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Review Article

# An Overview of Corrective Action and Preventive Action

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**ABSTRACT**
Corrective and Preventive Actions (CAPA) are crucial for enhancing and raising the quality of the finished good or service. It is essential to every industry's ongoing development. In any pharmaceutical or medical device sector, the main goal of Corrective Action and Preventative Action (CAPA) is to identify any weaknesses, deviations, or failures and conduct an inquiry, and take the necessary corrective action to ensure that these issues don't recur. An approach known as CAPA also entails taking preventive actions right away to stop any incidence from happening in the first place. In a pharmaceutical company, it is both a legal necessity and a component of the broader Quality Management System (QMS). The corrective and preventive action subsystem is governed by 21 CFR 820.100, which lays out the rules (CAPA).

**Keywords:** CAPA, Corrective action and Preventive action, Corrective action, Preventive action.

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## INTRODUCTION

### Objectives

#### *Corrective Action*

A series of actions taken to get rid of the reason for a procedure's Non-conformity is known as corrective action. Corrective Action (CA) is the process of responding to member participation, containing it by enclosure actions, and then following up with the necessary steps to ensure that it doesn't happen again. According to earlier versions of ISO 9001, CA will prevent the problem from spreading, whereas CA will forbid the repetition of difficulty.[1]

The technique includes the following steps:

1) Examining and describing the issue or Non-conformity.

2) Deciding the reason for the issue.

3) Devise a strategy for resolving the issue and preventing it from recurring.

4) Implementation of the strategy.

5) Evaluating the efficiency of the correction.

### Examples of Corrective Action

Corrective action in human resources is focused on discipline. A worker who harassed a worker, for example, could be disciplined, suspended, or fired. These actions attempt to minimize the root of the harassment by penalizing the harasser.

Accidents or security difficulties in the workplace frequently necessitate more substantial modifications, such as:

- Alarms are installed.
- Equipment redesigning or replacement.
- Tools for recalibrating.
- Processes are being updated.
- Employees need to be trained on policies and procedures.[2]

### Preventive Action

Before a possible process problem arises, preventive action is taken to resolve the source of the problem. In a management system, a Preventive Action (PA) definition may be: "the activities carried out by the company to remove the source of a potential process non-conformity." Preventive activity is defined as identifying possible problems that may arise in a process, recognizing what may be causing these issues, and taking efforts to avoid the problem from arising before it happens.

The technique includes the following steps:

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- Identify the probable source of the problem or non-conformance.
- Figure out what's causing the potential problem.
- Make a strategy to prevent this from happening again.
- Put your plan into action.
- Assess the procedures taken and their effectiveness in averting the issue.[3]

## Examples of Preventive Action

- Preventive actions are much less noticeable than corrective actions. They usually don't involve a visible bodily change and instead take place behind the scenes. Listed below are a few descriptions:
- New employee training programs are being introduced.
- Regularly reviewing and upgrading company paperwork, such as regulations, processes, and ethical codes of conduct.
- Internal audits are carried out.
- Performing routine maintenance on equipment and machinery.
- Including "alarms" in your work procedures to alert you to potential problems.
- Creating disaster plans in the event of emergencies, security problems, and other unforeseen circumstances.[4]

## Process of CAPA[5]

For the pharmaceutical or medical device sectors, there are eight core CAPA steps.

## Determine the process problem

Describe the issue. Check again to be sure the issue is genuine and not made up. If you can formulate the problem as a need to assess, often known as a "Should Be" and "Is" statement, it will pass the test (e.g., Parts should be nickel-plated, parts were received painted black). You might not have seen a serious issue if you can't state what the outcome should be (or is likely to be).

## Determine the size of the problem

What is the extent of the issue? Make sure you are aware of how serious the issue is. Are the items destroyed only today, or were items from yesterday also harmed? Is it restricted to a single object, or does it affect other things as well? Make sure you are aware of the issue's nature and, more importantly, what it is not. This could be important information if the problem only happens on Wednesday.

## Take steps to contain the problem

When addressing the fundamental cause, how can we stop the issue from getting worse? While you look for the issue and address the main cause, make a temporary fix to address the issue. What quick checks or band-aid systems are you setting up to guarantee that you'll have the option to detect the mistake regardless of whether it returns while you're attempting to address it?

