



## Review on Corrective and Preventive Actions

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### Abstract:

The major aim of corrective action and preventative action (CAPA) in any pharmaceutical or medical device company is to identify any weaknesses, deviations, or failures and to conduct an inquiry and take the necessary corrective action to prevent a recurrence of those issues. CAPA is another a technique whereby preventive steps are implemented right away in order to stop any incidence from happening. It is a prerequisite for a pharmaceutical company's regulatory framework and a component of the overall Quality Management System (QMS).

**Keywords:** CAPA, corrective action, Preventive action, nonconformity, action plan, root cause analysis

### Introduction:

CAPAs (corrective and preventative actions) are a crucial component of pharmaceutical quality systems and the industry that manufactures medical devices. Investigations into the cause(s) should start as soon as it is determined that there are flaws, including problems in the production and/or testing of medications. Corrective measures should be implemented in order to address any current product non-conformity or quality issues and to stop the issue from recurring (preventive actions). The "band-aid approach" is a term frequently used by FDA (Food and Drug Administration) inspectors and compliance officers to describe the practise of just fixing the current issue. This practise frequently results in a warning letter. The overall Quality Management System includes CAPA (QMS)<sup>[1]</sup>

### Definitions:

**Correction:** The removal of a current nonconformity and involves repair, rework, or adjustment.

**Corrective action:** The process used to get rid of the root causes of a nonconformity, fault, or other unwanted circumstance in order to stop it from happening again.

**Preventive action:** The action made in order to prevent the emergence of a prospective nonconformity, defect, or other unwanted condition.

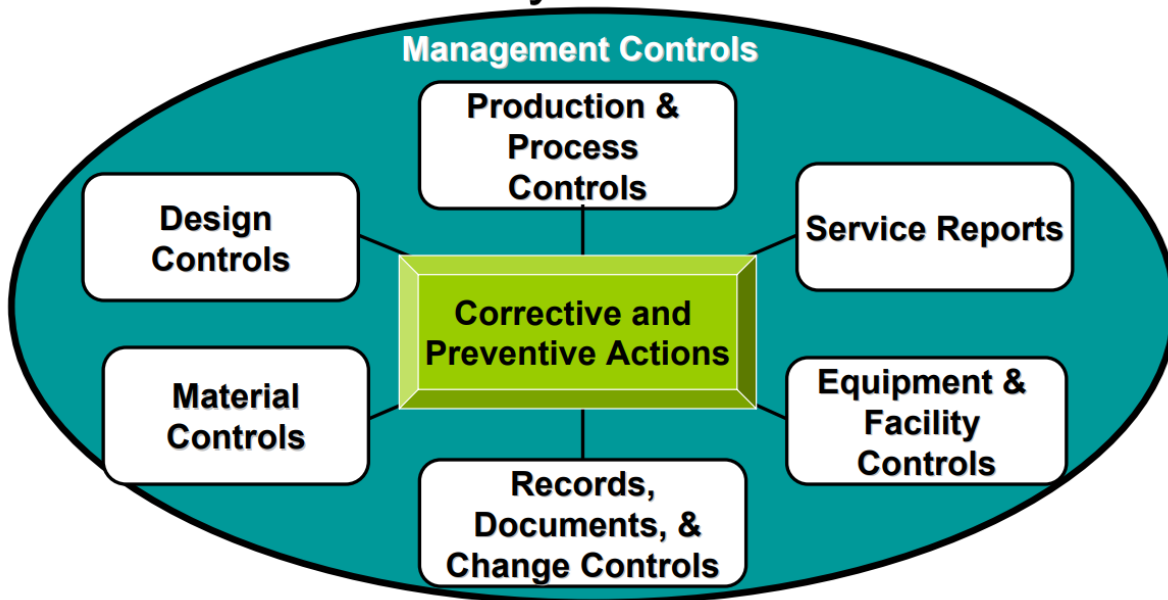
**Nonconformity:** Failure to meet a specific requirement.

**Purpose of the CAPA subsystem:**

- To find recurring quality issues, gather and analyse information using the proper statistical methodology.
- Take the proper, efficient, and thorough corrective and/or preventative measures.
- Identify and research product and quality issues that are current and possible.<sup>[3]</sup>

**CAPA Subsystem in context:**

## CAPA Subsystem in Context



1. Fig. reference

<https://fmdic.org/wp-content/uploads/2012/05/Lewandowski-CAPA.pdf>

**Compliance requirement:****International Conference of Harmonization (ICH Q10):**

A system for putting corrective and preventive measures into place should be in place at the pharmaceutical or medical device company. This system should be based on the analysis of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring. With the aim of identifying the root cause, an organised investigation procedure should be adopted. According to ICH Q9, the effort, formality, and documentation of the inquiry should be proportionate with the degree of risk (Quality Risk Management). The CAPA technique should lead to improvements in products and processes as well as greater product and process comprehension.

