GOOD DOCUMENTATION PRACTICE

GDP QUIZ COMPETITION

How to Play

- 10 questions • 1 point each
- Read the visual example carefully before answering.
- Choose A, B, C or D.
- Use the answer key at the end for scoring.
- Suggested use: classroom / QA training / GMP awareness competition.

ALCOA+ — Remember the Essentials

- A — Attributable
- L — Legible
- C — Contemporaneous
- O — Original
- A — Accurate
- + — Complete, Consistent, Enduring, Available

Visual Example 1 — Good Documentation

GOOD ENTRY

12-OCT-2026 09:30 25.0 °C

Initials: RS

Clear • readable • traceable

GOOD ENTRY

12-OCT-2026 09:30 25.0 °C

Initials: RS

Clear • readable • traceable

NOT ACCEPTABLE

~~125 mg~~ → 120 mg

Original data cannot be reconstructed

ACCEPTABLE CORRECTION

~~125 mg~~ 120 mg

Reason: entry error

RS / 12-OCT-2026

NOT ACCEPTABLE

Date: 01/03/26

Time: 4:20

Initials: _____

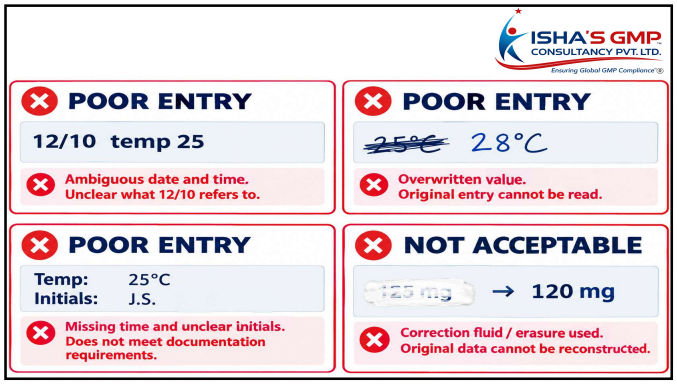
Visual Example 2 — Poor Documentation

POOR ENTRY

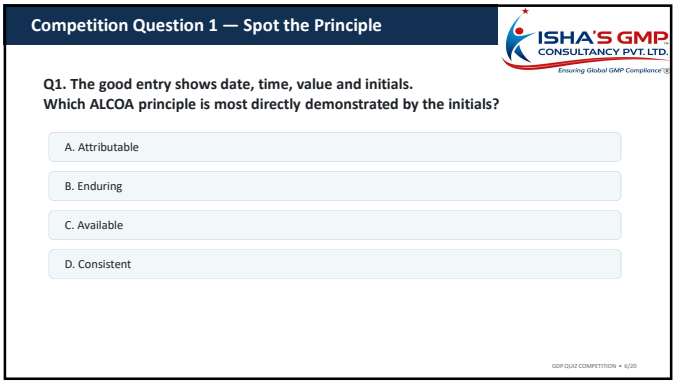
12/10 temp 25

Overwritten value

Missing time / unclear initials



Competition Question 1 — Spot the Principle



Q1. The good entry shows date, time, value and initials.
Which ALCOA principle is most directly demonstrated by the initials?

