CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Completed Example — Urinary Catheter Labeling Issue

CAPA Number:	2025-01-08	**CAPA Owner:**	Quality / Production
Source:	HIGH (Regulatory / Major Quality)	**Target Date:**	2025-06-20

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

Problem Statement	On 2025-01-06, customer complaint CC-2025-0042 was received from St. Anna Hospital, Munich. The complaint reported that 47 units of sterile urinary catheters (REF UC-200-16FR) from lot #L2024-1187 displayed an incorrect expiration date on the primary packaging. **Label showed:** EXP 2025-06 (incorrect) **Correct date:** EXP 2027-06 (per stability study STB-2022-014) The shortened expiration date would cause premature disposal of compliant product, resulting in unnecessary waste and potential supply issues. **Detection method:** Customer complaint received via email on 2025-01-06, 09:15 CET
Affected Products	Sterile Urinary Catheter, 16FR (REF UC-200-16FR) **Lot:** #L2024-1187 — 2,400 units produced **Process step:** Final labeling (Line 3, Building B)
Impact Assessment	**(1) Patient Safety:** LOW — Product sterility and function not affected, only label error **(2) Product Quality:** MEDIUM — Product compliant, but label nonconforming **(3) Regulatory:** HIGH — Mislabeling violates 21 CFR 820.120 and EU MDR Annex I §23.2 **(4) Business:** MEDIUM — Customer trust affected, potential recall costs **Scope:** 2,400 units distributed to 12 customers across EU and US markets
Estimated Cost Impact	€ 35,900 (corrective labels, investigation, SOP revision, training, audit)
Reference Documents	CC-2025-0042, DHR-L2024-1187, NC-2025-0023, RA-2025-008, STB-2022-014

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

Containment Actions	1. Production line for UC-200 series stopped immediately (2025-01-06, 14:30) 2. Remaining inventory of lot L2024-1187 quarantined (312 units in warehouse) 3. Customer notification sent to all 12 affected customers within 24 hours 4. Advisory issued: Product safe to use, apply corrective label over expiry date 5. Corrective labels printed and shipped to customers (2025-01-08) 6. No field safety corrective action (recall) required per risk assessment RA-2025-008
Scope of Affected Product	2,400 units total: 2,088 distributed (12 customers), 312 quarantined in warehouse
FSCA Required?	☐ **Yes** — Reference: ___ ☑ **No** — Justification: Product safety and performance not affected. Label error limited to expiration date display. Risk assessment RA-2025-008 confirms no patient safety risk.
Containment Verified By	Thomas Weber, Production Manager — 2025-01-08

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

RCA Method(s) Used	☑ 5-Why Analysis ☑ Fishbone / Ishikawa Diagram (attached as Appendix A) ☐ Fault Tree Analysis ☐ Pareto Analysis
Investigation Team	Dr. M. Schmidt (QM), T. Weber (Prod), K. Hoffmann (Labeling), S. Braun (QC)

⚠ *Remember: "Human error" is never an acceptable root cause — always ask WHY the error occurred.*

Why #	Question	Finding
Why 1	Why was the wrong expiration date printed?	Label template contained incorrect shelf life parameter (24 months instead of 48 months)

Why 2	Why did the template have the wrong shelf life?	Template was copied from UC-100 series (24-month shelf life) when creating UC-200 series
Why 3	Why wasn't the shelf life updated after copying?	No checklist exists for verifying all parameters when creating new label templates
Why 4	Why wasn't the error caught during label approval?	Label approval SOP focuses on text/graphics review, no explicit verification against DHF/DMR data
ROOT Why 5	Why doesn't the SOP require DHF/DMR verification?	**SOP-LAB-002 Rev 3 (2018) was never updated to include mandatory DHF/DMR cross-check for critical label parameters**

