CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Form

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

Source: ☐ Internal Audit ☐ External Audit ☐ Customer Complaint ☐ Nonconformance ☐ PMS/Vigilance ☐ Management Review ☐ Supplier Issue ☐ Process Deviation ☐ Other: _____	**Priority / Risk Level:** ☐ Critical (Patient Safety Impact) ☐ High (Regulatory/Major Quality) ☐ Medium (Moderate Impact) ☐ Low (Minor / Improvement)

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.*
Affected Product(s) / Process(es)	*List product names, part numbers, lot/batch numbers if applicable*
Reference Documents	*NC#, Complaint#, Audit Finding#, Deviation#, etc.*
Impact Assessment	*Describe the impact on product quality, patient safety, regulatory compliance, and business operations.*

2. IMMEDIATE CONTAINMENT ACTIONS [FDA 820.100(a)(3)]

Containment Actions Taken	*What immediate actions were taken to contain the issue and prevent further impact? (e.g., quarantine, stop shipment, rework, notification)*
Containment Verified By	*Name and date of verification*

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 and functions of team members*

5-Why Analysis (attach Fishbone diagram if used)
Why 1:
Why 2:
Why 3:
Why 4:
Why 5:

Root Cause Statement	*State the identified root cause clearly. What is the fundamental reason the problem occurred?*
Evidence / Data Supporting Root Cause	*What evidence supports this conclusion? List data, records, observations, interviews.*

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

#	Corrective Action	Responsible	Due Date	Status
1				
2				
3				
4				

5				

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

Preventive Actions	*What actions will prevent this issue from occurring in other products, processes, or areas? Consider: SOP updates, training, process changes, design changes.*
Horizontal Deployment	☐ Other products reviewed for similar risk ☐ Other processes reviewed for similar risk ☐ Supplier/vendor notification required ☐ Not applicable (justify below)
Justification / Notes	

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

Verification Activities	☐ Actions completed as planned ☐ Documentation updated (SOPs, WIs, Forms) ☐ Training completed and documented ☐ Process/Design changes implemented ☐ Actions do not adversely affect product safety/performance ☐ Relevant personnel informed (memos, emails, meetings)
Evidence of Implementation	*List document numbers, training records, change orders, etc.*
Verified By / Date	

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

Effectiveness Check Date	*Minimum 30-90 days after implementation*
Effectiveness Criteria	*What measurable criteria will determine if the CAPA was effective? (e.g., no recurrence, reduced defect rate, audit finding closed)*
Effectiveness Results	*Document the results of the effectiveness check. Include data comparison (before vs. after).*
Effectiveness Determination	☐ EFFECTIVE - Root cause eliminated, no recurrence

	☐ PARTIALLY EFFECTIVE - Improvement observed, monitoring continues ☐ NOT EFFECTIVE - New CAPA required (Reference: CAPA-____-___)

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

Management Review Reference	*Document MR meeting date/minutes where CAPA was reviewed*
Lessons Learned	*Key takeaways for organizational improvement*

APPROVALS		
CAPA Owner	Signature:	Date:
Quality Manager	Signature:	Date:
Management Representative (if Critical/High)	Signature:	Date:

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