STANDARD OPERATING PROCEDURE

Corrective and Preventive Action (CAPA)

Document Number:	SOP-CAPA-001	**Revision:**	2.0
Effective Date:	[DATE]	**Review Due:**	[DATE + 2 Years]
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Supersedes:	Rev. 1.0	**Classification:**	Controlled Document

1. PURPOSE

This Standard Operating Procedure (SOP) defines the process for initiating, investigating, implementing, verifying, and closing 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 (ISO 13485, FDA 21 CFR 820, EU MDR)
- Provide data-driven input to Management Review and Post-Market Surveillance

2. SCOPE

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

- Customer complaints and field feedback
- Internal and external audit findings (including notified body and regulatory inspections)
- Nonconforming product or process deviations (per SOP-NC-001)
- Post-market surveillance and vigilance data (per EU MDR Art. 83–86)
- Supplier quality issues and supplier CAPA requests
- Management review outputs and quality objectives
- Trend analysis and statistical data (see Section 5.1 for quantitative triggers)
- Risk assessment outputs requiring risk control measures

NOTE: This SOP does not apply to immediate corrections or containment actions that do not require root cause analysis. For the distinction between Correction, Corrective Action, and Preventive Action, see the CAPA Quick Reference Card (QRC-CAPA-001).

3. DEFINITIONS

Term	Definition
CAPA	Corrective and Preventive Action — a systematic approach to identifying, investigating, and resolving quality issues to prevent recurrence (corrective) or first occurrence (preventive).
Correction	Immediate action to eliminate a detected nonconformity (e.g., rework, scrap, re-inspection). Does NOT address root cause.

Corrective Action	Action to eliminate the cause of a detected nonconformity or other undesirable situation to prevent recurrence. Requires root cause analysis.
Preventive Action	Action to eliminate the cause of a potential nonconformity or other undesirable situation to prevent occurrence. Based on trend analysis, risk assessment, or proactive identification.
Root Cause	The fundamental, systemic reason for a nonconformity, which if eliminated, would prevent recurrence. Must be actionable and specific.
Containment	Immediate action to prevent further impact of a nonconformity while root cause investigation is ongoing (e.g., quarantine, stop shipment).
Effectiveness Verification	Objective evidence-based assessment that implemented actions have achieved their intended outcome: elimination of the root cause (corrective) or prevention of occurrence (preventive).
Horizontal Deployment	Systematic evaluation of whether a root cause or corrective action applies to similar products, processes, or systems beyond the original scope.
CAPA Reopen	Reopening of a previously closed CAPA when effectiveness verification demonstrates that the root cause has not been eliminated or has recurred.

4. RESPONSIBILITIES

4.1 CAPA Owner

- Lead the investigation and root cause analysis
- Coordinate implementation of corrective and preventive actions
- Ensure timely completion within defined target dates
- Document all activities on the CAPA Form (FRM-CAPA-001)
- Perform and document effectiveness verification
- Evaluate need for horizontal deployment to similar products/processes

4.2 Quality Manager

- Review and approve all CAPA records at each phase gate
- Assign CAPA numbers and designate CAPA Owners
- Monitor CAPA metrics and KPIs (see Section 9), initiate escalation per Section 5.9
- Perform trend analysis of CAPA data quarterly (minimum)
- Ensure regulatory compliance of the CAPA process

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 KPIs and trends in Management Review
- Approve all Critical and High priority CAPAs at initiation and closure

- Review escalated overdue CAPAs and allocate resources
- Ensure CAPA process effectiveness is evaluated during Management Review

5. PROCEDURE

The CAPA process follows a structured lifecycle as depicted in the CAPA Process Flowchart (FLC-CAPA-001). Each phase has defined inputs, outputs, and approval gates.