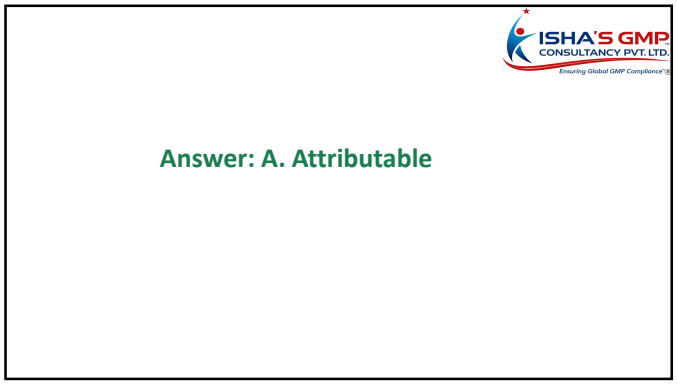
A. Attributable

B. Enduring

C. Available

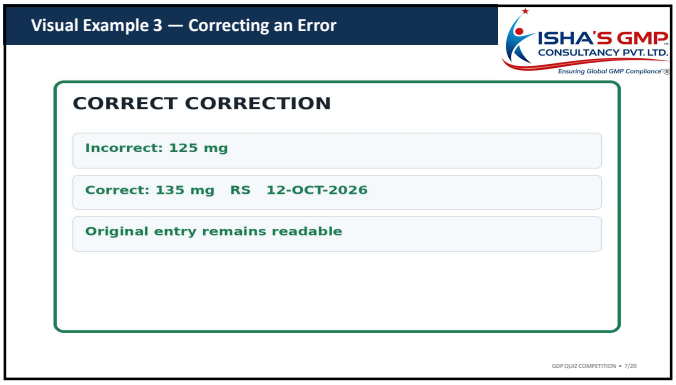
D. Consistent

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Answer: A. Attributable

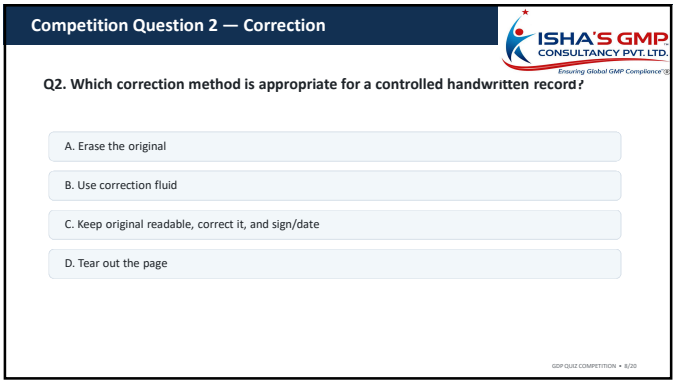
Visual Example 3 — Correcting an Error



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Competition Question 2 — Correction



Q2. Which correction method is appropriate for a controlled handwritten record?

A. Erase the original

B. Use correction fluid

C. Keep original readable, correct it, and sign/date

D. Tear out the page

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Answer:
C. Keep original readable, correct it, and sign/date

Visual Example 4 — What NOT to Do

NOT ACCEPTABLE

- 125 mg → erased
- Correction fluid used
- Original data cannot be reconstructed

NOT ACCEPTABLE

Dose: ~~125 mg~~ → 120 mg

Correction fluid used. Original data cannot be reconstructed.

ACCEPTABLE CORRECTION

Dose: ~~125 mg~~ 120 mg
Reason: Dose adjusted per protocol.
Initials / Date: JP 03-Jan-2026

Original entry remains readable. Proper correction with initials, date and reason.

NOT ACCEPTABLE

Date: 01/03/26
Time: 4:20
Initials: _____

Ambiguous date and time. Missing initials and date.

ACCEPTABLE ENTRY

Date / Time: 03-Jan-2026 16:50
Parameter: Temperature: 22.4 °C
Recorded at time of activity.
Initials / Date: AB 03-Jan-2026

Clear date and time. Recorded at the time of activity. Initials and date present.

NOT ACCEPTABLE

1. Erased Entry

Date	Parameter	Result	Initials
12/10/2026	Temp	25.0 °C	AB
12/10/2026	Temp	[illegible]	AB
12/10/2026	Temp	24.8 °C	CD

Erasing is not permitted. Original data cannot be reconstructed.

2. Correction Fluid Used

Batch No.	PG4587
Product	Paracetamol
Quantity	1000
Date	~~12-10-2026~~
Checked by	SK

Correction fluid is not allowed. Original entry is obscured.

3. Overwritten Value

Date	Time	Reading	Initials
12/10/2026	09:15	50.2	AB
12/10/2026	10:20	~~51.3~~ 52.8	CD
12/10/2026	11:10	53.1	EF

Overwriting is not permitted. Original data must remain readable.

Competition Question 3 — Identify the Violation

Q3. In the visual example, erasing the original entry primarily creates a problem with which ALCOA concept?

A. Original / traceability

B. Legibility only

C. Training records

D. Document color

Answer:
A. Original / traceability

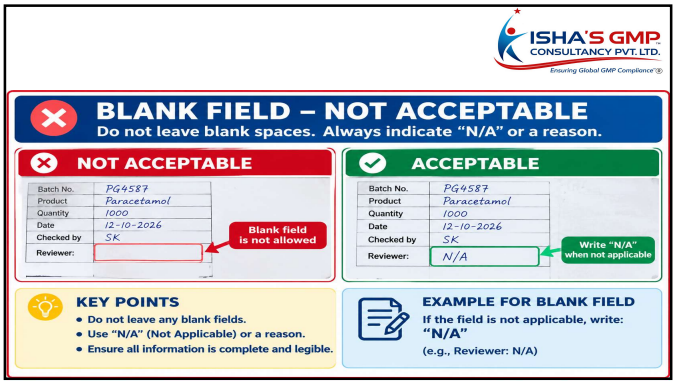
Visual Example 5 — Blank Field

BLANK FIELD

Result: 18.2 mg

Reviewer: _____

Use approved notation when applicable



Competition Question 4 — Blank Field

Q4. A field is not applicable. What should the user do?

A. Invent a value

B. Leave it unexplained

C. Use the approved notation according to SOP

D. Delete the field

Answer:
C. Use the approved notation according to SOP

Visual Example 6 — Electronic Data Integrity

ELECTRONIC RECORD

User ID: RS

12-OCT-2026 09:30

Audit trail: ON



Competition Question 5 — Electronic Records

Q5. Which control best supports attribution and traceability in an electronic system?

