ComplianceWorxs
THE RECORD BEHIND THE DECISION

INSPECTION RESPONSE RECORD

Fictional GMP CAPA Effectiveness Closure · CAPA-2025-0118

Who authorized this decision, and why?

An examination of the supplied account of evidence, reasoning, risk, and authorization behind one completed quality decision.

SUPPORTED WITH GAPS

Record CW-IDP-2026-FC03BE03

Evidence cited

Environmental-monitoring trends, analyst retraining, a revised procedure, and an internal audit observation.

Decision rationale

The supplied justification relies on four sources converging, not on the absence of recurrence alone.

Risk documentation

No risk evaluation or residual-risk acceptance statement was supplied.

Authorization

P. Trubl, Director, Quality Systems & CAPA; decision dated 12 August 2025.

Finding identified

Detailed authorizer conclusions and risk evaluation are not documented in the supplied information.

Recorded, not reconstructed.

Fictional example. Not regulatory guidance. Based on supplied intake information; cited documents were not independently reviewed.

SUPPORTED WITH GAPS

EXECUTIVE BRIEF

The record supports the closure decision relying on multiple evidence elements, but the single largest exposure is the absence of detailed authorizer review and explicit conclusions. Prior to inspection, efforts should focus on locating or documenting authorizer notes or reviews to strengthen defensibility.

WHAT TO EXAMINE FIRST

Ranked by what the intake reports. Each item starts by checking whether the record already exists in your source quality system; an intake that is silent does not show that the record is missing there.

1. IS THERE A DOCUMENTED RECORD OF WHAT THE AUTHORIZER SPECIFICALLY REVIEWED AND CONCLUDED FOR CAPA-2025-0118 CLOSURE?

WHY IT RANKS HERE

Without this information, it cannot be fully demonstrated how the authorization was justified at the time; the intake does not describe the authorizer's direct review or conclusions.

BASIS IN THE INTAKE

The intake states 'Not specified' for what the authorizer reviewed and concluded.

FIRST STEP

Check if authorizer review notes or CAPA closure forms exist in the source quality system; if absent, prepare a dated clarification documenting the detailed review and conclusions.

2. ARE THE ALTERNATIVE CORRECTIVE OR PREVENTIVE ACTIONS CONSIDERED DURING CAPA RESOLUTION DOCUMENTED?

WHY IT RANKS HERE

Alternate options underpin the rationale for choosing closure and affect defensibility; the intake did not supply any alternatives.

BASIS IN THE INTAKE

The intake states 'Not provided by user' regarding alternatives considered.

FIRST STEP

Search CAPA documentation or risk assessments for alternative actions; if none found, prepare a dated clarification describing alternatives considered and reasons for rejection.

3. IS RESIDUAL RISK ACCEPTANCE DOCUMENTED, INCLUDING ANY ONGOING MONITORING PLANS AFTER CAPA CLOSURE?

WHY IT RANKS HERE

Understanding residual risk management is important for compliance and future assurance; intake does not mention this.

BASIS IN THE INTAKE

The intake lacks residual risk or monitoring information.

FIRST STEP

Review risk assessment or CAPA closure files for residual risk records; if unavailable, prepare a dated clarification describing residual risk acceptance and monitoring.

4. ARE FACILITY AND ESCALATION CHAIN INFORMATION DOCUMENTED IN THE CAPA CLOSURE CONTEXT?

WHY IT RANKS HERE

Facility context and escalation paths are relevant for traceability and responsibility; none are supplied in the intake.

BASIS IN THE INTAKE

The intake states facility name and escalation chain are 'Not specified'.

FIRST STEP

Check CAPA metadata or quality system records for this operational data; if missing, prepare a dated contextual clarification.

FLAGS

AMBER — JUSTIFICATION INSUFFICIENT — INSPECTION RISK

AUTHORIZATION SUMMARY

The CAPA decision for CAPA-2025-0118 (originating from deviation DEV-2025-0042) was authorized by P. Trubl, Director, Quality Systems & CAPA on 12 Aug 2025. The operational context is the closure of the CAPA after the 90-day effectiveness window. Facility name and role are not specified. The authorization owner and date are supplied. No information on what the authorizer reviewed or concluded is specified in the intake.