5.1 CAPA Initiation

5.1.1 CAPA Triggers

A CAPA shall be initiated when any of the following conditions are met:

- A significant or recurring nonconformity is identified
- An audit finding (internal or external) requires systemic corrective action
- Customer complaint investigation reveals a quality system gap
- Trend analysis exceeds defined thresholds (see table below)
- Regulatory inspection results in an observation or citation
- Risk assessment identifies an unacceptable residual risk requiring additional risk control
- Post-market surveillance data indicates adverse trend (per PMS Plan thresholds)

5.1.2 Quantitative Trend Triggers

The following thresholds define mandatory CAPA triggers from trend data. The Quality Manager shall evaluate these thresholds quarterly.

Data Source	Threshold / Trigger	Action
Nonconformance Log	≥3 NCs of same root cause category within 6 months	Mandatory CAPA initiation
Customer Complaints	≥2 complaints on same failure mode within 12 months	Mandatory CAPA initiation
Process Monitoring / SPC	Trend toward specification limit (rule of seven, 2-sigma shift)	Evaluate for Preventive CAPA
Audit Findings	Any Major finding; repeat Minor finding within 2 audit cycles	Mandatory CAPA initiation
Post-Market Surveillance / Vigilance	Any reportable event; adverse trend per PMS plan thresholds	Mandatory CAPA initiation

NOTE: These thresholds are minimum requirements. Organizations should adjust based on their risk profile, product portfolio, and regulatory environment. Thresholds shall be reviewed during annual Management Review.

5.1.3 Initiation Steps

5.1.3.1 Complete Section 1 (Problem Description) of the CAPA Form (FRM-CAPA-001). Include: source of the issue, affected product(s)/process(es), date of detection, and initial risk assessment.

5.1.3.2 Assign a unique CAPA number using format: CAPA-YYYY-XXX (e.g., CAPA-2026-001).

5.1.3.3 Classify the priority level based on risk assessment:

Priority	Criteria	Target Closure	Escalation After	Approval Required
CRITICAL	Patient safety impact, field safety corrective action required	30 days	15 days overdue	Management Representative
HIGH	Regulatory non-compliance, major quality system gap	60 days	30 days overdue	Management Representative
MEDIUM	Moderate quality impact, repeat minor nonconformities	90 days	45 days overdue	Quality Manager
LOW	Minor improvement opportunity, optimization	120 days	60 days overdue	Quality Manager

5.1.3.4 Assign a CAPA Owner with appropriate authority, technical expertise, and cross-functional access.

5.1.3.5 Enter the CAPA into the CAPA Log (FRM-CAPA-002) for tracking.

5.1.3.6 For Critical/High priority: obtain Management Representative approval before proceeding.

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. Include in-process, finished goods, and distributed product.

5.2.2 Implement appropriate containment (e.g., quarantine, stop shipment, customer notification, labeling hold, production stop).

5.2.3 Document containment actions in Section 2 of the CAPA Form, including scope, responsible person, and date of implementation.

5.2.4 Verify containment effectiveness before proceeding to root cause investigation.

IMPORTANT: For product already distributed to customers or in the field: evaluate whether a Field Safety Corrective Action (FSCA) is required per EU MDR Art. 83 and FDA 21 CFR 806.

5.3 Root Cause Investigation

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

5.3.1 Assemble a cross-functional investigation team as appropriate to the complexity and impact of the issue.

5.3.2 Collect and analyze relevant data, records, and objective evidence.

5.3.3 Apply appropriate root cause analysis techniques using the RCA Toolkit (RCA-CAPA-001):

- 5-Why Analysis — recommended for most investigations; continue until systemic cause is reached
- Fishbone (Ishikawa) Diagram — for complex, multi-factor issues across multiple categories
- Fault Tree Analysis — for safety-critical events requiring systematic logic analysis
- Pareto Analysis — for trend-based investigations to identify the vital few contributors

5.3.4 Document the investigation process, evidence reviewed, and findings in Section 3 of the CAPA Form.

5.3.5 Clearly state the root cause — it must explain WHY the problem occurred and be specific enough to derive targeted actions.

