Procedure: Corrective and Preventative Action

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| Document information, authorship and approvals | | | |
| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
| Authorised by: | Job title: | Signature: | Date: |

Table of Contents

[1. Purpose 3](#_Toc407018047)

[2. Scope 3](#_Toc407018048)

[3. Responsibilities 3](#_Toc407018049)

[4. Procedure 4](#_Toc407018050)

[4.1. Initiating a CAPA 4](#_Toc407018051)

[4.2. CAPA investigation 5](#_Toc407018052)

[4.3. CAPA implementation plan 6](#_Toc407018053)

[4.4. Implementing CAPA actions 7](#_Toc407018054)

[4.5. Post-implementation approval of CAPA 8](#_Toc407018055)

[4.6. Cancelling or extending a CAPA 8](#_Toc407018056)

[4.7. Trending CAPA metrics 9](#_Toc407018057)

# Purpose

The purpose of this procedure is to describe the requirements for managing and performing corrective and preventative actions (CAPA) at [Company].

# Scope

The scope of this procedure includes the correction and prevention of GMP non-conformities related to raw materials, products, manufacturing processes, utilities and services, and the quality management system at [Company].

The quality systems that may raise CAPA to address deficiencies include, but are not limited to:

* Deviations
* Complaints
* Laboratory / Stability Out of Specification (OOS)
* Audit citation or observation (both internal and external audits)
* Recall
* Environmental Monitoring
* Validation Review
* Annual Product Quality Review (PQR)
* Continuous Process Verification
* Changes in mandatory regulations or standards.

The following is excluded from the scope of this procedure:

* Business, administrative or other corrective actions not covered by the QMS and/or that are not GMP.

# Responsibilities

Amend to reflect company structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager | Has general oversight of the CAPA quality system and provides quality oversight for all CAPA.  Approves CAPAs to commence and at close out. |
| Managing Director | Provides resources to enable corrective and preventative actions to be completed in a timely manner |
| CAPA Initiator | Initiates a CAPA request |
| Department Manager (CAPA Owner) | Ensures CAPA are raised and completed in a timely manner |
| All staff | May identify or initiate a corrective or preventative action |

# Procedure

The CAPA procedure focuses on the systemic investigation of events in an attempt to eliminate an existing non-conformity or to prevent a non-conformity from occurring.

* Corrective Action – eliminates the cause of nonconformities to *prevent recurrence*
* Preventive Action – determines and eliminates the causes of potential non-conformities *to prevent occurrence*

Refer to **Definitions** section for further details.

Any quality system or GMP process may trigger the need for a CAPA arising from root cause determined out of a deviation, customer complaint, recall, etc. Additionally, CAPAs may arise from other quality systems or continuous improvements that may not require investigation into root cause (referred to as ‘stand-alone’ CAPAs). Refer to Section 2 for examples of the quality systems that may give rise to a CAPA.

## Initiating a CAPA

The Initiator (or Department Manager if there is no delegated Initiator) initiates a **FP809-1 -** **CAPA Form** and records the following details.

| CAPA Form | Description |
| --- | --- |
| CAPA ID | Unique number to be issued by the Quality function |
| CAPA description | Provide a summary of the issue / problem / situation giving rise to the CAPA |
| Associated records | The primary quality system records associated with the CAPA (e.g. deviation number, OOS number, audit number etc.), if applicable |
| Impacted batches or registrations | List any impacted batches related to the CAPA and/or any registration impacts |

### Determine the CAPA criticality

Determine the criticality (Critical/Major/Minor) of the CAPA according to the following criteria and record on **FP809-1 - CAPA Form**.

| Type of CAPA | Criticality |
| --- | --- |
| Associated with a recall | Critical CAPA |
| Associated with an audit finding | Assign the same criticality as the audit observation requiring a CAPA.  **Example:** If an external / internal auditor assigns an observation as Critical, then assign the resulting CAPA as a Critical CAPA. |
| Associated with a deviation, complaint or OOS | Assign the same risk level for the CAPA criticality as for the original event in the “parent” quality system.  **Example:** If a deviation is a Major deviation, then assign the associated CAPA as a Major CAPA. |
| All other CAPAs  [unless alternatively defined in company QRM policies] | Determine the criticality based on the following guidance.   * Critical – Significant impact to product/process quality, regulatory impact, or patient safety * Major – Potential impact to product quality, regulatory impact or patient safety * Minor – No potential impact to product quality, regulatory impact or patient safety. |

