Systems**	Use validated electronic or paper-based systems to ensure version control, access, and retrieval.
05	**Train All Users on Document Control**	Ensure staff understand document-control procedures; verify compliance through periodic audits.

INSPECTION OBSERVATION

Uncontrolled copy found on the manufacturing floor.

01 **Observation**
Outdated SOP photocopy found in use on the manufacturing floor — not a controlled document.

02 **Impact**
Staff may follow obsolete procedures, creating risk of product non-conformance and regulatory findings.

03 **Immediate corrective action**
Remove all uncontrolled hard copies from production areas; verify only current approved versions are accessible.

04 **Prevention**
Implement electronic document management; restrict printing; schedule periodic hard-copy audits per site SOP.



RED FLAG: OBSOLETE IN USE

Using outdated instructions risks product quality and compliance.

OBSOLETE DOCUMENTS — WITHDRAWAL CONTROLS

Prevent obsolete SOPs and forms from reaching the floor.

STEP 01
Verify
Check the document number, version, and effective date before use. Confirm the document is the current approved revision in the document management system.

STEP 02
Issue
Distribute only the current controlled version. Ensure all issued copies are stamped or identified as controlled and traceable to the recipient.

STEP 03
Withdraw
Retrieve and destroy or archive all obsolete copies promptly. Log withdrawal in the document control register per site SOP.

STEP 04
Confirm
Verify correct document use during periodic QA review. Schedule document audits and record findings to close any gaps promptly.

CHANGE CONTROL

Requirements for authorized document changes.

01	**Formal Change Request**	All proposed changes to controlled documents must be initiated via an approved change request form before any amendment is made.
02	**Impact Assessment**	Assess the effect of the proposed change on product quality, related SOPs, validated systems, and applicable GMP/GDP requirements.
03	**Approval by Authorized Personnel**	Changes must be reviewed and approved by designated quality and functional owners prior to implementation, per site SOP.
04	**Training & Communication**	Affected staff must receive documented training or formal communication on the revised document before it becomes effective.
05	**Controlled Implementation & Audit**	Implement on the approved effective date; retire obsolete versions; verify compliance through periodic document control audits.

INCOMPLETE DOCUMENT REVISION HISTORY

Complete revision history — step by step.

STEP 01
Record Date
Enter the exact revision date when the change is approved and becomes effective. Never leave the date blank or approximate.

STEP 02
Describe Change
Summarise what was changed, why it was changed, and which sections are affected. Vague entries such as "updated" are insufficient.

STEP 03
Identify Approver
Record the name, title, and signature of the authorised approver. Every revision requires documented approval per change-control SOP.

STEP 04
Link Records
Cross-reference the change-control number, implementation record, and associated training completion evidence to ensure full traceability.

INSPECTION OBSERVATION

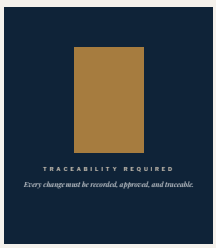
Incomplete document revision history.

01 **Missing key revision details**
Revision logs must capture the date, description of change, and approver name for every version.

02 **Traceability gaps**
Incomplete history makes it impossible to track what changed, when, and by whose authority.

03 **Regular document audits**
Schedule periodic reviews of all controlled documents to verify revision logs are complete and current.

04 **Document-control training**
Train all document owners and approvers on SOP requirements for maintaining complete revision histories.



TRACEABILITY REQUIRED

Every change must be recorded, approved, and traceable.

OBSERVATION

Missing Document Number, Version & Effective Date

01	**Document Number**	Every controlled document must carry a unique document number for unambiguous identification and retrieval.
02	**Version / Revision Number**	Current revision must be clearly stated; superseded versions must be withdrawn and marked obsolete per site SOP.
03	**Effective Date**	The date from which the document is authorised for use must be printed on every page; no undated documents in operation.
04	**Approved Status & Authorised Signatures**	Documents must carry evidence of review and approval by designated roles in line with the site document-control SOP.
05	**Verification Before Use**	Users must confirm they hold the current approved version before commencing any activity. Facilitator: ask how staff currently verify document currency.

INSPECTION OBSERVATION

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Incomplete Batch Manufacturing Records.

01 **Observation**
Critical data fields missing from batch records — including raw material batch numbers and process-parameter entries.

02 **Example**
Weighing records omit raw material batch numbers; sterilization batch record lacks critical temperature data.

03 **Impact**
Risk to product quality assurance and batch release; incomplete traceability for investigations or recalls.

04 **Prevention**
Use checklists for all required fields; implement automated monitoring and electronic batch records with mandatory-field controls; conduct QA batch record reviews.



PACKAGING & RECONCILIATION

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Batch packaging records: observations & controls.

01 **Missing label-reconciliation signature**
Label reconciliation completed without required sign-off; full traceability and dual verification mandatory per SOP.

02 **Material-usage mismatch**
Raw material quantities in packaging record do not reconcile with batch record inputs; discrepancy not investigated.

03 **Investigate and document all discrepancies**
All reconciliation discrepancies must be formally investigated, root-caused, and documented before batch release.

04 **QA oversight and dual verification**
Implement QA review checkpoints and dual-person sign-off on all packaging and reconciliation records.



THANK YOU

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