## Determine the problem's root cause

Not simply how it seems on the surface, but what is the root cause of the issue? It is the most difficult part. How would you know when you've located the problem's root cause? The ways of doing this reach from straight forward ones like inquiring "Why" multiple times until you distinguish the main driver to additional complicated ones like the Ishikawa (or Fishbone) Graph. This notion has been covered in-depth in training courses, but it is sufficient to convey the idea that you should focus on the root of the issue rather than just the symptoms. After this stage, additional containment measures will be required because the focus hasn't widened by a factor of two.

## Make a plan to address the root problem

What has to change to fix the issue? Identify the steps that must be made to remove the problem's primary cause. You'll need to calculate the cost and return based on the circumstances. If a time-consuming and expensive fix is required, who must approve the expenses and how will this be paid for? Check to see if the anticipated modifications will lead to any new issues.

## Execute your strategy

Execute your plans. It's as simple as following through on your plan. Following the preventative maintenance schedule stated earlier and installing new equipment could solve the problem if the old one was no longer accurate enough.

## Verify that your strategy worked

Examine your plan to evaluate if it was successful. Simply, after making your adjustments, await a reasonable period to verify the problem does not recur. If it does, think about whether you've found the underlying cause of the problem. It is the most important step, but most companies struggle with it. People often want to complete the documentation as soon as possible because they assume the registry expects it to be completed on time, but proper follow-up is essential.[5]

## Objectives

- To fix any product non-compliance or quality issues already present and stop the issue from recurring.
- To gather data, evaluate data, pinpoint and look into product and quality issues, then take the necessary corrective and/or preventative action to stop them from happening again.

To collect and evaluate data as needed to uncover reoccurring quality issues using the appropriate statistical methodology.

- Verify to see if the right steps have been done in response to severe product and quality issues that data sources have revealed.
- Product and quality issues, both existing and potential, should be detected and explored.
- To take the corrective and/or prevention methods that are required, effective, and thorough.

When choosing solutions, the following elements must be considered:

1. **Feasibility:** The ideas must be realistic in terms of resources and timeliness for the company.

2. **Effectiveness:** The solutions must have a reasonable likelihood of resolving the problem.

3. **Budget:** The solution's cost is within the company's capital while also being reasonable for the problem's scope.

4. **Employee Involvement:** Employees and departments affected by the problem must be included in the development of the solution.

5. **Systemic Concerns:** The focus of solutions should be on systemic issues.

6. **Contingency Planning:** Every solution is established to achieve the goal of achieving a certain level of success.[6]

## Expectations from Regulatory

### *ICH Q10 (Pharmaceutical Quality System)*

A system for attempting to put corrective and preventive measures resulting from inquiries into issues, product failures, non-conformances, recollects, variations, audits, regulatory audits and observations, and correlations from procedure performance and overall quality monitoring should be in place at a pharmaceutical or medical device company. To find the root cause, the investigative process should be conducted systematically. According to ICH Q9, the amount of effort, formality, and documentation put into the investigation should correspond to the degree of risk (Quality Risk Management). The CAPA technique should lead to improvements in the processes and products as well as a better understanding of the processes and products (Code of Federal Regulations CFR, 2015).[7]

## 21 CFR 820 regulatory requirements

### *(Procedures)*

- Each manufacturer must create and maintain a plan for implementing corrective and preventative actions.
- Protocols must assure that the requirements of the CAPA subsystem are met.
- Establishment aids in the definition, documentation (electronically or physically), and implementation of a plan.
- Procedures vary in amount and complexity depending on the organization.[8]

## CAPA Data Analysis–21 CFR 820.100

Analyzing processes, work activities, obligations, audit report files, quality standards, service records, complaints, returned goods, and other sources of quality data to determine the actual and potential reasons for a nonconforming product or other quality problems. To find recurring quality issues, the relevant statistical methodology will be applied as needed.[9]

## Identifying the Source

### *Internal Source*

- Data from inspections and tests
- Reports on Non- conforming Materials

**Corrective Action vs. Preventive Action**

| | Corrective Action | Preventive Action |
|---|---|---|
| When it is used | After a problem happens in a process | Before a problem happens, when a risk is identified |
| Role in ISO 9001, ISO 14001, ISO 22301, ISO 27001, ISO 45001, etc. (the majority of ISO management system standards) | Includes assessment of root cause and a plan to prevent recurrence | Replaced by risk-based thinking and improvement, rather than a formal process |
| Role in ISO 13485, IATF 16949 | Includes assessment of root cause and a plan to prevent recurrence | Includes assessment of root cause and a plan to prevent occurrence |
| Type of activity | Reactive activity – Happens after the fact | Proactive activity – Takes action when a risk is identified |

