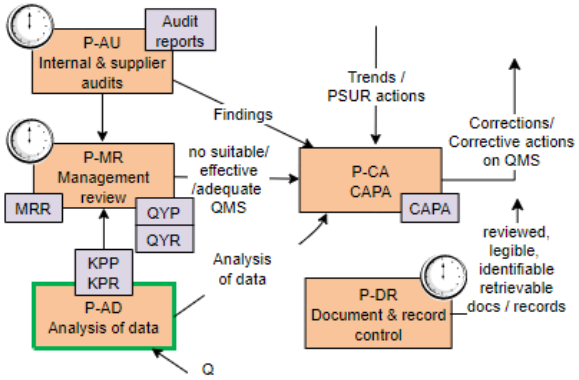
# 1. INTRODUCTION

## 1.1. Purpose & Scope

The purpose of CORRECTIVE AND PREVENTIVE ACTIONS (CAPA) is to ensure QMS processes, product concessions, quality audit reports, quality records, complaints, returned product, and other sources of quality data are analyzed to identify causes of existing or potential nonconforming product, or other quality problems.




This CAPA SOP describes the identification, analysis, resolution, and prevention of MyCompany **process** NONCONFORMITIES.
Sources for this CAPA SOP:

- Internal audit finding per [P-AU]
- External audit finding
- Trend in NCRs per [P-NC]
- Trend in Complaints per [P-CO]
- Results of KPI reports per [P-AD]
- Follow up actions from PSUR per [P-PMS]
- Any other information related to a (potential) nonconformity

Out of scope of this SOP are MyCompany **product** NONCONFORMITIES.
They are covered by:

| SOP | Lifecycle phase | Output record |
|---|---|---|
| Design Change Management [P-DCM] | Design and development | CR/PR |
| Control of nonconforming product [P-NC] | Production | NCR |
| Complaint Handling [P-CO] | Installed base including installation and servicing | complaint |

Above records include CORRECTION(s), ROOT CAUSE analysis and CORRECTIVE ACTION(s) for the product NC.

## 1.2. Terms

Throughout this document, terms are in SMALL CAPS* font. All terms are copied from [M-QT], the latter is leading.

| Term | Description |
|---|---|
| CONTAINMENT ACTION | Immediately prevent producing or delivery of more non-conforming product, i.e. damage control. |
| CORRECTION | Eliminate the nonconformity. |
| CORRECTIVE ACTION | Eliminate the root cause of a nonconformity to prevent recurrence |
| EFFECTIVENESS CHECK | Verify that root cause of the nonconformity is removed or sufficiently reduced. |
| HORIZONTAL ANALYSIS | Investigation whether the nonconformity is an incident or that is a systemic failure that occurs in similar cases or records. |
| NONCONFORMITY | (Possible) Non-fulfillment of requirement |
| PREVENTIVE ACTION | Eliminate the cause of a potential nonconformity to prevent occurrence. |
| ROOT CAUSE | Identifies the fundamental cause of nonconformity. |

*VERDANA 8 CAPS

## 1.3. Responsibilities and Authorities

The procedure defines the roles 'initiator', 'investigator' and 'implementer'. These roles are no formal QMS defined roles and can be assigned to all MyCompany staff.

**CAPA Review Board**

- Monitoring (in monthly QARA meeting) and decision making of CAPAs
- Permanent members: QA Manager (chair) and the CEO

