CAPA MANAGEMENT BUNDLE

Complete Corrective & Preventive Action System

ISO 13485 | FDA 21 CFR 820.100 | EU MDR 2017/745

Thank You for Your Purchase!

This bundle provides you with a complete, audit-ready CAPA system. All templates are designed to meet the requirements of ISO 13485:2016, FDA 21 CFR 820.100, and EU MDR 2017/745. Simply customize the templates with your company information and you're ready to go.

What's Included

File	Purpose	When to Use
CAPA-Form.docx	Interactive form with checkboxes for documenting individual CAPAs from initiation to closure	*Every new CAPA*
CAPA-Example.pdf	Fully completed example showing a realistic MedTech scenario with proper 5-Why analysis	*Training & reference*
CAPA-Log.xlsx	Tracking register with automated dashboard, KPIs, and status monitoring	*Ongoing tracking*
CAPA-SOP.docx	Standard Operating Procedure defining your CAPA process, roles, and timelines	*QMS documentation*
RCA-Toolkit.xlsx	Root Cause Analysis tools: 5-Why template, Fishbone diagram, Pareto analysis	*During investigation*
CAPA-QuickRef.docx	One-page cheat sheet with process flow, timelines, and golden rules	*Print & post on wall*

Quick Start Guide

Step 1: Customize the SOP

Open CAPA-SOP.docx and replace [COMPANY NAME] with your company. Review timelines and responsibilities – adjust if needed. Get management approval.

Step 2: Set Up Your Tracking Log

Open CAPA-Log.xlsx. Delete the sample data rows (keep headers). Save to your QMS folder. The dashboard will update automatically as you add CAPAs.

Step 3: Train Your Team

Use CAPA-Example.pdf to show what a properly completed CAPA looks like. Print CAPA-QuickRef and post it in your quality area. Walk through the 5-step process.

Step 4: Start Using!

When a CAPA is needed, copy a fresh CAPA-Form.docx, assign a CAPA number, and follow the process. Use the RCA-Toolkit for investigation. Log everything in CAPA-Log.xlsx.

How It All Fits Together

Issue Identified

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Open **CAPA-Form** → Log in **CAPA-Log**

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Investigate using **RCA-Toolkit** (reference **CAPA-Example**)

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Implement & Verify → Update **CAPA-Log** status

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Close CAPA → Dashboard updates automatically

Regulatory Compliance

✓ This bundle addresses the requirements of:

- ISO 13485:2016 – Clause 8.5.2 (Corrective Action) & 8.5.3 (Preventive Action)
- FDA 21 CFR Part 820.100 – Corrective and Preventive Action
- EU MDR 2017/745 – Annex IX, Quality Management System
- ISO 14971:2019 – Risk Management integration points

Note: These templates provide a framework. You are responsible for ensuring your completed documents meet your specific regulatory requirements and company procedures.

Pro Tips

- **Keep it simple:** Don't over-document. A clear, concise CAPA is better than a 20-page novel nobody reads.
- **Root cause matters:** Spend 80% of your effort on finding the true root cause. The rest follows naturally.
- **Never accept 'human error':** Always ask WHY the error occurred. The root cause is the system that allowed it.
- **Verify before closing:** Wait 30-90 days and measure results. Closing too early is a common audit finding.
- **Use the Dashboard:** Review CAPA metrics in management review. Trends tell you where to focus.

Need Help?

QCore Consulting

We offer implementation support, training, and full QMS consulting for medical device companies.

🌐 Website: **qcore-consulting.de**
📧 Email: **info@qcore-consulting.de**

Services: CAPA System Implementation • Internal Audits • Supplier Qualification • EU MDR Compliance • FDA 510(k) Support

Thank you for choosing QCore Consulting.
We wish you successful audits and zero repeat CAPAs!