# corrective & preventative action

## Purpose & SCOPE

Corrective & Preventative Action (CAPA) is a continuous improvement tool used by which *(Insert manufacturer’s name)* to prevent the occurrence or recurrence of non-conformances and is a part of the Compliance Management system. Corrective and Preventative Action is vital to continued improvement of both product and process.

## Responsibilities

The responsibilities of the Quality Manager, Quality Coordinator and Facility Director for the Compliance Management system are documented in *Quality Management.*

CAPA specific responsibilities:

Quality Management personnel are responsible for:

* Raising corrective action where required
* Managing effective and timely corrective and preventative actions

Facility Director and Scientist in Charge are responsible for:

* Timely initiation of action to identify the root cause of a non-conformance or non-compliance
* Conducting a risk analysis, if required.
* Proposing corrective and preventative actions
* Initiating effective and timely corrective and preventative actions

## definitions

**Corrective Action:** Actions to eliminate the causes of a detected non-conformance. The corrective action should eliminate recurrence of the non-conformance. Corrective action in this context is not intended to mean the immediate action taken to address a non-conformance, rather longer-term corrective actions, planned following thorough investigation, to eliminate the root cause of non-conformances.

**Preventative Action:** Actions to eliminate the causes of a potential non-conformance. Preventative action should prevent the occurrence of the potential issue.

## Procedure

Implement corrective and preventative action procedures when actions are required to eliminate root causes of non-conformances to prevent the problem from occurring, or recurring.

The Quality Manager (or delegate) is responsible for determining the requirement for a CAPA to be raised. A CAPA may arise from:

* Customer complaints
* Non-conformance reports
* Management review findings
* Supplier evaluations
* Internal and external audits
* Post-market feedback
* Review of data indicating a need for preventive action

Corrective and preventative actions are identified following root cause investigations by the Quality Manager, refer to *Root Cause Analysis.*

Document corrective and preventative actions in non-conformance reports using *(Insert name of quality software application)*, refer to *(Insert name of quality software application document)*.

## CAPA PROCESS

1. **Initiate Corrective or Preventative Action (CAPA)**

The Quality Manager (or delegate) is to raise a Corrective or Preventative Action Request in *(Insert name of quality software application)*, refer to *(Insert name of quality software application document)*.

A staff member is assigned to the corrective action and provided with a due date for completion of the activity.

The time frame allocated to the action is dependent upon the severity of the non-conformance related to the CAPA and the complexity of the action. The following table is used as a guide for allocating time frames.

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-conformance severity** | **Complexity** | | |
| **Low** | **Medium** | **High** |
| **Critical** | 3 Days | 1 Week | 2 Weeks |
| **Major** | 1 Week | 2 Weeks | 1 Month |
| **Minor** | 2 Weeks | 1 Month | 2 Months |

1. **Implement Corrective / Preventative Action**

The corrective/preventative action is implemented by the personnel assigned to the action, in consultation with the Quality Manager.

1. **Follow-up Evaluation**

The Quality Manager is to verify that the action has been completed and monitor its effectiveness.

The Quality Manager is to assess the effectiveness of the action(s) through monitoring of the processes impacted in the action for the occurrence/recurrence of non-conformances. The level of monitoring varies, depending upon the severity of the related non-conformance. For example, for minor non-conformances the next 1-3 processes may be monitored for occurrence/recurrence, or for major or critical non-conformances more than 3 processes may be reviewed. A time frame for monitoring may also be used, for example for CAPA associated with major non-conformances the action may be monitored for 3 months for effectiveness.

1. **Management Review**

CAPA reports and actions are reviewed by the *(Insert manufacturer’s name)* Management Meeting, refer to *Compliance Management*.

1. **Closure**

The Quality Manger may close the Corrective and Preventative Action when there is documented evidence that the corrective action has eliminated the root cause or that the pre-emptive action implemented has prevented an occurrence of a related non-conformance.

## Records

Maintain all CAPA records in accordance with *Record Management* and file, with the related non-conformance, in the CM Report files stored in the office of the Scientist in Charge.

## documents

*Compliance Management* DOC148

*Quality Software Application* DOCXX

*Quality Management* DOC50

*Record Management* DOC52

*Root Cause Analysis* DOC156

## Procedure History

| Revision | **Date** | **Modification** | **Approved** | **Implemented** |
| --- | --- | --- | --- | --- |
| 1.0 | *(Insert date)* | Originally drafted by (*Insert name*) | (*Insert name*) | (*Insert date*) |
| 2.0 | *(Insert date)* | Revised by (*Insert name & description of changes*) | (*Insert name*) | (*Insert date)* |