## 2. PROCEDURE DESCRIPTION

| # | Input | Activity | Output | Responsible |
|---|---|---|---|---|
| | | **Initiation** | | |
| 1. | Non-conformity, Improvement | Fill "initiation" part of CAPA form [T-CA].<br>Generate CAPA number according to CAPA index list [T-CPI]<br>Set CAPA status in Index list to ***New***.<br>Inform QA Manager to take next step | New CAPA, | Initiator |
| | | **Check** | | |
| 2. | New CAPA | Evaluate CAPA on validness and duplicates.<br>If applicable, take CONTAINMENT ACTIONS<br>Approve or reject.<br>Inform initiator of decision via e-mail.<br>If rejected, set CAPA status in Index list to ***Rejected,*** this process ends.<br>Assign investigator<br>Set CAPA form status in Index list to ***Checked***.<br>Inform investigator to take next step | CONTAINMENT ACTION,<br>Assigned CAPA | QA manager |
| | | **Investigation** | | |
| 3. | Assigned CAPA | Perform a HORIZONTAL ANALYSIS.<br>Define CORRECTION(s) including due date(s).<br>Determine the ROOT CAUSE.<br>Define CORRECTIVE AND/OR PREVENTIVE ACTION(s) including due date(s). Actions shall be proportionate to the effects of the nonconformities and shall be taken without undue delay.<br>Define EFFECTIVENESS CHECK with due date (default 6 months after verification).<br>Document justification for any of above actions that are not performed.<br>Inform a Review Board member within 30 days after CAPA submission date.<br>Set CAPA form status in Index list to ***Investigated.*** | Investigated CAPA | Investigator |
| | | **Review** | | |
| 4. | Investigated CAPA | Evaluate ROOT CAUSE & actions and determine if they will effectively address the non-conformance. If needed, let it be reworked.<br>Check that the defined actions do not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.<br>Assign implementer.<br>Sign off CAPA for review. For an audit finding, also auditor signs off. Set CAPA form status in Index list to ***Approved.*** | Reviewed CAPA | Review Board member |
| | | **Implementation** | | |
| 5. | Reviewed CAPA | Implement CORRECTIVE AND PREVENTIVE ACTIONS<br>Store evidence in CAPA folder.<br>Inform QA manager.<br>Set CAPA form status in Index list to ***Implemented.*** | Implemented CAPA | Implementer |
| | | **Verification** | | |
| 6. | Implemented CAPA | Verify implemented CORRECTIVE AND/OR PREVENTIVE ACTIONS.<br>Inform all involved persons that actions are verified.<br>Sign off CAPA for verification.<br>Set CAPA form status in Index list to ***Verified.*** | Verified CAPA | QA manager |
| | | **Effectiveness Check and Closure** | | |
| 7. | Verified CAPA | Execute EFFECTIVENESS CHECK.<br>If the problem re-occurred, initiate a new CAPA.<br>Sign off CAPA for closure.<br>Set CAPA form status in Index list to ***Closed.*** | Closed CAPA, possible new CAPA | QA manager |

# 3. DOCUMENT INFO

## 3.1. References

| Input docs | Document title |
|---|---|
| [M-QT] | QMS Terms |
| [P-AD] | Analysis of Data SOP |
| [P-AU] | Internal & Supplier audit SOP |
| [P-CO] | Complaint Handling SOP |
| [P-NC] | Control of nonconforming product SOP |
| [P-PMS] | Post-market Surveillance SOP |

| Subsidiary docs | Version | Document title |
|---|---|---|
| [T-CA] | 01 | CAPA template |
| [T-CPI] | 01 | CAPA Index List template |

(*) not a quality record

## 3.2. Document History

All changes are labelled as blue text. Only the latest 3 entries are recorded.

| Version | Release date dd-Mmm-yyyy | Author(s) Initials | Description of changes | Impact analysis | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Installed base | Supply Chain | Projects | Training | SOPs |
| 01 | See table below | <Initials> | Initial | No impact | No impact | Current projects | Classroom | <Ids> |

## 3.3. Review and approve

Approval of this document also approves the versioned subsidiary docs and provides training evidence of the signees. By approving this document, I declare that it is reviewed for adequacy and that I agree with its content.

| Full Name | Role | Release date dd-Mmm-yyyy | Signature |
|---|---|---|---|
| <Full Name> | SOP Owner | | |
| <Full Name> | QA Manager | | |