**Document approval**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Date** | **Signature** |
| **Author’s designation****e.g., Quality Specialist** |  |  |  |
| **Reviewer’s designation****e.g., Quality Management Director Deputy** |  |  |  |
| **Approver’s designation****e.g., Quality Management Director** |  |  |  |

|  |  |
| --- | --- |
| **Effective Date** |  |

**Table of Contents**

[1 Purpose 2](#_Toc95307591)

[2 Scope 2](#_Toc95307592)

[3 Responsibilities 2](#_Toc95307593)

[4 Definitions, terms and abbreviations 2](#_Toc95307594)

[5 Workflow 3](#_Toc95307595)

[6 Applicable documents 3](#_Toc95307596)

[7 Appendices 3](#_Toc95307597)

[8 Document revision history 3](#_Toc95307598)

# Purpose

This Standard Operating Procedure (SOP) provides the requirements for identification, evaluation, implementation, effectiveness monitoring, closure and documentation of Corrective Actions and Preventive Actions (CAPA).

# Scope

This SOP is valid at Company CDE for all Organization. The respective training shall be given in accordance with **SOP-10 CDE Training Management.**

# Responsibilities

Responsible for the content of this SOP is e.g., Quality Management Director*.*

|  |  |
| --- | --- |
| **Role** | **Definition/Task** |
| Quality Organization | * performs Effectiveness Monitoring for Corrective Actions
* reports on CAPA system metrics and trends
* CAPAs initiating and closures
* assigns CAPA Numbers
* assigns CAPA Owners
* reviews **CAPA Requests**
* compiles, updates **CAPA Tracker**
* approves **CAPA Reports**
 |
| e.g., Quality Management Director | * approves **CAPA Requests**
* monitors CAPA system performance indicators and reports according to **SOP-04 CDE Management Review**
 |
| Initiator | * Reviews and initiates the CAPA, submits **CAPA Request** toQuality Organization.
* Obtains reviews from other departments who are stakeholders in developing the CAPA.
* proposes the Effectiveness Monitoring Criteria, resource requirements to support actions, and the expected completion date.
* assess the impact on the activities that are to be carried out until the implementation of the CAPA and to build adequate controls during the interim period of CAPA implementation.
 |
| Department Heads | * monitoring own processes to evaluate the need for initiating a CAPA
* requesting CAPAs
* ensuring CAPAs are implemented in their departments
 |
| CAPA Owner | * is responsible for the CAPA through all phases of the CAPA process (initiation closure).
* regularly reviews CAPA implementation status and progress.
* is responsible for the implementation of CAPA
* reviews **CAPA Requests**, undertakes to fulfill.
* Assures timely completion of implementation activities, tracks progress in completing the CAPA and submitting **CAPA Report** to Quality Organization for review following implementation.
* CAPA revision, correction, addition, if required.
 |

# Definitions, terms and abbreviations

| **Term/abbreviation** | **Definition at Company CDE** |
| --- | --- |
| CAPA Effectiveness Criteria | Measurable standards that, if met, demonstrate a CAPA has prevented the recurrence of detected non-conformity or other undesirable situations. |
| CAPA Effectiveness Monitoring | A post-execution assessment of CAPAs to verify that implemented actions have the desired outcome, as defined by CAPA Effectiveness Criteria. |

# Workflow

## General

Company CDEhas a system for implementing Corrective Actions and Preventive Actions resulting from non-conformities or other undesirable situations, such as:

* Process monitoring results,
* Regulatory Inspection findings, official laboratory testing results, regulatory notifications,
* Deviations,
* Internal/External Audit Observations,
* OOS Results,
* OOT Results,
* Complaints,
* Product Recalls,
* Quality Defects,
* Returned Products,
* Investigation results,
* Annual Product Quality Review,
* Risk Assessments,
* Management Review.

Each Department is responsible for ensuring appropriate handling of CAPA process flow.
CAPA Management process flow is described on ***Figure 1.***

***Figure 1:*** ***CAPA Management Process***

## Initiation

In the event of the occurrence of non-conformities or other undesirable situations specified in section 5.1, the requirements of the procedures that describe the actions to be taken when such events or situations occur, e.g. **SOP-06 CDE Deviation and Nonconformance Management, SOP-08 CDE Audits Management, SOP-11 CDE Annual Product Quality Review, SOP-12 CDE Complaints and Recalls Management, SOP-09 CDE Quality Risk Management.**

As a result of the implementation of such processes, there is a need for the implementation of CAPA measurements.

Any person responsible or interested in the implementation of the proposed CAPA activities initiates the CAPA process and acts as the Initiator.

The Initiator fills out the **CAPA Request Form** and submits it to Quality Organization for final approval of proposed activities.

If the proposed action may have an impact on other functions / departments or the implementation of such actions depends on other functions / departments, such a proposal must be reviewed and agreed with them.