### Complete initial QA review

The Initiator submits the **FP809-1 -** **CAPA Form** to QA who will then:

| Stage | Description |
| --- | --- |
|  | Perform an initial review of the CAPA to ensure appropriate details have been included on the **CAPA Form**. |
|  | Log the CAPA into the register and issue a unique CAPA number. |
|  | Confirm that the CAPA criticality has been assigned and that it is appropriate. |
|  | Confirm that impacted batches have been placed on hold. |
|  | Sign the form to indicate that the initiator can progress to investigation/implementation planning. |
|  | Return the form to the initiator to progress. |

## CAPA investigation

The purpose of the CAPA investigation is to establish root cause if this has not previously been determined by the parent quality system (eg, deviation, recall, etc).

Using the Quality Risk Management (QRM) tools, the investigation should begin with a well-defined and agreed **problem statement** upon which to perform the root cause analysis (RCA). The following tools may be used to guide the investigation team into forming an effective problem statement:

* Flowchart – task analysis
* Chronology or timeline
* Change analysis
* Barrier analysis

The following tools may be used to guide the investigation team through the RCA process (*note there may be more than one root cause*):

* Brainstorming
* 5 ‘Why’s’
* Fishbone diagrams
* Root cause mapping
* Comparison matrix

Record the investigative tools used to identify root cause on **FP809-1 -** **CAPA Form** and record the most probable root cause(s). If the root cause was unable to be determined, this must be detailed on the form and the methodology used to come to this conclusion documented.

If the root cause was determined in the ‘parent’ quality system, record the relevant reference number.

## CAPA implementation plan

| Important: | The implementation plan must be completed and approved by the Quality Manager before any implementation activities can commence. |
| --- | --- |

Following the identification of root cause(s) in Section 4.2, list the following actions in **FP809-1 -** **CAPA Form**:

* Corrective actions – these are the actions required to address the current issue or problem and will generally be short term in nature
* Preventative actions – these are the actions to address any future potential instances of the current problem and take a broader outlook as to potential impact at site level

The CAPA implementation plan must translate the above actions into the following aspects of the implementation:

* CAPA implementation tasks
* Consideration for change control to manage implementation
* Risks associated with implementation tasks – is a formal risk assessment required?
* Effectiveness measures to be used to determine if the CAPA addresses root cause (where required)

### CAPA implementation tasks

Clearly document the tasks required to complete the CAPA including the following details:

* Individual task numbers for traceability
* Task description
* Person responsible for completing the task
* Due date for task completion
* Date and who completed the task
* Evidence that the task has been satisfactorily completed

### Change control

If change control is to be used to support the implementation of the CAPA, record the change control number on **FP809-1 -** **CAPA Form.**

### Determination of implementation risks

Determine the risk of each implementation task to GMP, product quality and manufacturing efficiency using a Failure Modes Effects Analysis (FMEA), Risk Assessment (RA) or other QRM tool. If a formal RA is required, attach to **FP809-1 -** **CAPA Form.**

### Effectiveness measures

Determine measures of effectiveness to confirm that the CAPA has addressed the root cause as expected – effectiveness measures may be for the whole CAPA or individual tasks (as appropriate).

**Note**: Minor CAPAs may not require an effectiveness check. Major or critical CAPAs must address the root cause and so require an effectiveness check.

Designing effectiveness checks should consider timeframes required to ensure there is sufficient data available to accurately assess the effectiveness, based on the frequency of the activity.

### Pre-implementation approval of CAPA

When the implementation plan is complete, it must be approved by the:

* CAPA Owner
* Primary stakeholder(s)
* Quality Manager.

Submit **FP809-1 -** **CAPA Form** (with all attached documentation) to the Quality Manager for approval. The Quality Manager:

* assesses the appropriateness of the overall plan
* determines an appropriate due date for the close of the CAPA after discussion with the CAPA Owner and relevant stakeholders, taking into consideration the risk and other initiatives and actions on site. Record the due date on **FP809-1 -** **CAPA Form**
* approves the implementation to commence by signing **FP809-1 -** **CAPA Form**
* ensures that the CAPA Register is updated with the status of the CAPA
* Forwards **FP809-1 -** **CAPA Form** (with all attached documentation) to the Initiator to implement actions.

## Implementing CAPA actions

Once the CAPA implementation plan is approved to commence by the Quality Manager, then all actions must be implemented according to the requirements stipulated in the plan by the CAPA Owner by the assigned due date.

