Good Documentation Practice (GDP) Practical Case-Study Training

OVERVIEW

What is Good Documentation Practice (GDP)?

01	**Data Integrity & Traceability**	GDP ensures that all data is accurate, complete, and fully traceable throughout the product lifecycle.
02	**ALCOA Principles**	Documentation must be Complete, Legible, Contemporaneous, Original, and Accurate at all times.
03	**Quality, Compliance & Patient Safety**	GDP underpins product quality, regulatory compliance, and ultimately the safety of every patient.
04	**Regulatory & Site Requirements**	Governed by current site SOPs, approved forms, applicable regulations, and validated systems.

WHY IT MATTERS

Documentation is the foundation of quality.

In GMP environments, every record tells the story of a product's journey. Accurate, complete, and timely documentation enables traceability, supports regulatory compliance, and protects patients, processes, and people at every stage of manufacturing and quality control.

I
Traceability
Enables full traceability of materials, processes, decisions, and personnel across the manufacturing and QC/QA lifecycle.

II
Audit Readiness
Supports regulatory inspections, internal audits, investigations, and quality reviews with reliable, retrievable records.

III
Error Prevention
Prevents deviations, process errors, and product recalls by ensuring documented controls are followed and verified consistently.

ALCOA+ PRINCIPLES

The foundation of data integrity — every GDP record must meet these standards.

ATTRIBUTABLE
Who & When
Every entry must identify who recorded the data and when. Sign, date, and time all entries. No anonymous records.

LEGIBLE
Readable
All entries must be clear, permanent, and readable throughout the document's retention period. No pencil, no correction fluid.

CONTEMPORANEOUS
At the Time
Record data at the moment of the activity or observation. Delayed entries undermine reliability and traceability.

ORIGINAL + ACCURATE
True & Correct
Use first-recorded or certified true copies only. Data must be truthful and error-free. + Complete, Consistent, Enduring, and Available throughout the record lifecycle.

COMMON FAILURES

Common documentation failures at a glance.

01	**Wrong or Missing Dates**	Date discrepancies or absent dates break contemporaneous recording and compromise traceability.
02	**Overwriting & Backdating**	Obscuring original entries or recording events after the fact violates data integrity and audit trail requirements.
03	**Blank Fields & Missing Entries**	Incomplete forms and unfilled mandatory fields impede review, release decisions, and compliance verification.
04	**Illegible Handwriting & Uncontrolled Documents**	Unreadable entries and use of obsolete or uncontrolled documents risk non-compliance and incorrect operations.
05	**Missing Signatures & Audit Trail Failures**	Absent verifications, unsigned records, and data gaps undermine accountability and regulatory auditability.

CASE STUDY 1 – WRONG DATE

Batch Record Date Does Not Match Activity Date

A batch record was reviewed during a routine internal audit. The date recorded for a critical in-process check did not correspond to the actual date the activity was performed. Review the situation and identify the GDP failures below.

01
Situation
During batch manufacturing, an operator recorded a date in the batch record that was two days earlier than the actual date of the in-process check. The discrepancy was flagged during a supervisory review prior to batch release.

02
The Documentation Issue
The recorded date does not reflect when the activity actually took place. This violates the ALCOA+ principle of contemporaneous recording and undermines the traceability of the batch record.

03
Impact on Traceability
An incorrect date creates a false timeline, making it impossible to accurately reconstruct events during investigations, audits, or product recalls. Regulatory reviewers may classify this as a data integrity failure.

CASE 2 – OVERWRITING

Situation & Issue: Overwriting in Records

Data overwritten without proper initialing or justification undermines data integrity and audit-trail clarity. Examine this case to identify the GDP failure and its compliance impact.

01
Situation
A batch record entry was overwritten with new data. The original value is no longer readable, and no initials, date, or justification were provided for the change.

02
Issue Identified
Loss of data integrity: the original entry cannot be recovered. Audit trail is broken, making it impossible to determine what was recorded and when.