- A. Shared login
- B. Unique user ID and audit trail
- C. No password
- D. Manual deletion of history

Answer:
B. Unique user ID and audit trail

Visual Example 7 — Backdating

BACKDATING

- Actual activity: 14:00
- Record entered: 17:30
- Date/time misrepresented



Competition Question 6 — Contemporaneous

Q6. An activity occurs at 14:00 but is documented at 17:30 as if it were recorded at 14:00. Which principle is affected?

- A. Contemporaneous
- B. Legible
- C. Enduring
- D. Available

Answer:
A. Contemporaneous

Visual Example 8 — Signature & User Control

SIGNATURE CONTROL

- Each user uses their own credentials
- No shared login
- Signature must be attributable

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SIGNATURE CONTROL — GOOD PRACTICE

Electronic Record - Equipment Log

User ID:	RS
Individual login:	RS
Date / Time:	12-OCT-2026 09:30
Entry:	Temperature 25.0 °C
Electronic signature:	RS
Audit trail:	ON

- Individual credentials
- No shared login
- Signature attributable

TRACEABLE • UNIQUE USER • ACCOUNTABLE

Competition Question 7 — Signature Control

Q7. Which practice is unacceptable?

A. Use your own credentials

B. Keep login credentials confidential

C. Share a password with a colleague

D. Make records attributable

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Answer:
C. Share a password with a colleague

Competition Question 8 — uncontrolled pencil entries

6. UNCONTROLLED PENCIL ENTRY

WRONG / ERROR



Easily erased or altered

CORRECT PRACTICE



Durable • Readable • Traceable

Competition Question 8 — uncontrolled pencil entries

Q7. Why are uncontrolled pencil entries generally unacceptable for controlled records?

A. Pencil is too dark

B. Pencil can be easily altered or erased

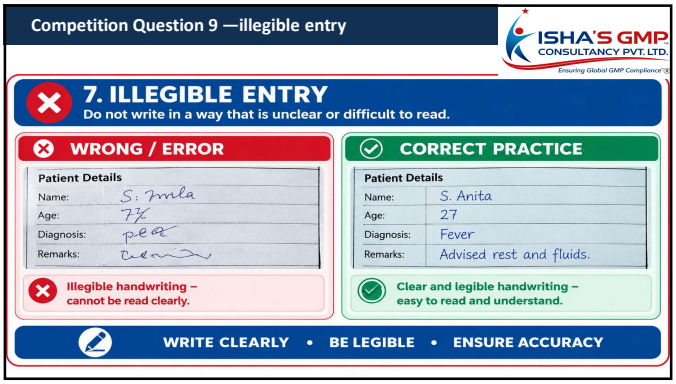
C. Pencil is expensive

D. Pencil cannot be sharpened

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Answer:
B — Pencil can be altered or erased, so approved permanent recording methods should be used.

Competition Question 9 —illegible entry



Competition Question 9 illegible entry

Q7. What is the key problem with an illegible entry?

A. It uses too much ink

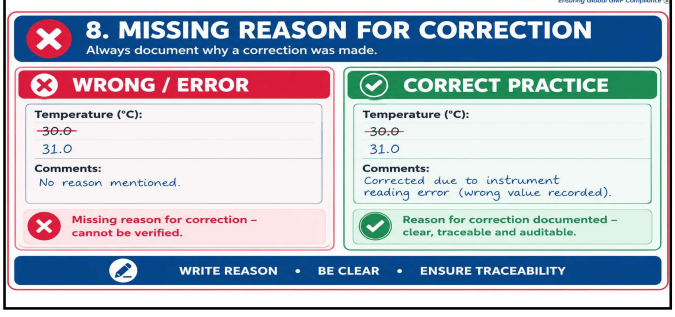
B. The information cannot be reliably understood

C. It has too many initials

D. It is always a false entry

Answer:
B — Data must be readable so that it can be accurately reviewed and understood.

Competition Question 10 —correction is missing



Competition Question 10 correction is missing

Q7. A value is corrected and initialed, but the required reason for correction is missing. What GDP principle is affected?

A. . Traceability and completeness

B. Paper size

C Storage temperature

D Page numbering only

Answer:
A — Corrections need sufficient traceability, including required reason, initials/date, according to the SOP.

Answer Key & Golden Rules

- Answer key: 1-A • 2-C • 3-A • 4-C • 5-B • 6-A • 7-C • 8-C • 9-B • 10-A
- GOLDEN RULE 1: Record what you do.
- GOLDEN RULE 2: Record it when you do it.
- GOLDEN RULE 3: Never hide or destroy the original data.
- GOLDEN RULE 4: Every record must be attributable and traceable.
- GOLDEN RULE 5: Follow your approved SOPs.

THANK YOU

FOR YOUR ATTENTION

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