SOP Corrective and Preventive Action (CAPA)

ISO 13485:2016 Section	Document Section
8.5.1	(All)
8.5.2	(All)
8.5.3	(All)

Summary

This SOP describes how CAPAs are implemented and tracked.

Process Owner	*<enter role of process owner>*
Key Performance Indicators	*<enter KPIs to be tracked for the Management Review>*

Process Steps

1. Input for CAPA

Various events may lead to creation of CAPA. Examples include:

- Product or QMS non-conformities
- Customer complaints
- Internal bug reports, e.g. by developers
- Audit findings
- Post-market surveillance findings, including trends
- Management review findings, including trends

These inputs may be received from any person inside or outside the company. The QMO is responsible for creating the CAPA and tracking its resolution.

CAPAs are tracked in the CAPA list.

Participants
QMO

Input	Output
Non-conformity, complaint, etc.	CAPA created

2. Decision on Next Steps and Immediate Action

If immediate action is necessary (e.g. field safety corrective action or a notification to authorities according to SOP Vigilance), the QMO consults the Person Responsible for Regulatory Compliance. Immediate action is carried out without undue delay (see ISO 13485 para. 8.5.2).

In any case, the QMO discusses the next steps with the person closest to the issue, e.g. for software bugs, the Head of Software Development.

Participants
QMO Medical Device Safety Officer / Person Responsible for Regulatory Compliance (optional)

Input	Output
CAPA	CAPA, updated with action

3. Root Cause Analysis

The QMO coordinates a root cause analysis with the person closest to the issue. The preferred method for this is Five Whys. The result is added to the CAPA list.

Participants
QMO Other people in company (optional)

Input	Output
CAPA	CAPA, updated with root cause

4. Implementation of Action

The QMO coordinates defining and implementing corrective and preventive action. Additionally, the QMO takes into account adverse negative implications and verifies that the actions do not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device. Outcomes are documented in the CAPA list.

Participants
QMO Other people in company (optional)

Input	Output
CAPA	CAPA, updated with action plan

5. Verification and Check of Effectiveness

The QMO conducts the verification and effectiveness review of the implemented action. These are defined as below. Thereafter, the QMO closes the CAPA.

- Verification: Documenting proof of implementation of actions taken.
- Effectiveness: Review of the effectiveness of actions taken.

Participants
QMO

Input	Output
CAPA	CAPA, updated with verification, effectiveness review, closed date