STANDARD OPERATING PROCEDURE

Corrective and Preventive Action (CAPA)

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1. PURPOSE

This Standard Operating Procedure (SOP) defines the process for initiating, investigating, implementing, and verifying Corrective and Preventive Actions (CAPA) to:

- Eliminate the root cause of existing nonconformities and prevent recurrence
- Identify and eliminate potential causes of nonconformities before they occur
- Ensure continuous improvement of the Quality Management System (QMS)
- Maintain compliance with applicable regulatory requirements

2. SCOPE

This procedure applies to all CAPA activities within the organization, including those arising from:

- Customer complaints and feedback
- Internal and external audit findings
- Nonconforming product or process deviations
- Post-market surveillance and vigilance data
- Supplier quality issues
- Management review outputs
- Trend analysis and statistical data
- Regulatory inspection observations

📌 **NOTE:** This SOP does not apply to immediate corrections or containment actions that do not require root cause analysis.

3. DEFINITIONS

Term	Definition
CAPA	Corrective and Preventive Action – a systematic approach to identifying, investigating, and resolving quality issues.
Corrective Action	Action taken to eliminate the cause of a detected nonconformity or other undesirable situation to prevent recurrence.
Preventive Action	Action taken to eliminate the cause of a potential nonconformity or other undesirable potential situation to prevent occurrence.

Root Cause	The fundamental reason for a nonconformity or problem, which if eliminated, would prevent recurrence.
Containment	Immediate action taken to prevent further impact of a nonconformity while investigation is ongoing.
Effectiveness	Verification that implemented actions have prevented recurrence of the root cause.

4. RESPONSIBILITIES

4.1 CAPA Owner

- Lead the investigation and root cause analysis
- Coordinate corrective and preventive action implementation
- Ensure timely completion of assigned actions
- Document all activities on the CAPA Form
- Verify effectiveness of implemented actions

4.2 Quality Manager

- Review and approve all CAPA records
- Assign CAPA numbers and owners
- Monitor CAPA metrics and report to management
- Ensure regulatory compliance of the CAPA process
- Escalate overdue or ineffective CAPAs

4.3 Department Managers

- Provide resources for CAPA activities in their area
- Ensure personnel complete assigned actions on time
- Participate in cross-functional investigations as needed

4.4 Management Representative

- Review CAPA trends in Management Review
- Approve CAPAs with significant regulatory or business impact
- Allocate resources for systemic improvements

5. PROCEDURE

5.1 CAPA Initiation

A CAPA shall be initiated when:

- A significant or recurring nonconformity is identified
- An audit finding (internal or external) requires systemic action
- Customer complaint investigation reveals a quality system gap
- Trend analysis indicates a negative pattern
- Regulatory inspection results in an observation
- Risk assessment identifies an unacceptable risk level

To initiate a CAPA:

5.1.1 Complete Section 1 (Problem Description) of the CAPA Form (FRM-CAPA-001)

5.1.2 Assign a unique CAPA number using format: CAPA-YYYY-XXX

5.1.3 Classify the priority level based on risk assessment:

- Critical: Patient safety impact – target completion within 30 days
- High: Regulatory or major quality impact – target within 60 days
- Medium: Moderate impact – target within 90 days
- Low: Minor/improvement – target within 120 days

5.1.4 Assign a CAPA Owner with appropriate authority and expertise

5.1.5 Enter the CAPA into the CAPA Log for tracking

5.2 Containment Actions

Immediate containment actions shall be implemented to limit the impact of the nonconformity:

5.2.1 Evaluate the scope of affected product, processes, or documents

5.2.2 Implement containment (e.g., quarantine, stop shipment, customer notification)

5.2.3 Document containment actions in Section 2 of the CAPA Form

5.2.4 Verify containment effectiveness before proceeding to investigation

5.3 Root Cause Investigation

A thorough investigation shall be conducted to identify the root cause:

5.3.1 Assemble a cross-functional investigation team as appropriate

5.3.2 Collect and analyze relevant data, records, and evidence

5.3.3 Apply appropriate root cause analysis techniques:

- 5-Why Analysis (recommended for most investigations)
- Fishbone (Ishikawa) Diagram for complex, multi-factor issues
- Fault Tree Analysis for safety-critical events
- Pareto Analysis for trend-based investigations

5.3.4 Document the investigation process and findings in Section 3

5.3.5 Clearly state the root cause – it must explain WHY the problem occurred

> 📌 **NOTE:** The root cause must be actionable. 'Human error' alone is not an acceptable root cause – identify why the error occurred (training gap, unclear procedure, inadequate verification, etc.).

5.4 Action Planning

Corrective and preventive actions shall address the root cause:

5.4.1 Define specific, measurable actions to eliminate the root cause

5.4.2 Assign responsible persons and target completion dates for each action

5.4.3 Document actions in Section 4 (Corrective) and Section 5 (Preventive)

5.4.4 Consider horizontal deployment – does this issue affect other products/processes?

5.4.5 Evaluate whether actions require change control (ECO) or validation

5.4.6 Assess impact on Risk Management File – update risk assessment if applicable (ISO 14971)

5.4.7 Obtain Quality Manager approval before implementation

5.5 Implementation

Execute the approved action plan:

5.5.1 Implement each action per the defined timeline

5.5.2 Document evidence of implementation (updated SOPs, training records, etc.)

5.5.3 Update the CAPA Form status as actions are completed

5.5.4 Notify affected personnel of process or document changes

5.6 Verification of Implementation

Verify that all actions have been completed as planned:

5.6.1 Review objective evidence for each completed action

5.6.2 Confirm documentation has been updated and approved

5.6.3 Verify training has been completed and documented

5.6.4 Confirm actions do not adversely affect product safety or quality

5.6.5 Complete Section 6 (Verification) of the CAPA Form

5.7 Effectiveness Verification

Effectiveness shall be verified to ensure the root cause has been eliminated:

5.7.1 Define measurable effectiveness criteria before closure

5.7.2 Allow adequate time for effectiveness monitoring (typically 30-90 days)

5.7.3 Collect quantitative data to demonstrate improvement

5.7.4 Compare pre- and post-implementation metrics

5.7.5 Document results in Section 7 of the CAPA Form

5.7.6 Determine effectiveness:

- Effective: Root cause eliminated, no recurrence – proceed to closure
- Partially Effective: Improvement observed – extend monitoring or add actions
- Not Effective: Issue recurred – initiate new CAPA

5.8 Closure and Management Review

Close the CAPA after successful effectiveness verification:

5.8.1 Complete Section 8 (Closure) including lessons learned

5.8.2 Obtain CAPA Owner and Quality Manager signatures

5.8.3 For Critical/High priority CAPAs, obtain Management approval

5.8.4 Update the CAPA Log with closure date and effectiveness status

5.8.5 Include CAPA summary in the next Management Review

5.8.6 Retain CAPA records per document retention requirements

6. REGULATORY REFERENCES

- ISO 13485:2016 – Clause 8.5.2 (Corrective Action), Clause 8.5.3 (Preventive Action)
- ISO 14971:2019 – Medical devices – Application of risk management to medical devices
- FDA 21 CFR Part 820.100 – Corrective and Preventive Action
- EU MDR 2017/745 – Annex IX, Chapter I (Quality Management System)
- FDA Quality System Inspection Technique (QSIT) Guide

7. RELATED DOCUMENTS

- FRM-CAPA-001: CAPA Form
- FRM-CAPA-002: CAPA Log
- SOP-NC-001: Nonconforming Product Control
- SOP-CC-001: Customer Complaint Handling
- SOP-AUD-001: Internal Audit
- SOP-CHG-001: Change Control
- SOP-TRN-001: Training and Competence

8. REVISION HISTORY

Rev	Date	Description of Change	Author
1.0	[DATE]	Initial release	[Name]