Root Cause Statement	**ROOT CAUSE:** SOP-LAB-002 "Label Design and Approval" lacks a mandatory verification step requiring cross-check of critical label parameters (expiration date, shelf life, storage conditions) against the Device Master Record (DMR) and Design History File (DHF). **CONTRIBUTING FACTOR:** No standardized template creation checklist exists, allowing copy-paste errors to propagate undetected.
Evidence / Data	• Review of SOP-LAB-002 Rev 3 confirms no DHF/DMR verification requirement • Interview with K. Hoffmann confirmed template was copied from UC-100 • Label approval record LAB-2024-0892 shows no shelf life verification performed • DMR-UC-200 clearly states 48-month shelf life based on STB-2022-014 • Similar near-miss found in UC-150 template (caught before production)

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

#	Corrective Action	Responsible	Due Date	Status	Evidence
1	Correct UC-200 label template, update shelf life to 48 months	K. Hoffmann	2025-01-15	COMPLETE	ECO-2025-0010
2	Revise SOP-LAB-002 to include mandatory DHF/DMR verification step	Dr. M. Schmidt	2025-02-01	COMPLETE	ECO-2025-0012
3	Create Label Template Creation Checklist (FRM-LAB-015)	K. Hoffmann	2025-02-15	COMPLETE	FRM-LAB-015 v1
4	Train all labeling personnel on revised SOP and checklist (6 people)	S. Braun	2025-02-28	COMPLETE	TR-2025-0089–0094
5	Audit all active label templates against DMR (32 SKUs)	QC Team	2025-03-15	COMPLETE	QA-RPT-2025-008

HORIZONTAL DEPLOYMENT ASSESSMENT (MANDATORY)

☑ **Similar Products Assessed?** Yes — All 32 active product label templates audited. One additional discrepancy found in UC-150 template (storage temp) — corrected under NC-2025-0031.

☑ **Similar Processes Assessed?** Yes — Labeling processes for all product lines reviewed. Same SOP gap existed across all lines.

☐ **Supplier Notification Required?** No — Label printing performed in-house. No supplier involvement.

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

ⓘ *Preventive actions address potential problems that have NOT yet occurred. They go beyond correcting the current issue to prevent similar problems in other areas.*

#	Preventive Action	Responsible	Due Date	Status	Evidence
1	Implement automated label parameter validation in ERP (Project IT-2025-04) — system flags mismatches between label template and DMR before print approval	IT / QM	2025-09-30	PLANNED	—
2	Add annual label audit to internal audit schedule	Dr. M. Schmidt	2025-02-15	COMPLETE	AUD-PLAN-2025 v2
3	Include labeling process review in next Management Review	Dr. M. Schmidt	2025-04-15	COMPLETE	MR-2025-Q1 Item 5.7

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

ⓘ *This section verifies WHAT was done (actions completed as planned). It does NOT verify WHETHER the actions were effective — that is Section 7.*

☑ All corrective actions completed as planned

☑ Documentation updated (SOPs, WIs, Forms) — SOP-LAB-002 Rev 4, FRM-LAB-015 v1

☑ Training completed and documented — TR-2025-0089 through TR-2025-0094 (6 employees)

☑ Change control records complete — ECO-2025-0010, ECO-2025-0012

☑ Actions verified not to adversely affect product safety/performance

☑ All affected personnel informed of changes

☑ Label audit report QA-RPT-2025-008 completed (32 SKUs reviewed)

Evidence: SOP-LAB-002 Rev 4 effective 2025-02-01, FRM-LAB-015 approved 2025-02-15, TRN records TR-2025-0089–0094, ECO-2025-0010, ECO-2025-0012, QA-RPT-2025-008

Verified By: S. Braun, QC Supervisor (someone other than CAPA Owner) — 2025-03-15