EVIDENCE REVIEWED

Environmental-monitoring trend EM-DAILY, 14 May to 12 Aug 2025: no recurrence across the 90-day verification window — the intake reports this shows no repeat excursion during the effectiveness window

Analyst retraining records TRAIN-EM, completed 2 May 2025 — the intake reports this shows the analysts completed retraining

Revised procedure SOP-EM-318 R04, in force — the intake reports this shows the revised procedure was effective at the time

Internal audit observation AUDIT-2025-031, 18 Jul 2025 (day 65): compliant execution observed — the intake reports this shows an independent audit confirmed compliant execution during the window

EVIDENCE TRACEABILITY

EVIDENCE	CITED IN THE INTAKE	MENTIONED IN RATIONALE
Environmental-monitoring trend EM-DAILY, 14 May to 12 Aug 2025: no recurrence across the 90-day verification window	Yes	Yes
Analyst retraining records TRAIN-EM, completed 2 May 2025	Yes	Yes
Revised procedure SOP-EM-318 R04, in force	Yes	Yes
Internal audit observation AUDIT-2025-031, 18 Jul 2025 (day 65): compliant execution observed	Yes	Yes

RISK EVALUATION

Not addressed in inputs.

ALTERNATIVES CONSIDERED

Not provided in inputs.

AUTHORIZATION RATIONALE

The decision justification states closure relied on multiple converging evidence streams, including no recurrence in the environmental monitoring trend during the 90-day window, completion of analyst retraining, the revised procedure being in force, and an internal audit confirming compliant execution at day 65. The intake does not specify what the authorizer reviewed beyond these documents or what conclusions were explicitly drawn.

CLAIM STATUS

CLAIM	STATUS
Closure relied on the four sources converging, including no recurrence, retraining, revised procedure, and audit observation	Claimed in rationale
P. Trubl authorized the CAPA closure decision on 12 Aug 2025	Claimed in rationale
Authorizer reviewed all four evidence items and concluded effectiveness	Not traceable in record
Residual risk was evaluated and accepted	Not traceable in record
Alternative actions were considered and rejected	Not traceable in record

REGULATORY ALIGNMENT

No specific regulatory citations or SOPs are supplied in the intake to align with cGMP or QMS regulations such as 21 CFR 211 or 21 CFR 820 or ICH guidelines.

RESIDUAL EXPOSURE STATEMENT

The intake does not provide details on residual risk acceptance or ongoing monitoring plans, leaving some uncertainty about continuing risk management after closure.

KNOWN LIMITATIONS

The intake does not specify what exactly was reviewed by the authorizer beyond the documents listed. It lacks details on the authorizer's explicit conclusions. No facility information or escalation chain is supplied. Alternatives considered and residual risk acceptance are not addressed. The primary source record and reference IDs are not provided.

CLAIMS THIS RECORD DOES NOT SUPPORT

This record does not establish what the authorizer specifically reviewed or what conclusions were explicitly drawn beyond the summary justification.

This record does not establish that alternative actions were considered or why the chosen path was selected.

This record does not establish acceptance of residual risk or ongoing monitoring plans.

This record does not establish facility name or role to provide context to the decision.

This record does not establish the escalation chain or review participants to document organizational governance.

RESPONSE KIT

A documentation scaffold, not finished text — every bracketed field is a blank you fill from your own records. Anything you prepare now must carry its actual date and author and be presented as a later clarification, never as a document that existed when the decision was authorized.

AUTHORIZER REVIEW AND CONCLUSION DOCUMENTATION

LOCATION

CAPA-2025-0118 closure package or CAPA effectiveness files

PURPOSE

To record what was specifically reviewed and concluded by the authorizer at the time of closing CAPA-2025-0118, thereby strengthening documentation of authorization rationale.

