CORRECTIVE AND PREVENTIVE ACTION

(CAPA) PROCEDURE

Standard Operating Procedure

Document Number:	SOP-CAPA-001
Title:	Corrective and Preventive Action (CAPA) Procedure
Version:	1.0
Effective Date:	[Date]
Regulatory Basis:	ISO 13485:2016 §8.5.2/8.5.3 | FDA 21 CFR 820.100 | EU MDR 2017/745

TABLE OF CONTENTS

1. PURPOSE

This procedure defines the process for identifying, documenting, investigating, and resolving quality issues through Corrective and Preventive Actions (CAPA). It ensures systematic elimination of root causes to prevent recurrence and continuous improvement of the Quality Management System.

2. SCOPE

This procedure applies to all CAPAs initiated within the Quality Management System, including those resulting from:

- Internal and external audit findings
- Customer complaints and feedback
- Nonconforming product investigations
- Process deviations and out-of-specification results
- Trend analysis from quality data
- Management review decisions
- Post-market surveillance data

3. DEFINITIONS

Term	Definition
CAPA	Corrective and Preventive Action - systematic approach to identifying, investigating, and eliminating the c
Corrective Action	Action to eliminate the cause of a detected nonconformity or undesirable situation
Preventive Action	Action to eliminate the cause of a potential nonconformity or undesirable situation
Root Cause	The fundamental reason for the occurrence of a nonconformity
Effectiveness	Extent to which planned activities are realized and planned results achieved

4. RESPONSIBILITIES

Role	Responsibilities
Quality Manager	• Overall CAPA system management • Approval of CAPA closure • Trend analysis and reporting
CAPA Owner	• Investigation and root cause analysis • Action plan development • Implementation tracking
Department Manager	• Resource allocation • Implementation support • Effectiveness verification

This sample shows the document structure and first sections. The complete document contains additional sections with detailed procedures, forms, and implementation guidance.

Get the full document at qcore-consulting.de