- Equipment Specifications
- Yield/Scrap Data
- Revise the data
- Product that has been returned
- Audits conducted internally
- Control Data Processing
- Activities of Acceptance.[10]

## External Source

- Complaint
- Field Service Report
- Legal Claims
- Warranty Claims
- External Audit
- Medical Device Report (MDRs).[11]

## Technique for data analysis: Statistical technique

When the statistical technique is required, the FDA recommends that the right statistical techniques be used. The FDA has seen far too many instances of firms misusing statistics in an attempt to minimize rather than solve an issue. This provision would be violated if statistics were used in this manner.

## Common Statistical Techniques

- Pareto charts
- Run charts
- Control charts
- Mean and standard deviation
- T - tests for comparisons
- Experimental design (DoE)
- Graphical methods (fishbone diagrams, histograms, scatter plots, spreadsheets, etc.)[12]

## CAPA Investigation

According to 21 CFR 820.100(a), the investigation of the root cause of issues with the product, process, and quality system is required (2). The CAPA standard is more comprehensive than Complaint Handling, 21 CFR 820.198, requiring investigations into the disputed device as well as the process and quality system.

## Steps in a Typical Investigation

- Define and characterize the issue
- Determine the scope and impact of the project
- Look at data, procedures, operations, and other information sources
- If feasible, determine the root cause.[13]

## Root Cause Analysis (RCA)

- The term "root cause" is difficult to define accurately. The description of the root cause is up for debate, but these four points include all facets of the phenomenon:
- The fundamental reasons for the observable problem are known as root causes.
- The root causes would be those that can be properly identified and, as a result, corrected.
- The root causes would be the condition that is dependent on management and can be corrected by management.
- Root causes are those which effective solutions for preventing recurrences and so eliminating the effect they produce can be generated.[14]

## The RCA consists of four steps

- Data Collection.
- Graphing of causal factors.
- Finding the root of the problem.
- Developing and implementing recommendations.

## Step One-Data Collection

The gathering of data is the first step in data study. The causal variables and root causes linked with the incident cannot be recognized without comprehensive information and comprehension of the event. Gathering data takes up the majority of the time spent evaluating an event.

## Step Two-Graphing of causal factors

As the investigation develops, causal factor charting provides the structure for inspectors to organize and analyze the information obtained during the investigation, as well as identify gaps and weaknesses in knowledge. The causal factor flowchart is a simple sequence of stages with logical tests that explains the circumstances leading up to and around an occurrence. As soon as investigators begin gathering information about the occurrence, they should begin preparing the causal factor chart. They start with a fishbone chart, which is updated as new information becomes available. By specifying data requirements, the potential cause chart would guide the data gathering process.

## Step Three-Finding the root of the problem

The investigators commence root cause analysis after all of the causal elements have been discovered. The fundamental cause or causes for each causal element are identified using a decision diagram in this step. The graphic aids the investigators' thinking process by assisting them in answering questions about why specific causal elements exist or occurred. The identification of root causes assists the investigator in determining the reasons for the occurrence so that the problems associated with it can be addressed.

## Step Four-Developing and implementing recommendations

The creation of recommendations is the next phase. Following the identification of root reasons for a certain causal factor, feasible solutions for minimizing its recurrence are developed. The root cause analyser is frequently not in charge of putting the study's suggestions into action. Therefore, if the suggestions are not followed, the time and effort spent on the study would be squandered. Furthermore, the incidents that prompted the investigation are likely to occur again.[15]

## Possible Root Causes

- Training
- Design
- Manufacturing
- Management
- Change Control
- Purchasing/Supplier
- Quality
- Testing
- Documentation
- Maintenance.[16]

## Root cause analysis tools

- Commonly used tools
- Fishbone diagrams
- 5 "whys"
- Fault - tree analysis
- Among others.[17]

## CAPA and Risk Management

The FDA agrees that the amount of corrective and preventive action required to remove or limit current or anticipated nonconformities must be proportional to the severity of the problem and the risks involved. Depending on the risk assessment, the FDA expects the manufacturer to design tools for evaluating the risk, the measures that must be done for various degrees of risk, and how to remedy or prevent problems from repeating.

