CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Form

** = mandatory field*

CAPA Number *	*CAPA-20XX-XXX*	**Date Initiated ***	
CAPA Owner *		**Target Completion ***	
Department *		**Actual Completion**	

Source *	**Priority / Risk Level ***
☐ Internal Audit ☐ External Audit / Regulatory Inspection ☐ Customer Complaint (Ref: CC-____-____) ☐ Nonconformance (Ref: NC-____-____) ☐ PMS / Vigilance Data ☐ Management Review ☐ Supplier Issue (Ref: SCAR-____-____) ☐ Trend Analysis (see threshold justification below) ☐ Risk Assessment Output ☐ Other: _____	☐ CRITICAL — Patient safety impact (30 days) ☐ HIGH — Regulatory / major quality (60 days) ☐ MEDIUM — Moderate impact (90 days) ☐ LOW — Minor / improvement (120 days) **Risk Assessment Justification: *** *Briefly describe how the priority level was determined*

1. PROBLEM DESCRIPTION *[ISO 13485 §8.5.2a / FDA 820.100(a)(1)]*

Problem Statement *	*Describe what happened, when, where, and how it was identified. Be specific and factual. Include detection date and method.*
Affected Product(s) / Process(es) *	*List product names, part numbers, lot/batch numbers, serial numbers. For process issues: identify process name and step.*
Reference Documents *	*NC#, Complaint#, Audit Finding#, Deviation#, PMS Report#, Risk Assessment#, etc.*
Impact Assessment *	*Describe the impact on: (1) Patient safety, (2) Product quality, (3) Regulatory compliance, (4) Business operations. Quantify where possible.*
Estimated Cost Impact	*Direct costs (scrap, rework, returns) and indirect costs (investigation time, production delay). Optional but recommended for Management Review.*

2. IMMEDIATE CONTAINMENT ACTIONS *[FDA 820.100(a)(3) / EU MDR Art. 83]*

Containment Actions Taken *	*What immediate actions were taken to prevent further impact? (e.g., quarantine, stop shipment, rework, customer notification, labeling hold, production stop)*

Scope of Affected Product	*Quantity affected, lots/batches, distributed vs. in-stock, in-process inventory. Include product already shipped to customers if applicable.*
FSCA Required? *	☐ Yes — Field Safety Corrective Action initiated (Ref: FSCA-____-____) ☐ No — Justification:
Containment Verified By *	*Name, function, date of verification. Attach evidence if available.*

3. ROOT CAUSE INVESTIGATION *[ISO 13485 §8.5.2b / FDA 820.100(a)(2)]*

RCA Method Used *	☐ 5-Why Analysis ☐ Fishbone / Ishikawa Diagram ☐ Fault Tree Analysis ☐ Pareto Analysis ☐ Other: _____
Investigation Team *	*List names, functions/departments, and roles in the investigation.*

5-Why Analysis *(attach Fishbone diagram or other RCA tools as appendix)*	
Why 1:	
Why 2:	
Why 3:	
Why 4:	
Why 5:	

Root Cause Statement *	*State the identified root cause clearly and specifically. What is the fundamental systemic reason the problem occurred? Must be actionable.*
Evidence / Data Supporting Root Cause *	*What objective evidence supports this conclusion? List data, records, observations, interviews, test results.*

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

4. CORRECTIVE ACTION PLAN *[ISO 13485 §8.5.2c-d / FDA 820.100(a)(3-4)]*

#	Corrective Action Description	Responsible	Due Date	Status	Evidence

1					
2					
3					
4					
5					

MANDATORY: Horizontal Deployment Assessment *[FDA QSIT / ISO 13485]*	
Similar Products Assessed? *	☐ Yes — Products assessed: _____ ☐ No — Justification (required):
Similar Processes Assessed? *	☐ Yes — Processes assessed: _____ ☐ No — Justification (required):
Supplier Notification Required?	☐ Yes — SCAR issued (Ref: SCAR-____-____) ☐ No ☐ N/A

5. PREVENTIVE ACTION *[ISO 13485 §8.5.3 / FDA 820.100(a)(3)]*

Guidance: *Preventive actions address POTENTIAL issues to prevent first occurrence. Consider: What similar failures COULD happen that have NOT yet occurred? What systemic changes prevent this entire category of failure?*