The Initiator describes in detail:

* non-conformity, undesirable situation that has arisen, the anticipated potential risks that could lead to such events,
* investigation results,
* Identified root cause,
* Risk Assessment results,
* Proposed CAPA actions,
* CAPA Implementation expected timelines,
* CAPA Effectiveness Criteria,
* Affected Functions/Departments and their responsibilities,
* Expected CAPA Owner.

If such detailed information is contained in other documents (investigation reports, Risk Assessment reports, etc.) the Initiator makes a brief description and indicates the reference number of such documents.

The Initiator discusses the proposed CAPA with the stakeholders, on which the implementation of the proposed activities will depend, including the scope of the CAPA, timelines, CAPA Effectiveness Criteria, Expected CAPA Owner, etc.

When the **CAPA Request** is finalized, the Initiator signs the document and submits it to Quality Organization.

## Evaluation

Quality Organization representatives:

* assign a CAPA number,
* check the completeness, completeness, accuracy of the **CAPA Request,**
* coordinates reviews of the Request with other involved functions/departments,
* assign CAPA Owner,
* Compile, update **CAPA Tracker.**

Affected functions/departments representatives, CAPA Owner, Quality Organization representative evaluate and review **CAPA Request**, e.g., Quality Management Director approves **CAPA Request.**

The Initiator often becomes the CAPA Owner. The decision on the choice of the CAPA Owner is made and approved as a result of agreement with all stakeholders. Quality Organization appoints and, if necessary, re-appoints Owners for all pending CAPAs.

## Implementation

CAPA Owner The Owner performs all actions in accordance with the approved **CAPA Request** within the specified time frame and finalizes report according to **CAPA Report Form**.

CAPA Owner informs Quality Organization in the event of circumstances that do not allow the completion of the planned activities in full or at the specified time. Any departures from the planned activities must be justified and authorized by Quality Organization. Such departures and their justification should be stated in the **CAPA Report** by CAPA Owner as well as in **CAPA Tracker** by Quality Organization representatives.

## Effectiveness Monitoring

After CAPA implementation completion CAPA Owner finalize **CAPA Report** and submits to Quality Organization for further CAPA Effectiveness Monitoring and **CAPA Report** closure.

Quality Organization representatives check the results of the implementation of CAPA, evidence, evaluate the effectiveness. All Effectiveness Monitoring results and conclusions shall be recorded in the relevant section of **CAPA Report.**

Effectiveness Monitoring is performed only for Corrective Actions. A clear conclusion about effectiveness should be made. When checking the Preventive Actions, the confirmation of their completion is evaluated and it is concluded that the CAPA is considered to be closed.

If deficiencies were identified in **CAPA Report**, or lack of evidence of the completion of actions or if CAPA was recognized ineffective, Quality Organization representatives return **CAPA Report** to the CAPA Owner for revision. The finalization includes both the correction of the text of **CAPA Report** and the correction of the CAPA actions, Effectiveness Monitoring criteria.

If the inefficiency is due to the shortcomings of the action itself and it needs to be changed or supplemented, CAPA Owner shall initiate new **CAPA Request** according to this SOP.

## Closure

Quality Organization representative makes a conclusion about the completion of the process and approves **CAPA Report**. If the report cannot be closed, Quality Organization representative must indicate the reason and the next action expected (revision, correction, addition, new request, etc.). Quality Organization keeps all approved reports.

## Documentation

Quality Organization keeps all approved **CAPA Requests, CAPA Reports**. Quality Organization timely compiles and updates **CAPA Tracker.**

The following Internal CAPA’s numbering principle applies:

**CAPA/YY/NN**, where **YY** means the year, **NN** means the serial subsequent number (begins with 01 annually).

In the case of external suppliers, СAPA procedure is determined by the respective quality agreements according to **SOP-13 CDE Supplier Management**. All external CAPAs shall be tracked in **CAPA Tracker.**

The following External CAPA’s numbering principle applies:

**CAPA EXT/YY/NN**, where **YY** means the year, **NN** means the serial subsequent number (begins with 01 annually).

# Applicable documents

MD-01 CDE Quality Manual

SOP-01 (CDE) Documentation Management

SOP-04 CDE Management Review

SOP-05 CDE Change Management

SOP-06 CDE Deviation and Nonconformance Management

SOP-08 CDE Audits Management

SOP-09 CDE Quality Risk Management

SOP-10 CDE Training Management

SOP-11 CDE Annual Product Quality Review

SOP-12 CDE Complaints and Recalls Management

SOP-13 CDE Supplier Management

SOP-16 CDE Archiving

# Appendices

The following appendix(ces) is/are integral part of this SOP:

Appendix CAPA Request Form

Appendix CAPA Report Form

Appendix CAPA Tracker Form

# Document revision history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Valid from** | **Description of the revision** | **Reason for the revision** |
| 1 | See header | Document created | QMS implementation |