[1]

## **Process of CAPA:**

### **1. Determine whether the issue is real or potential:**

Whether it's a non-conformance or a system failure, the first step in any attempt to establish a CAPA programme is to precisely characterise the prospective or present problem. This calls for a thorough description of the problem and any evidence that the problem exists, as well as an accurate and comprehensive account of the precise information source that sparked the action. Information may come from either an internal or external source, such as a service request, customer complaint, risk assessment, or internal quality audit. The problem should be succinctly described yet with enough details so that it can be read and comprehended without difficulty.<sup>[2]</sup>

### **2. Assess the risk and probable consequences:**

The issue should be assessed after being presented and documented to decide whether action is necessary and at what level. To determine the actual hazards to the business and its clients as well as the prospective effects of the situation, impact and risk evaluations are required.

An explanation of the problem's precise significance, including any potential effects on costs, product quality, safety, or reliability, is a component of the evaluation. The outcome of this impact analysis should be utilised to determine how serious the issue is.

### **3. Create a methodology for your investigation**

Writing a procedure for examining the problem is crucial after assessing the situation's possible impact and danger. A written plan should include at least the following components to guarantee that the investigation is thorough and nothing is missed: a purpose for the activities to be taken, the investigative technique and dates to be followed, and the responsibilities and resources needed.<sup>[2]</sup>

### **4. Examine the issue using the information at hand**

The problem's root cause should be looked into using the newly developed investigation process. Analysis is gathering pertinent data, looking into all potential sources of the issue, and using the facts at hand to identify the main issue.

The maker must compile a list of all potential reasons and utilise it as the foundation for gathering pertinent data, test results, etc. It is important to organise and document the data collection's findings, which may incorporate test results as well as a review of documents, procedures, etc. The generated documentation should cover all previously identified potential reasons because it will be utilised to identify the problem's underlying cause.<sup>[2]</sup>

### **5. Using the analysis, draught an action plan**

The study' findings should be put to use in creating an action plan for fixing and/or preventing the issue. Tasks to be accomplished, revisions to documents, specifications, processes, etc., employees accountable for each task, staff training, and an anticipated completion date should all be included in a CAPA action plan.

The manufacturer should include a list of all papers that will be amended along with a broad description of the anticipated adjustments in the action plan. The predicted results of any modifications to processes, procedures, or systems should be stated and should be detailed in sufficient depth so that it is evident what has to be done.<sup>[2]</sup>

### **6. Carry out and record the tasks in the action plan**

The necessary tasks identified and explained in the plan should be started, finished, and documented as soon as the CAPA action plan is established and prepared for implementation. It is impossible to overstate how crucial accurate documentation is to carrying out the action plan.

To develop an implementation summary, all actions completed in accordance with the action plan's specifications should be documented and condensed, establishing a comprehensive record of the steps taken to fix the issue and stop it from happening again. Among other crucial information, this comprises adjustments, preventative actions, process controls, and training. Any revisions should be disclosed to the individuals and departments who will be impacted, and all altered papers and/or other requirements should be documented.<sup>[2]</sup>

## 7. Evaluate the acts' efficacy and completeness

The CAPA process requires a detailed analysis of the activities done once the plan has been implemented. This follow-two up's main objectives are to confirm that all tasks have been completed and to ensure that

All changes, controls, training, etc., should be implemented, completed, and the verification of these actions' completion should be documented. Additionally, a thorough evaluation should be performed to confirm the effectiveness of the actions taken to guarantee the following: the problem's root cause has been fixed; any resulting secondary situations have been corrected; appropriate controls have been established; sufficient monitoring of the situation is in place; and any unfavourable effects of the actions taken have been addressed.<sup>[2]</sup>

### Root cause analysis: (RCA)

Root cause analysis (RCA) is a technique for figuring out what, how, and why an event happened so that preventative measures can be done in the future. It entails the procedures of data gathering, root cause analysis, and the creation and application of recommendations. In other words, RCA is the application of procedures that enables you to delve deeper and investigate causal relationships between the problem and its actual root causes.

The root causes of these issues are the precise, underlying causes that can be clearly identified, which management can address, and which result in practical recommendations to stop recurrences.<sup>[4]</sup>

### Conclusion:

The efficacy of the Quality Management System can be improved by corrective and preventive action. It's crucial to the Quality Risk Management System. By using CAPA, the root cause analysis of any issue or deviation may be completed quickly. The pharmaceutical, medical device, and healthcare businesses should closely adhere to CAPA implementation in their organisations.

### References:

1. Code of Federal Regulations CFR, 2015) (Figure 1)
2. <https://www.gmp-journal.com/current-articles/details/capa-seven-steps-for-an-effective-process.html>
3. <https://fmdic.org/wp-content/uploads/2012/05/Lewandowski-CAPA.pdf>
4. <https://blog.safetychain.com/root-cause-analysis-informs-capa>