03
GDP Failure Type
Violation of ALCOA+ principles: data is no longer original, attributable, or accurate. Overwriting without proper correction protocol is a critical GDP non-conformance.

CASE 3 – BACKDATING

Situation & Issue: Backdating Documentation.

A record is signed and dated after the actual event, yet presented as though it was completed at the time of activity. This violates contemporaneous recording and raises serious data integrity concerns.

01
The Situation
A batch record entry is signed and dated two days after the actual manufacturing step was completed, with the recorded date matching the activity date — suggesting it was done in real time.

02
The Issue Identified
The signature date and activity timestamp do not align. Witness accounts and system logs confirm the entry was made retroactively, violating contemporaneous recording requirements.

03
What Is Wrong
Backdating obscures the true timeline of events, undermines audit trail integrity, and misrepresents when data was actually recorded — a critical GDP and data integrity violation.

04
Compliance Concern
Backdating is considered falsification of records under GMP regulations. It can trigger regulatory action, product recall, and loss of manufacturing authorization if identified during audit.

CASE 4 – MISSING CONTEMPORANEOUS ENTRY

Situation & Issue: No record at the time of activity.

Data entered hours or days after the operation undermines reliability and raises serious data integrity concerns. Contemporaneous recording is a core GDP requirement.

14
Situation
No record was made during the manufacturing process. Data was entered into the logbook hours or days after the activity was completed.

02
Issue Identified
Lack of contemporaneous recording undermines data reliability and creates traceability gaps that cannot be justified.

03
Evidence of Failure
Logbook shows delayed entries with timestamps inconsistent with actual process times, and visible gaps between recorded activities.

04
Regulatory Risk
Retrospective entries may be flagged as data integrity violations during audits, potentially leading to observations, warning letters, or batch rejection.

CASE 5 – WRONG BATCH NUMBER

Situation & Issue: Incorrect Batch Number in Records

A batch record references a different or incorrect batch number, directly compromising traceability for investigation, product release, and recall readiness. This case examines the situation, the GDP issue raised, and the risks involved.

01
The Situation
A batch record in the QC/production area references a batch number that does not match the actual batch being processed or tested, discovered during routine review.

02
The GDP Issue
Incorrect batch identification undermines traceability, making it impossible to reliably link records to the correct batch for investigation or product release decisions.

03
Traceability Risk
In the event of a recall or deviation investigation, a wrong batch number creates a critical gap — the affected batch cannot be reliably identified, tracked, or isolated.

04
Release & Compliance Risk
Product release decisions based on records with incorrect batch numbers risk releasing the wrong batch or blocking the correct one, exposing the site to regulatory non-compliance.

CASE 6 – BLANK FIELDS

Situation & Issue: Incomplete Records

Critical fields in batch records and QC forms are left blank. Missing data impedes review, compliance verification, and traceability during audits and investigations.

01
The Situation
A completed batch record is submitted for QA review. Multiple mandatory fields — including quantity dispensed, operator ID, and in-process check results — are left entirely blank.

02
The Core Issue
Blank mandatory fields constitute an incomplete record, directly violating GDP requirements for complete and accurate documentation at the time of activity.

03
Compliance Impact
Missing data prevents effective batch review, blocks product release decisions, and raises data integrity concerns during regulatory inspections and internal audits.

CASE STUDY 7 — SITUATION & ISSUE

Illegible Entry: When Records Cannot Be Read.

Entries in logbooks or batch records that are unclear or unreadable prevent understanding, auditability, and regulatory review. Legibility is a core GDP requirement.

01
Situation
During a QA audit, entries in the in-process logbook are found to be unclear, smudged, or written in a style that cannot be reliably interpreted by the reviewer.

02
GDP Issue Identified
Illegible entries violate the Legible principle of ALCOA+. Data that cannot be read cannot be verified, reviewed, or relied upon for compliance decisions.

03
Impact on Auditability
Unreadable records impede investigations, product release decisions, and regulatory inspections — creating significant compliance and quality risk.