TEMPLATE

```
Prepared on: [date]
Prepared by: [name, role]
Relates to the decision of: 12 Aug 2025

Documents reviewed by authorizer:
• Environmental-monitoring trend report: [reference]
• Analyst retraining records: [reference]
• Revised procedure SOP-EM-318 R04: [reference]
• Internal audit observation report: [reference]

Summary of findings and conclusions drawn by authorizer:
• [Detailed summary]

Authorizer name: [name]
Authorizer title: [title]
Review date: [date]
```

FACILITY AND OPERATIONAL CONTEXT DETAILS

LOCATION

CAPA decision metadata or facility quality records

PURPOSE

To document facility name, facility role, and other operational context information relevant to the CAPA closure decision.

TEMPLATE

```
Prepared on: [date]
Prepared by: [name, role]
Relates to the decision of: 12 Aug 2025

Facility name: [facility name]
Facility role: [facility role]
Escalation chain if applicable: [names and roles]
Review participants: [names and roles]
Reference IDs related: [list]

Prepared for context of CAPA-2025-0118 closure.
```

ALTERNATIVE ACTIONS CONSIDERED

LOCATION

CAPA decision documentation or risk management records

PURPOSE

To document any alternative corrective or preventive actions considered and reasons for their rejection, supporting the choice made for CAPA closure.

TEMPLATE

```
Prepared on: [date]
Prepared by: [name, role]
Relates to the decision of: 12 Aug 2025

List of alternative actions considered:
• [Action 1 and rationale]
• [Action 2 and rationale]

Reason for final authorization selection:
• [Explanation]

Prepared as a supplemental rationale for CAPA-2025-0118 closure.
```

RESIDUAL RISK ACCEPTANCE AND MONITORING PLANS

LOCATION

CAPA risk assessment or closure documentation

PURPOSE

To record acceptance of residual risk post-closure and any planned ongoing monitoring or controls following CAPA effectiveness confirmation.

TEMPLATE

```
Prepared on: [date]
Prepared by: [name, role]
Relates to the decision of: 12 Aug 2025

Residual risk accepted: [description]
Ongoing monitoring plan: [description]
Responsible person(s): [names, titles]
Review schedule: [dates]

This record supports understanding of risk management decisions with CAPA closure.
```

COMPLETE PRIMARY SOURCE AND REFERENCE RECORDS IDENTIFICATION

LOCATION

CAPA documentation or deviation file DEV-2025-0042

PURPOSE

To document precise reference IDs and source records pertaining to the CAPA decision for traceability and audit purposes.

TEMPLATE

```
Prepared on: [date]
Prepared by: [name, role]
Relates to the decision of: 12 Aug 2025

Primary source record(s): [IDs and descriptions]
Reference IDs: [list]
Location and version control status: [location details]

Supports traceability of CAPA-2025-0118 closure justification.
```

AUTHORIZER SPECIFIC REVIEW DETAILS

LOCATION

CAPA review or authorization forms

PURPOSE

To clarify what documents or data the authorizer personally reviewed and assess, reflecting their decision basis.

TEMPLATE

```
Prepared on: [date]
Prepared by: [name, role]
Relates to the decision of: 12 Aug 2025

Documents personally reviewed by authorizer:
• [List documents]
Authorizer assessments or notes:
• [Detailed description]

Prepared to clarify review details supporting CAPA closure authorization.
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INVESTIGATOR CHALLENGE GUIDE

WHO SPECIFICALLY REVIEWED AND CONCLUDED THE EFFECTIVENESS OF CAPA-2025-0118, AND WHAT WAS THEIR DOCUMENTED RATIONALE?

The intake states that P. Trubl, Director, Quality Systems & CAPA, authorized the closure on 12 Aug 2025 based on four key evidence items without specifying the detailed review or conclusion.

WEAKNESS TO ACKNOWLEDGE

The detailed authorizer review notes or explicit conclusions are not provided in this record.

WERE ALTERNATIVE CORRECTIVE OR PREVENTIVE ACTIONS CONSIDERED BEFORE CLOSING THIS CAPA?

The intake does not provide information on consideration of alternative actions for this CAPA closure.

WEAKNESS TO ACKNOWLEDGE

No documentation of alternatives considered is present in the record.

WAS RESIDUAL RISK EVALUATED AND ACCEPTED AS PART OF THE CAPA CLOSURE?

Residual risk acceptance or evaluation is not addressed in the intake.

WEAKNESS TO ACKNOWLEDGE

No residual risk documentation is attached or referenced in this record.