Reporting should be completed according to the requirements in the implementation plan. All the outcomes of implementing each deliverable should be documented on **FP809-1 -** **CAPA Form** (or attached as a report).

| **Important**: | Any changes to the approved implementation plan, addition or removal of tasks, significant changes to tasks or delays in progress must be justified and approved by the Quality Manager. |
| --- | --- |

## Post-implementation approval of CAPA

The CAPA Owner and Quality Manager ensure that the following requirements are completed as part of providing objective evidence and closeout activities.

| Role | Description |
| --- | --- |
| CAPA Owner | * Summarise the outcome of the CAPA actions on **FP809-1 -** **CAPA Form** * Complete the CAPA so that it effectively addresses the root cause and implementation plan, and an effectiveness check has been completed * Review completed documentation to ensure it is appropriate * Ensure controlled documentation have been updated according to the specific requirement of the CAPA implementation plan * Ensure all training records are completed for all affected personnel * Ensure any installation, maintenance or validation reports are completed * Ensure all updated documents are effective |
| Quality Manager | * Ensure all phases of the investigation and supporting data are recorded, referenced and attached to **FP809-1 -** **CAPA Form** * Evidence supports closure of the CAPA and is attached to **FP809-1 -** **CAPA Form** * Any batch disposition is completed (or scheduled for completion) |

When all aspects of the CAPA are complete and meet GMP standards, the Quality Manager closes out the CAPA by:

* Signing **FP809-1 -** **CAPA Form**
* Closing the CAPA record in the QA CAPA Register.

When the CAPA is incomplete or missing information, **FP809-1 -** **CAPA Form** is returned to the Initiator, indicating required amendments.

## Cancelling or extending a CAPA

The Department Manager may request the CAPA to be either:

* Cancelled – when the CAPA is no longer required
* Extended – when the CAPA will legitimately take longer to complete than planned or unforeseen circumstances have delayed the implementation. Poor planning is not a legitimate reason for extension.

Justification for either cancellation or extension must be documented on the original **FP809-1 -** **CAPA Form**. The Quality Manager reviews the extension or cancellation and approves/rejects the request as appropriate.

## Trending CAPA metrics

The Quality Manager should report to executive management the following metrics on a monthly basis:

* number of CAPAs opened each month
* number of CAPAs closed each month
* number of critical/major/minor CAPAs raised each month
* number of CAPAs past the expected close-out date (overdue CAPAs).

Include for each of the trending metrics a breakdown of:

* CAPAs per department
* overdue CAPAs per department.

CAPA metrics are an indication of the continual improvement of the site and the QMS. Repeated instances of similar CAPAs (product, process, system or area specific) may indicate root cause has not been determined or effectively mediated and should be further investigated.

Ongoing overdue CAPAs are an indication that CAPAs are not being appropriately managed or resourced and should be escalated to executive management.

**Definitions**

Amend as required or delete.

| Term | Definition |
| --- | --- |
| CAPA | Corrective and Preventative Action |
| Correction | Repair, rework or adjustment action taken to eliminate the outcome of a non-conformance |
| Corrective action | An action required to stop the reoccurrence of a problem that has already happened.  Corrective actions are often required to be implemented quickly to resolve an actual non-conformance. Determining root cause and implementing measures to limit the potential for a repeated non-conformance should be included.  **Examples:**   * Changing the supplier of a starting material as a result of a customer complaint. * Implementing changes to storage of inwards goods in response to an audit citation. * Changing the cleaning solutions used in manufacturing area to prevent the reoccurrence of microbial growth detected. * Changing the frequency of fridge qualification and maintenance in response to fridge storage temperatures not meeting temperature specifications. |
| Preventative action | An action required to stop the occurrence of a problem that could happen.  Preventative actions may be initiated when quality performance data indicates that there are trends of decreasing quality capability and/or effectiveness of quality systems, such as during an annual product review.  **Examples:**   * Updating a manufacturing line with the most recent equipment to ensure the highest standard of product quality and people safety. * Changing the requirements within the change control procedure to improve the closure rate of open change control requests. * Changing the supplier of a starting material to ensure the highest level of product quality and safety.   Preventative actions may be implemented over a longer period than corrective actions and/or involve capital projects across a site. |
| Root cause | The underlying cause of a non-conformance |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QM001 | Quality Manual |
| FP809-1 | CAPA Form |
| PE 009-11 | PIC/S Guide to Good Manufacturing Practice for Medicinal Products |
|  |  |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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