IMPORTANT: "Human error" alone is never an acceptable root cause. Always identify the systemic reason WHY the error occurred: inadequate training, unclear procedure, missing verification step, poor ergonomics, excessive workload, insufficient competence assessment, etc.

5.4 Action Planning

Corrective and/or preventive actions shall be planned to address the identified root cause:

5.4.1 Define specific, measurable actions to eliminate the root cause. Each action must have a clear deliverable.

5.4.2 Assign responsible person(s) and target completion dates for each action.

5.4.3 Document actions in Section 4 (Corrective Actions) and Section 5 (Preventive Actions) of the CAPA Form.

5.4.4 Perform mandatory horizontal deployment assessment: evaluate whether the root cause or corrective action applies to similar products, processes, production lines, or sites. Document the assessment and rationale in Section 4 of the CAPA Form, even if the conclusion is "not applicable."

IMPORTANT: Horizontal deployment is a mandatory assessment per FDA QSIT and ISO 13485:2016. Failure to evaluate similar products/processes is a common audit finding. Always document the assessment, including the rationale when horizontal deployment is deemed not applicable.

5.4.5 Evaluate whether actions require change control (per SOP-CHG-001) or process validation.

5.4.6 Mandatory Risk Management File review: assess whether the CAPA impacts the risk analysis (FMEA/FTA) per ISO 14971:2019. Complete the Risk Assessment Impact check in the CAPA Form:

- Does the root cause represent a new hazard or hazardous situation not previously identified?
- Does the corrective action change the risk profile of an existing hazard?
- Is an update to the Risk Management File required? If yes, reference the updated document.

5.4.7 Define effectiveness criteria BEFORE implementation (see 5.7 for guidance on selecting appropriate criteria).

5.4.8 Obtain Quality Manager approval before implementation. For Critical/High CAPAs, obtain Management Representative approval.

5.5 Implementation

Execute the approved action plan:

5.5.1 Implement each action per the defined timeline and responsible assignments.

5.5.2 Document objective evidence of implementation (e.g., updated SOPs, training records, process validation reports, equipment qualification records).

5.5.3 Update the CAPA Form status as actions are completed.

5.5.4 Notify affected personnel of process or document changes. Ensure training is completed and documented before affected processes resume.

5.6 Verification of Implementation

Verify that all planned actions have been completed as defined (this is NOT the same as effectiveness verification):

5.6.1 Review objective evidence for each completed action item.

5.6.2 Confirm all affected documentation has been updated, reviewed, and approved per document control procedures.

5.6.3 Verify required training has been completed and documented.

5.6.4 Confirm implemented actions do not introduce new risks or adversely affect product safety, quality, or regulatory compliance.

5.6.5 Complete Section 6 (Verification of Implementation) of the CAPA Form.

> **NOTE:** Verification of Implementation confirms WHAT was done (actions completed). Effectiveness Verification (Section 5.7) confirms WHETHER it worked (root cause eliminated). Both are required for CAPA closure.

5.7 Effectiveness Verification

Effectiveness shall be verified with objective, measurable evidence to confirm the root cause has been eliminated:

5.7.1 Define measurable effectiveness criteria at the time of action planning (Section 5.4.7). Criteria must be:

- Specific and measurable (not vague statements like "no more complaints")
- Time-bound (define the monitoring period and sample size rationale)
- Related to the root cause (not just symptoms)

> **NOTE:** Examples of good effectiveness criteria: "Zero recurrence of NC type X in 50 consecutive production batches" or "Incoming inspection reject rate for supplier Y ≤1% over 90 days (n≥30 lots)." Avoid criteria that cannot be objectively measured or that rely solely on absence of complaints.