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

Monitoring Period	**Priority:** HIGH → Minimum 60 days / 5 production cycles **Actual monitoring:** 2025-03-16 to 2025-06-15 (92 days, exceeds minimum)
Effectiveness Criteria	**Criterion 1:** Zero label-related nonconformances in 90-day monitoring period **Criterion 2:** 100% compliance with new FRM-LAB-015 checklist (verified by audit of 10 random label approvals) **Criterion 3:** Zero customer complaints related to labeling errors
Sample Size / Monitoring Rationale	10 random label approvals sampled from 47 total approvals in the monitoring period (~21% sample). Rationale: Per ANSI/ASQ Z1.4, AQL=0.1%, general inspection level II, sample size of 8 required for lot size 50. Sample of 10 exceeds requirement.
Effectiveness Results	**Criterion 1:** Label NCs in period: 0 (vs. 3 in prior 90-day period) ✓ **Criterion 2:** Checklist compliance audit: 10/10 approvals compliant (100%) ✓ **Criterion 3:** Customer complaints (labeling): 0 ✓ New label templates created in period: 4 (all verified against DMR per new SOP)

☑ **EFFECTIVE** — Root cause eliminated, all criteria met. Proceed to closure.

☐ **PARTIALLY EFFECTIVE** — Extend monitoring / add supplementary actions

☐ **NOT EFFECTIVE** — Reopen CAPA, escalate priority one level (see Section 9)

8. RISK MANAGEMENT FILE REVIEW *[ISO 14971 / EU MDR Annex I §3]*

ⓘ *EU MDR and ISO 14971 require that CAPA outcomes are fed back into the risk management process. This section documents the mandatory review.*

New hazard identified?	☐ **Yes** — Description: ___ ☑ **No** — The labeling error does not introduce a new hazard. The underlying hazard (incorrect product information) was already identified in the risk management file.
Risk profile changed?	☐ Risk reduced (describe mitigation) ☐ New residual risk identified ☑ No change — Existing risk controls (SOP revision + checklist + training) address the hazard. Residual risk remains acceptable per risk matrix.
RM File update required?	☑ **Yes** — Updated dFMEA for labeling process (added new risk control: DHF/DMR verification step). Ref: RM-UC-200 Rev 5, updated 2025-03-20. ☐ **No** — Justification: ___
Risk Manager Review	**Reviewed By:** Dr. P. Neumann, Risk Manager — 2025-03-22 **RM File Reference:** RM-UC-200 Rev 5

9. CAPA REOPEN (if applicable) *[SOP-CAPA-001 §5.10]*

This CAPA was NOT reopened. Section included for reference — demonstrates the reopen workflow.

Reopen Triggers (check if applicable):

☐ Effectiveness verification result: NOT EFFECTIVE

☐ Recurrence of same issue within 12 months after closure

☐ Root cause investigation determined to be incomplete

Note: When reopened, priority auto-escalates one level (e.g., Medium → High). A supplementary investigation is required, and 2nd reopen requires Management Representative approval.

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

Management Review Ref.	MR-2025-Q2, Agenda Item 5.3, Meeting Date: 2025-07-10
Lessons Learned	1. Legacy SOPs require periodic review to ensure they address current regulatory requirements and process risks 2. Copy-paste workflow for templates needs systematic verification controls (checklists) 3. Automated validation (ERP integration) should be prioritized for critical parameters to prevent human-dependent checks 4. Cross-functional investigation teams significantly improve root cause identification quality 5. Horizontal deployment revealed a second discrepancy — confirms the value of systematic cross-product review
Record Retention	*Records shall be retained for minimum 10 years after last production date, or device lifetime + 5 years, whichever is longer (EU MDR Art. 10(8), ISO 13485 §4.2.5)*

APPROVALS

Role	Name	Signature	Date
CAPA Owner	Dr. Maria Schmidt	(signed)	2025-06-20
Quality Manager	Dr. Maria Schmidt	(signed)	2025-06-20
Management Representative (Critical/High priority)	Hans Müller, CEO	(signed)	2025-07-10
Risk Manager (if RM File updated)	Dr. P. Neumann	(signed)	2025-03-22