STANDARD OPERATING PROCEDURE

Corrective and Preventive Action (CAPA) SOP

Document no.	SOP-QA-003
Revision	1.0
Owner	Quality Manager
Effective date	September 15, 2026
Review cycle	Every 12 months

1. Purpose

To make sure nonconformances, customer complaints and audit findings are investigated for root cause and corrected in a way that prevents recurrence, following a consistent and documented process.

2. Scope

Applies to corrective and preventive actions raised from internal audits, customer complaints, nonconforming product or service, and management review, from initiation through root cause analysis, action implementation and effectiveness verification.

Definitions

Corrective action	An action taken to eliminate the root cause of an existing nonconformance so it does not recur.
Preventive action	An action taken to reduce the risk of a similar issue occurring elsewhere, even where no nonconformance has happened yet.
Containment	An immediate action to limit the impact of an issue while the root cause is still being investigated.
Effectiveness verification	Confirming after a defined period that the corrective action actually prevented the issue from recurring.

3. Responsibilities

CAPA Owner	Raises the CAPA record and tracks it through to closure.
Investigator	Determines root cause and identifies corrective and preventive actions.
Process Owner	Contains the immediate issue and implements the agreed actions.
Quality Manager	Assigns investigations, approves actions, and verifies effectiveness before closure.

RACI matrix

Activity	CAPA Owner	Investigator	Process Owner	Quality Manager
Raise the CAPA and contain the issue	R	I	R/A	I
Investigate and determine root cause	I	R/A	C	I
Approve corrective and	I	C	C	R/A

Activity	CAPA Owner	Investigator	Process Owner	Quality Manager
preventive actions				
Implement the actions	I	C	R/A	I
Verify effectiveness and close the CAPA	I	C	I	R/A

R = Responsible, A = Accountable, C = Consulted, I = Informed

4. Materials and PPE

Materials, tools and systems

- CAPA log or tracking system
- Root cause analysis tools, such as five whys or fishbone templates
- Investigation checklist
- Affected procedure or document references

5. Procedure

Step	Task	Owner	Done
5.1	**Raise the CAPA** The CAPA Owner raises a CAPA record for a nonconformance, a complaint trend, or an audit finding, describing the issue and where it was found.	CAPA Owner	☐
5.2	**Contain the immediate issue** The Process Owner takes containment action to limit further impact of the issue while the root cause investigation is still underway. **Warning:** Containment is not the same as a fix; do not close the CAPA once containment is in place.	Process Owner	☐
5.3	**Assign an investigator** The Quality Manager assigns an investigator to the CAPA and sets a target completion date for the investigation.	Quality Manager	☐
5.4	**Investigate root cause** The Investigator determines the root cause using a structured method, such as five whys or a fishbone diagram, rather than assuming the first plausible explanation. **Checkpoint:** The identified root cause is supported by evidence gathered during the investigation, not just an assumption.	Investigator	☐
5.5	**Identify the corrective action** The Investigator, working with the Process Owner, identifies the corrective action needed to eliminate the confirmed root cause.	Investigator	☐
5.6	**Identify preventive actions** The Investigator, working with the Process Owner, identifies preventive actions that reduce the risk of a similar issue occurring in other areas.	Investigator	☐
5.7	**Approve the proposed actions** The Quality Manager reviews and approves the proposed corrective and preventive actions, confirming each has a named owner and a realistic due date. **Checkpoint:** Every action has a named owner and a realistic due date before it is approved.	Quality Manager	☐

Step	Task	Owner	Done
5.8	**Implement the actions** The Process Owner implements the approved corrective and preventive actions by their due dates.	Process Owner	☐
5.9	**Update affected procedures** The Process Owner updates any affected procedures, training materials or controls as a result of the corrective action.	Process Owner	☐
5.10	**Verify implementation** The Quality Manager verifies that the approved actions were actually completed as planned.	Quality Manager	☐
5.11	**Verify effectiveness** The Quality Manager checks after a defined period that the original issue has not recurred, confirming the action actually worked.	Quality Manager	☐
5.12	**Close or reopen the CAPA** The Quality Manager closes the CAPA once effectiveness is confirmed, or reopens it and restarts investigation if the issue recurs.	Quality Manager	☐
5.13	**Report CAPA trends** The CAPA Owner reports open and overdue CAPAs and overall trends from the CAPA log to management review.	CAPA Owner	☐

6. Quality checks

- Every CAPA has a documented root cause supported by evidence.
- Corrective actions are not closed before effectiveness verification is complete.
- Overdue CAPAs are flagged and escalated.
- Containment actions are recorded separately from the permanent corrective action.

7. Records

- CAPA record with investigation notes
- Root cause analysis documentation
- Effectiveness verification evidence
- CAPA log and trend report

8. KPIs

- Average time to close a CAPA
- Percentage of CAPAs closed on time
- Recurrence rate after CAPA closure
- Number of open or overdue CAPAs

9. Common mistakes

- Closing a CAPA right after implementing the fix without verifying effectiveness.
- Treating a quick containment action as the permanent corrective action.
- Skipping structured root cause analysis and guessing at a fix.
- Not assigning a clear owner and due date to each action.

10. Revision history

Revision	Date	Description	Reviewed by
1.0	September 15, 2026	Initial release	Ilia Pirozhenko

Approval

Prepared by	Approved by	Date

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