5.7.2 Allow adequate monitoring time based on priority and production volume. Minimum monitoring periods:

- Critical: 30 days minimum or 3 production cycles (whichever is greater)
- High: 60 days minimum or 5 production cycles
- Medium/Low: 90 days minimum or 10 production cycles

5.7.3 Collect quantitative data to demonstrate improvement. Use pre- vs. post-implementation comparison where possible.

5.7.4 Document results in Section 7 of the CAPA Form.

5.7.5 Determine effectiveness outcome:

- **Effective:** Root cause eliminated, effectiveness criteria met — proceed to closure (5.8)
- **Partially Effective:** Improvement observed but criteria not fully met — extend monitoring period and/or define additional actions
- **Not Effective:** Root cause not eliminated or issue recurred — proceed to CAPA Reopen (5.10)

5.8 Closure and Management Review

Close the CAPA after successful effectiveness verification:

5.8.1 Complete Section 8 (Closure) of the CAPA Form including:

- Summary of actions taken and evidence of effectiveness
- Lessons learned and best practices identified
- Impact on Quality Management System documentation (if any)

5.8.2 Obtain CAPA Owner and Quality Manager signatures.

5.8.3 For Critical/High priority CAPAs: obtain Management Representative approval for closure.

5.8.4 Update the CAPA Log with closure date, effectiveness status, and total CAPA duration.

5.8.5 Include CAPA summary in the next Management Review per Section 9.

5.8.6 Retain CAPA records per document retention requirements: minimum 10 years after last production, or lifetime of device plus 5 years (whichever is longer), per EU MDR Art. 10(8) and ISO 13485:2016 Clause 4.2.5.

5.9 Escalation Procedure

Overdue CAPAs shall be escalated according to the following schedule. The Quality Manager is responsible for monitoring due dates and initiating escalation.

Overdue Status	Action	Responsible
Approaching due date (7 days before)	Automated reminder to CAPA Owner	Quality Manager
Overdue 1–14 days	Written escalation to CAPA Owner and Department Manager; document reason for delay and revised target date	Quality Manager
Overdue 15–30 days	Escalation to Management Representative; root cause for delay required; revised action plan with weekly status	Quality Manager
Overdue >30 days	Escalation to Top Management; inclusion in Management Review agenda as open issue; resource reallocation if necessary	Management Representative

NOTE: All escalation actions shall be documented in the CAPA Log. Escalation history is reviewed during Management Review as part of CAPA KPI reporting.

5.10 CAPA Reopen Process

A closed CAPA shall be reopened when:

- Effectiveness verification demonstrates the root cause has not been eliminated (5.7.5 — "Not Effective")
- The same root cause recurs within 12 months of CAPA closure
- New information reveals the original root cause analysis was incomplete or incorrect

Reopen procedure:

5.10.1 Document the reason for reopening in the CAPA Form (Section 8 addendum).

5.10.2 Update the CAPA Log status to "Reopened" with the date and reason.

5.10.3 Reassess priority level — reopened CAPAs are automatically escalated one priority level (e.g., Medium → High).

5.10.4 Conduct a new or supplementary root cause investigation, considering why the original actions were insufficient.

5.10.5 Define and implement revised corrective/preventive actions.

5.10.6 Repeat effectiveness verification with enhanced criteria.

IMPORTANT: A CAPA that has been reopened twice requires Management Representative review and approval of the revised action plan. Consider whether external expertise (consultant, supplier, Notified Body feedback) is needed.

6. NC-TO-CAPA DECISION CRITERIA

Not every nonconformity requires a CAPA. The following criteria guide the decision to escalate from NC to CAPA:

CAPA Required (Corrective Action)	Correction Only (No CAPA)
Recurring nonconformity (same root cause ≥2 times)	Isolated, one-time nonconformity with clear assignable cause
Systemic issue affecting multiple products/processes	Contained to single lot/batch with no systemic implication
Patient safety or regulatory compliance impact	Minor cosmetic or administrative deviation
Audit finding classified as Major or repeat Minor	First-time Minor audit observation with obvious correction
Trend threshold exceeded (see 5.1.2)	Below trend threshold, no pattern identified
Supplier-related issue affecting product quality	Supplier administrative deviation (e.g., late CoC delivery)

NOTE: When in doubt, escalate to CAPA. It is always preferable to investigate and close a CAPA with "root cause confirmed as isolated event" than to miss a systemic issue. Document the decision rationale in the NC record.