04
Root Causes
Poor handwriting habits, use of fading ink, inadequate training on documentation standards, and absence of legibility checks during record review.

CASE 8 – UNCONTROLLED PHOTOCOPY

Situation & Issue: Using an Uncontrolled Photocopy

Photocopied documents used in place of originals without control stamps, approval markings, or validation. This introduces risk of outdated or incorrect information entering the process undetected.

01
The Situation
An operator uses a photocopied SOP during manufacturing. The copy bears no control stamp, revision number, or approval signature, and its source is unknown.

02
The Core Issue
Uncontrolled copies may be outdated, altered, or incorrect. Using them undermines document integrity and introduces compliance and quality risk.

03
Document-Control Risk
No traceability to the approved master document. Superseded instructions may lead to process errors, deviations, or product failures.

04
Audit Exposure
Inspectors finding uncontrolled copies at the point of use is a critical GDP observation. It signals systemic document control failure and attracts further scrutiny.

CASE 9 – OBSOLETE SOP

Using a superseded SOP in operations.

Staff refer to or use a superseded or obsolete SOP during manufacturing or QC operations, creating non-compliance and potential quality risk.

01
Situation Identified
An operator on the production floor was found using a printed SOP marked Revision 02, while the current approved version in the document control system is Revision 05.

02
The Core Issue
The obsolete SOP contained outdated process steps and acceptance criteria superseded by procedural updates, creating direct non-compliance with current requirements.

03
GDP Violation
Only current, approved SOP versions are permitted for use. Retaining or using obsolete documents at point-of-use violates GDP and document control requirements.

04
Operational Impact
Operations performed using obsolete instructions may require re-work, investigation, or batch rejection, and may trigger a regulatory finding during audit.

CASE 10 – UNAUTHORIZED FORM REVISION

Situation & Issue: Unapproved Form Changes.

A form template was altered without authorization or version control. The document's controlled status is lost, raising immediate regulatory and data integrity concerns.

01
The Situation
A batch record form template was found with handwritten field additions and layout changes made directly on the controlled master — no change request, no approval signature, and no version update recorded.

02
The Core Issue
Unauthorized revisions strip the document of its controlled status. Regulatory inspectors cannot verify the form's integrity, and data recorded on it may be deemed unreliable or non-compliant.

03
GDP Failure Identified
Form revisions without formal change control violate GDP requirements. The absence of an approval signature and version history creates an uncontrolled document — a critical compliance gap.

04
Risk & Impact
Use of unauthorized forms can invalidate batch records, trigger regulatory observations, and undermine confidence in the site's document control system during audits or inspections.

CASE 11 – MISSING SECOND-PERSON VERIFICATION

The oversight gap, clearly identified.

A critical batch record is missing its required second-person check. Without dual verification, errors and fraud risk increase. This case examines the situation, the control gap, and the impact on compliance.

01
Situation
A critical batch manufacturing record was reviewed and signed by only one person. The second-person verification field was left blank at the time of batch release.

02
The Issue
Missing dual verification reduces oversight and removes a key error-detection control, increasing the risk of undetected mistakes or fraudulent entries.

03
GDP Principle Violated
ALCOA+ Accuracy and Completeness: required verifications must be performed and documented to ensure record integrity and accountability.

04
Control Gap Identified
No system or procedural check prevented the record from proceeding without the second signature, indicating a gap in the review and release workflow.

CASE 12 – EQUIPMENT LOGBOOK GAP

Situation & Issue: Missing Logbook Entries.

Equipment usage logbooks must capture every operation in real time. When entries are absent or time slots are left blank, traceability breaks down and maintenance history becomes unreliable.

01
Situation
The equipment usage logbook for a granulator in the manufacturing area shows several blank time slots between recorded operations, spanning multiple shifts over two days.

02
The Issue
Gaps in the logbook prevent verification of equipment status, cleaning intervals, and usage history — impairing traceability and maintenance records.

03
What Was Observed
Multiple consecutive time slots left blank. No entries for overnight shift. No explanation or N/A notation provided for the missing periods.

