Procedure: Corrective and Preventative Action

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This procedure addresses both corrective and preventative actions. However, ISO 13485:2016 (The ISO 13485 standard was updated to keep up with changes in the industry and to address changes in the underlying ISO 9001 standard. While the old ISO 13485 2003 standard was based on the old ISO 9001:2000 standard, the new one is based on ISO 9001: 2008. Since 2003, many jurisdictions had either revised or introduced new regulations for medical devices and these have been integrated with the new ISO 13485 standards) treats them separately so it is important that they are clearly differentiated.

It is important to have a system for identifying decreasing quality capability so that the likelihood of a non-conformance can be detected before it occurs. This should then lead to a preventative action.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for initiating, requesting, implementing and verifying the effectiveness of corrective and preventive actions at [Company].

The Corrective Action and Preventive Action (CAPA) process ensures that actual or potential problems which may affect the quality and reliability of products, processes or quality systems are defined, the root cause identified and eliminated and recurrence of the problem is prevented.

The process ensures that the activities and decisions made are documented such that there is a documented audit trail of the corrective and preventive activities from the identification of problems/potential problems to implementation of solutions and the follow up to evaluate effectiveness.

# Scope

The scope of this procedure includes correcting and preventing non-conformances related to materials, components, sub-assemblies, finished products, manufacturing processes and the quality system.

**Note:** [Company] recognises the difference between preventive and corrective actions. Sections 4.1 and 4.2 describe different processes for identifying the two different actions and Section 4.3 describes the subsequent common actions.

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| All personnel |  |
| CAPA Owner | The CAPA owner is responsible for:  • completing a CAPA as accurately as possible.  • performing the initial risk level assignment  • conducting the root cause investigation  • establishing the action plan  Note: The CAPA owner is also responsible for following up the entire CAPA process through to closure. |
| Department Managers |  |
| Quality Manager | Quality Manager or delegate is responsible for:  • confirming appropriate risk management has been perfomed  • approving the action plan  • verifying effectiveness of actions implemented  • final resolution and closure of the CAPA |
| Chief Executive Officer (CEO) |  |

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

## Corrective actions

Corrective actions are implemented to address non-conformities. Any member of staff may initiate a Corrective Action Request (CAR) but it must be authorised by QA or the CEO. This ensures appropriate prioritisation of resources.

A CAR is initiated using *Form FM810-1: Corrective Action Request* and forwarded to the Quality Manager or CEO. The request describes the unsatisfactory equipment/ system/condition and explains how quality is affected.

CARs may be directed to internal departments and/or suppliers and sub-contractors.

Corrective actions may be requested in the following cases:

Edit this list as appropriate to your company.

* identification of a non-conforming product
* problems with a process or work operation
* non-conformances identified during internal, regulatory or third-party audits
* field performance problem reported by servicing
* customer or regulatory complaint
* non-conforming delivery from a subcontractor
* identification of any other component, device, process or condition that does not conform to specifications, documented quality system, or requirements of ISO 13485 or regulatory code

Identify the regulatory code under which the company operates.

## Preventive actions

Preventive actions are implemented where there is an increased risk of non-conformances. The need for a preventive action is identified on the basis of the capability and performance of processes, work operations, product non-conformance rates, service, user feedback, customer complaints and effectiveness of the quality system.

The dot point list below may be edited but ensure that the Company is able to identify the need for preventive actions.

QA is responsible for collecting, compiling and reviewing pertinent information which includes:

* reject and scrap rates
* non-conformance reports
* service records and reports
* production equipment maintenance records
* customer complaints
* quality system audits

Preventive actions are initiated when performance data indicates there are trends of decreasing quality capability and/or effectiveness of the quality system (e.g. increasing non-conformances traceable to a common cause; excessive equipment breakdowns; increasing audit findings against the same element of the QMS; etc).

Once a preventive action is identified, a CAR is raised and processed the same as a corrective action (refer Section 4.3 below).

## Requesting and processing CARs

Refer to Section 8.5 of the Quality Manual. CARs are sometimes referred to as Corrective and Preventative Actions (CAPAs).

Both corrective and preventive actions are initiated using *Form FM810-1: Corrective Action Request*. The request includes a description of the unsatisfactory condition and is addressed to the responsible manager.

This same form is used to request suppliers and subcontractors to take an action.

When a CAR is received, the CAPA owner is responsible for investigation of the root cause of the problem, proposes a corrective or preventative action and indicates the date by which the action(s) will be implemented.

The CAPA owner organises a group of experts to participate in a root cause analysis session. The group could consist of representatives from QA, production, engineering and product development.

A Process map could be considered to identify process flow, inputs, outputs, documentation and uncontrolled variables.

A Root Cause Analysis tool such as a cause and effect diagram (See Appendix 2) shall be used unless justified by Quality Manager to identify all possible causes and establish relationships.

The results of the investigation into the non-conformance and the proposed action(s) are documented in the CAR. The form is then forwarded to QA for review and approval of the proposed action.

### Action Plan

On completion of root cause analysis, the CAPA owner establishes an action plan and it should include correction, corrective action and preventive actions. Activities to verify the effectiveness of actions taken should be included in the plan if deemed appropriate. This plan is then approved by QA before implementation.

These actions may include but are not restricted to:

• Changing the manufacturing process

• Revising labelling or use instructions

• Revising a raw material or product specification

• Increasing the level of process testing or inspection

• Conducting validation or re-validation

• Updating documents or instructions

• Training or re-training of personnel

The approved action plan should be implemented within the agreed timeframe. Monitoring activities should be undertaken to ensure that the actions are progressing at a satisfactory rate. Any actions taking longer than the agreed time will be escalated to the relevant senior manager.

Approval at this stage is not mandatory but ensures the proposed actions are relevant and practical and that there will be resources to implement them.

### Results

Results from the actions taken shall be documented and reviewed for completion by the CAPA owner once implemented. External documents shall be kept as evidence in Quality Record.

Implemented changes are reviewed to assess their impact on documentation and the validated status of equipment or processes. Documentation is updated as appropriate and changes are recorded in the CAR.

On, or immediately after, the due date for implementation of a CAR, the QA Manager follows up to determine if the corrective action has been implemented and if it is effective.

Where there is objective evidence, the CAR is closed out. If more work is needed, a new follow-up date is set.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
| CAPA | Corrective Action and Preventive Action |
| CAR | Corrective Action Request |
| Effectiveness | Extent to which planned activities are recognized and the desired results are achieved. |
| Root Cause | A root cause is the most basic and most directly attributed cause or reason for a defect or problem in a product or process. Elimination of the root cause leads to the elimination of the defect or problem and prevents reoccurrence. |
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Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
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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 |
| FM810-1 | Corrective Action Request |

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

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
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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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