#	Preventive Action Description	Responsible	Due Date	Status	Evidence
1					
2					
3					
4					
5					

6. VERIFICATION OF IMPLEMENTATION *[ISO 13485 §8.5.2e / FDA 820.100(a)(4-5)]*

Guidance: *This section verifies WHAT was done (actions completed as planned). This is NOT effectiveness verification (Section 7), which confirms WHETHER the actions worked.*

Verification Checklist *	☐ All corrective actions completed as planned ☐ All preventive actions completed as planned ☐ Documentation updated (SOPs, WIs, Forms, Specifications)

	☐ Training completed and documented for affected personnel ☐ Process/Design changes implemented and verified ☐ Actions do not adversely affect product safety or performance ☐ Relevant personnel informed (memos, emails, meetings) ☐ Change control records completed (if applicable, Ref: ECO-____-____)
Evidence of Implementation *	*List specific document numbers: updated SOPs, training records (TRN-____), change orders (ECO-____), validation reports, etc.*
Verified By / Date *	*Name, function, date. Must be someone other than the CAPA Owner.*

7. EFFECTIVENESS VERIFICATION *[ISO 13485 §8.5.2f / FDA 820.100(a)(4)]*

Effectiveness Check Date *	*Minimum monitoring: Critical 30d/3 cycles, High 60d/5 cycles, Medium/Low 90d/10 cycles.*
Effectiveness Criteria *	*Define specific, measurable, time-bound criteria. Example: "Zero recurrence of NC type X in 50 consecutive batches" or "Incoming reject rate for supplier Y ≤1% over 90 days (n≥30 lots)."*
Sample Size / Monitoring Rationale	*Justify the sample size or monitoring period chosen. Reference statistical basis where applicable.*
Effectiveness Results *	*Document results with quantitative data. Include pre- vs. post-implementation comparison (before/after metrics, trend charts, test data).*
Effectiveness Determination *	☐ **EFFECTIVE** — Root cause eliminated, criteria met. Proceed to Closure (Section 8). ☐ **PARTIALLY EFFECTIVE** — Improvement observed, criteria not fully met. Extend monitoring / add actions. ☐ **NOT EFFECTIVE** — Root cause not eliminated. Proceed to CAPA Reopen (Section 9).

8. RISK MANAGEMENT FILE REVIEW *[ISO 14971:2019 / EU MDR Annex I]*

Guidance: *This mandatory assessment ensures the CAPA process is linked to the Risk Management File. Under EU MDR and ISO 14971, any new information about hazards must be evaluated and, if necessary, reflected in the risk analysis.*

Does the root cause represent a new hazard or hazardous situation? *	☐ Yes ☐ No *If Yes, describe:*
Does the corrective action change the risk profile? *	☐ Yes — risk reduced ☐ Yes — new residual risk introduced ☐ No change

Risk Management File update required? *	☐ Yes — Updated document ref: RM-____-____ ☐ No — Justification:
Risk Management File reviewed by:	*Name, function, date. Should be the Risk Manager or designee.*

9. CAPA REOPEN *[if applicable — per SOP-CAPA-001 §5.10]*

Reason for Reopening	☐ Effectiveness verification: Not Effective (Section 7) ☐ Same root cause recurred within 12 months ☐ New information: original RCA was incomplete/incorrect **Details:**
Revised Priority Level	*Reopened CAPAs are automatically escalated one priority level (e.g., Medium → High). New level: _____*
Supplementary Investigation	*Document additional root cause analysis. Why were the original actions insufficient?*
Revised Actions	*Define revised corrective/preventive actions with new target dates.*
Reopened By / Date	

10. CAPA CLOSURE *[ISO 13485 §8.5.2g / FDA 820.100(a)(6-7)]*

Management Review Reference *	*Document the MR meeting date and minutes reference where this CAPA was reviewed.*
Lessons Learned *	*Key takeaways for organizational improvement. What would you do differently? What worked well?*
Record Retention	*Retain per document retention policy: minimum 10 years after last production, or lifetime of device + 5 years (whichever is longer). Ref: EU MDR Art. 10(8), ISO 13485 §4.2.5.*

APPROVALS	Signature	Date
CAPA Owner		
Quality Manager		
Management Representative (Critical/High CAPAs)		
Risk Manager (if RM File updated)		

This form complies with ISO 13485:2016 §8.5.2-8.5.3, FDA 21 CFR 820.100, EU MDR 2017/745 Annex IX, and ISO 14971:2019.
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