7. SUPPLIER CAPA PROCESS

When a CAPA investigation identifies a supplier as the root cause, the following additional steps apply:

7.1 Issue a Supplier Corrective Action Request (SCAR) to the supplier, referencing the internal CAPA number.

7.2 Define expected response timeline: 15 business days for initial response; full corrective action per CAPA priority timeline.

7.3 Review and approve the supplier's root cause analysis and proposed corrective actions.

7.4 Verify supplier corrective action implementation through incoming inspection data, supplier audit, or documented evidence.

7.5 Update the supplier quality record and supplier scorecard. Evaluate impact on approved supplier status.

7.6 Link the SCAR to the internal CAPA record for traceability.

8. REGULATORY REFERENCES

Standard / Regulation	Relevant Sections
ISO 13485:2016	Clause 8.5.2 (Corrective Action), Clause 8.5.3 (Preventive Action), Clause 8.2.5 (Monitoring & Measurement)

ISO 14971:2019	Risk management — Application of risk management to medical devices. Sections 7 (Risk Control), 9 (Production and Post-Production)
FDA 21 CFR 820.90	Nonconforming Product
FDA 21 CFR 820.100	Corrective and Preventive Action — (a)(1) through (a)(7)
FDA 21 CFR 820.198	Complaint Files
EU MDR 2017/745	Art. 10(9–10) — QMS obligations; Art. 83–86 — Vigilance; Annex IX Ch. I — QMS requirements
MDSAP	Chapter 6 — CAPA; interfaces with Ch. 3 (Device Marketing), Ch. 4 (Measurement/Analysis)
FDA QSIT Guide	CAPA Subsystem — inspection objectives and decision trees
ICH Q10	Section 3 — Pharmaceutical Quality System elements (for pharma-scope organizations)

9. CAPA KPIs FOR MANAGEMENT REVIEW

The following Key Performance Indicators shall be reported in each Management Review meeting. The Quality Manager is responsible for data collection and analysis.

KPI	Definition	Target
CAPA Closure Rate	% of CAPAs closed within target timeline per priority level	≥90% on-time closure
CAPA Effectiveness Rate	% of CAPAs rated “Effective” at first effectiveness review	≥85% effective at first review
Recurrence Rate	% of closed CAPAs where the same root cause recurs within 12 months	≤5% recurrence
CAPA Aging	Number of open CAPAs exceeding target closure date	0 CAPAs >30 days overdue
Time to Root Cause	Average days from CAPA initiation to documented root cause	≤30 days average
Preventive vs. Corrective Ratio	Ratio of Preventive Actions to Corrective Actions initiated	Increasing trend year-over-year

Additional data to be presented in Management Review:

- CAPA source distribution (complaints, audits, NCs, trends, PMS)
- Top root cause categories (Pareto analysis)
- CAPA by department and product line
- Trend comparison to previous reporting period

10. RELATED DOCUMENTS

Document ID	Document Title
FRM-CAPA-001	CAPA Form
FRM-CAPA-002	CAPA Log

RCA-CAPA-001	Root Cause Analysis Toolkit
QRC-CAPA-001	CAPA Quick Reference Card
FLC-CAPA-001	CAPA Process Flowchart
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
SOP-RM-001	Risk Management
SOP-PMS-001	Post-Market Surveillance

11. REVISION HISTORY

Rev	Date	Description of Change	Author
1.0	[DATE]	Initial release	[Name]
2.0	[DATE]	Major revision: Added quantitative trend triggers (5.1.2), escalation procedure (5.9), CAPA reopen process (5.10), NC-to-CAPA decision criteria (6), supplier CAPA process (7), KPI definitions (9). Enhanced risk management integration (5.4.6), effectiveness verification guidance (5.7), record retention requirements (5.8.6). Improved regulatory references (8).	[Name]