## A manufacturer can use risk analysis to

- Establish priorities.
- Assign resources.
- Evaluate the severity of the impact.
- Determine the scope of the inquiry.

## Common tools

- Hazard analysis.
- Used early for potential problems.
- Failure Mode Effects Analysis (FMEA).
- Bottom - up.
- Fault Tree Analysis (FTA).
- Top - down.

## Verify and Validate Corrective Action and Preventive Action

Trying to verify or evaluate the corrective and preventive action to guarantee that it is effective and has no negative impact on the final product.

Check to see whether any verification/validation protocols have been developed.

Data related to verification or validating actions should be reviewed.

Evaluate the efficacy of the corrective and preventative actions by looking at the data to see whether there are any similar quality issues after they've been implemented.[18]

## FDA Inspection

Manufacturers must consider how their documentation of corrective and preventive measures might demonstrate to the FDA that their quality system is effective and enables them to identify issues quickly and take efficient corrective and preventive actions.[19]

## Communicating CAPA information

Inform individuals who are directly in charge of ensuring the quality of such products or the prevention of such problems about quality issues or non-conforming products. 21 CFR 820.100 (a) (6).

Send pertinent data regarding any quality issues that have been found, together with any preventive and corrective measures, to management for review. 21 CFR 820.100 (a) (7).

## Documenting corrective action and preventive action activities

Keep records of all the actions taken and the outcomes for this section. 21 CFR 820.100 (b) (US FDA website; CFR, 2015).[20]

## Beginning of the CAPA

- The responsible department head must submit a source document to QA to start a CAPA (Quality Assurance).
- The QA manager will decide if CAPA is necessary.

- A CAPA form must be obtained by the department head from QA. Before sending the form to the relevant department, QA must write the source document's name and number on it.
- The department head must complete the CAPA form as follows:
- The day CAPA was started.
- The anticipated completion dates.
- Check the box next to the department that is initiating the CAPA.

Choose the applicable system that will be impacted and mark the corresponding box. Select "Not Applicable" if none of the systems printed are affected. Write the impacted system in the areas provided if any other systems except those indicated are involved.

Briefly describe the CAPA from the source document and the specifics of the corrective and preventive action.

The department head must sign their names and provide a date after properly signing.

The CAPA form must be sent to QA by the department leader.

QA must assign the CAPA form a reference number and make the necessary entries in the CAPA log. After that, QA will send the CAPA form to the relevant department.

### CAPA completion and confirmation

Upon completion of the actions, the department head shall verify that the proposed CAPA has been completed, implemented, and all necessary actions have been performed.

QA is required to certify the implementation and completeness of CAPA after reviewing the accompanying documentation.

The SOP on change control reference must be followed, and any modification that is suggested as a result of a CAPA must be stated in the CAPA format.

The CAPA form must be used to resolve any change control, deviations, discrepancies, or incident reports that result in CAPA.

Any facility renovations, material purchase requirements, major changes to the quality system, and compliance with regulatory commitments that result in CAPA must be handled using the CAPA form.

A record of every CAPA must be kept.

QA must give a copy of the completed CAPA to the head of the relevant department.

In the management review meeting, QA must compile the CAPA data and present a summary to management.

At the management review meeting, management shall evaluate and verify the same quarterly.

Information and documents about CAPA that are obtained through internal, external, or customer audits as well as regulatory inspections are deemed confidential and may only be provided for regulatory review with the director's technical and QA head's permission.[2]

## 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. Industry leaders in the pharmaceutical, healthcare, and medical device sectors should strictly adhere to CAPA adoption in their organizations.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest for this work.

## ABBREVIATIONS

**CA:** Corrective Action; **CAPA:** Corrective and preventive actions; **CFR:** Code of Federal Regulations; **DoE:** Design of Experiments; **FDA:** Food and Drug Administration, United States of America; **FMEA:** Failure Mode Effects Analysis; **FTA:** Fault Tree Analysis; **IATF:** International Automotive Task Force; **ICH:** International Council on Harmonization; **ISO:** International Organization for Standardization; **PA:** Preventive Action; **QA:** Quality Assurance; **QMS:** Quality Management Systems; **RCA:** Root Cause Analysis.

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