04
Why It Matters
Incomplete logbooks risk regulatory non-compliance, hinder batch investigations, and may indicate undocumented equipment use or maintenance failures.

CASE STUDY · 13 OF 17

Case 13 – Cleaning Record Error: Situation & Issue

A cleaning log with incomplete or incorrect entries creates serious contamination risks and compliance failures. Examine the documentation gap and identify what went wrong.

01
Situation
The cleaning log for a manufacturing vessel shows incomplete entries — missing agent concentrations, operator initials, and time stamps for several cleaning cycles.

02
Documentation Issue
Entries are either left blank or contain incorrect data, making it impossible to verify that cleaning was performed correctly and completely per the approved SOP.

03
Compliance Risk
Incomplete cleaning records indicate potential cross-contamination risk and constitute a GDP failure, triggering regulatory non-compliance and possible product rejection.

04
Key GDP Failure
Cleaning documentation must be complete, accurate, and contemporaneous. Errors or omissions in cleaning logs are a critical audit finding under GMP regulations.

CASE 14 – TEMPERATURE RECORD GAP / EXCURSION

Situation & Issue

Temperature monitoring records contain missing data intervals or unrecorded excursions, threatening product stability, regulatory compliance, and the integrity of environmental control evidence.

01
The Situation
Temperature monitoring logs for a storage area show multiple time gaps where no readings were recorded. In addition, two out-of-specification temperature excursions occurred but were never documented in the monitoring record.

02
Data Integrity Issue
Missing data intervals break the continuity required for contemporaneous records. Unrecorded excursions mean no investigation was triggered, violating ALCOA+ completeness and accuracy principles.

03
Compliance Risk
Products stored during unrecorded excursions may be compromised. Regulators and auditors expect continuous, unbroken temperature records with documented investigation of any out-of-specification event.

04
Patient Safety Impact
Failure to capture and act on temperature excursions risks releasing unstable or degraded product. This directly threatens patient safety and exposes the site to regulatory action and product recall.

CASE 15 – SITUATION & ISSUE

QC Raw-Data Issue / Audit Trail Failure

Missing or altered QC raw data without traceability undermines data integrity and regulatory compliance. Identify the gaps before they reach an audit.

01
Situation
QC raw data entries are missing from the analytical record, and some values appear altered with no corresponding audit trail entry to explain the change.

02
Core Issue
Absence of a complete audit trail makes it impossible to verify who changed data, when, and why — a critical data integrity failure.

03
Regulatory Impact
Compromised raw data violates ALCOA+ principles and exposes the site to regulatory action, product rejection, or investigation findings.

04
Observable Evidence
QC data printout shows blank rows, overwritten values, and no system-generated audit trail timestamps linking changes to a user ID.

CASE 16 – ELECTRONIC SIGNATURE / PASSWORD SHARING

Situation & Issue: Shared Credentials

Multiple users sharing electronic signatures or passwords undermines individual accountability and breaks the audit trail. This case examines the situation, the GDP failure, and the compliance risk.

01
Situation
Multiple personnel are found sharing a single electronic login and e-signature credential to access and approve records in the validated system.

02
GDP Issue
Shared credentials destroy individual attributability — records cannot be traced to the person who actually performed or approved the activity.

03
Access-Control Failure
System access controls were not enforced. No alerts were triggered for concurrent logins, and no periodic access review was conducted.

04
Compliance Risk
Violates 21 CFR Part 11, EU Annex 11, and ALCOA+ Attributable principle. May trigger data integrity findings and regulatory action during inspection.

THANK YOU

FOR YOUR ATTENTION

info@ishasgmp.com
ishasgmp@gmail.com
project@ishasgmp.com

Head Office:
Isha's GMP Consultancy Pvt Ltd,
Regency flat, Sri Hi-Tech construction,
55/66, 1st cross street, CRR puram, LNT colony, Manapakkam, Chennai-600125

+91 8667589984
+91 9976491578

www.ishasgmp.com

