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Review Article

Corrective Action and Preventive Actions and its Importance in Quality Management System: A Review

Tenzin Tashi[2], Vitalis B Mbuya[2], H V Gangadharappa[1]*

Department of Pharmaceutics, JSS College of Pharmacy, JSS University, Sri Shivarathreeswara Nagara, Mysuru 570015, Karnataka, India

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ABSTRACT

Every organization should have a written standard operating procedure (SOP) establishing the provisions for corrective and preventive actions. Instructions for how they should be handled within the organization in case of potential product problems, customer complaints or action to eliminate the cause of a detected Nonconformities or incident. Effective corrective action and preventive action (CAPA) systems are a key component to continuous improvement. This review provides a comprehensive view on steps involved in corrective action and preventive action, mechanism of taking CAPA enabling to improve the system of quality management and Application of CAPA System throughout the Product Lifecycle in pharmaceutical industry, and it is importance to establish change management system after CAPA which provide a high degree of assurance there are no unintended consequences of the change.

Keywords: corrective action, preventive action, Quality management system, Change management system.

INTRODUCTION

It is assumed that the medicinal product manufacturer has a QMS which requires the manufacturer to have documentation processes, to ensure that medicinal products placed on the market are safe and effective. For this purpose, the manufacturer will establish processes and define appropriate controls for measurement and analysis to identify nonconformities and potential nonconformities. Also, the manufacturer should establish processes, defining when and how corrections, corrective actions, or preventive actions should be undertaken. The ability to correct existing problems or implementing controls to prevent potential problems is essential for continued customer satisfaction and efficient business practice. Effective corrective action and preventive action (CAPA) systems are a key component to continuous improvement. Their risk-based CAPA requirements demand a well-documented system that determines the root cause of nonconformance's, system failures, or process problems, corrects the problems, and prevents them from recurring. The documentation must identify why something went (or may go) wrong and what has been done to make sure it does not happen again.

CAPA is a fundamental management tool that should be used in every quality system. This program provides a simple step-by-step process for completing and documenting corrective or preventive actions. The result will be a complete, well-documented investigation and solution that will satisfy regulatory requirements and form the basis for an effective continuous improvement plan for any Company[1].

Without a CAPA process, focusing on quality improvement efforts may not improve customer satisfaction.

Why CAPA?

Regulatory requirement

Both FDA and ISO require an active CAPA program as an essential element of quality system

Customer satisfaction: ability to correct existing problem or implement control to prevent potential problem which is essential for continuous customer satisfaction

Good business practice: quality problem can have significant financial impact on company[1]

Definition

Correction: A correction is any action that is taken to eliminate nonconformity. However, corrections do not address causes.

Corrective action: Corrective actions are steps that are taken to remove the causes of an existing nonconformity or undesirable situation. The corrective action process is designed to prevent the recurrence of nonconformities or undesirable situations. It tries to make sure that existing nonconformities and situations don't happen again. It tries to prevent recurrence by eliminating causes. Corrective actions address actual problems.

Preventive action: Preventive actions are steps that are taken to remove the causes of potential nonconformities or potential situations that are undesirable. The preventive action process is designed to prevent the occurrence of nonconformities or situations that do not yet exist. It tries to prevent occurrence by eliminating causes.

*Author for Correspondence

Note: While corrective actions prevent recurrence, preventive actions prevent occurrence. Both types of actions are intended to prevent nonconformities.

Preventive actions address potential problem. In general, the preventive action process can be thought of as a risk analysis process.

CAPA Procedures

Implementing an effective corrective or preventive action capable of satisfying quality assurance and regulatory documentation requirements is accomplished in seven basic steps:

The Identification of the problem, nonconformity, or incident or the potential problem, nonconformity, or incident.

An Evaluation of the magnitude of the problem and potential impact on the company.

The development of an Investigation procedure with assignments of responsibility.

Performing a thorough Analysis of the problem with appropriate documentation.

Creating an Action Plan listing all the tasks that must be completed to correct and/or prevent the problem.

The Implementation the plan.

A thorough Follow up with verification of the completion of all tasks, and an assessment of the appropriateness and effectiveness of the actions taken[1].

Identification

The initial step in the process is to clearly define the problem. It is important to accurately and completely describe the situation as it exists now. This should include the source of the information, a detailed explanation of the problem, the available evidence that a problem exists[1].

Report Source

Documenting the source of the information can be very useful when conducting an investigation into the problem and implementing the action plan that is created. It will also provide data for evaluating the effectiveness of the quality system and facilitate communicating the completion of the action to the appropriate individuals or departments[1].

Corrections/Corrective and preventive actions for Quality issues, risks and nonconformity should be identified from the following:

Customer Audits and regulatory inspections
Internal Audits
Customer complaints
Customer returns
Product recalls
Deviations
Out of specification
Out of calibration
Batch Failures / Rejected batches
Out of Trends
Annual product reviews
Output of management reviews
Any other GMP issues / observations and non-conformances[2]

Explanation of the Problem

A complete description of the problem is written. The description should be concise but must contain sufficient information to assure that the problem can be easily understood from reading the explanation[1].

Evidence

List the specific information available that demonstrates that the problem does exist

Evaluation

The situation that has been described and documented in the "Identification" section should now be evaluated to determine first, the need for action and then the level of action required. The potential impact of the problem and the actual risks to the company and/or customers must be determined. Essentially, the reasons that this problem is a concern must be documented[1].

Potential Impact

Part of the evaluation is a specific explanation of specifically why the problem is a concern. This may include the possible impact that the problem may have in terms of costs, function, product quality, safety, reliability, and customer satisfaction[1].

Assessment of Risk

Using the result of the impact evaluation, the seriousness of the problem is assessed. The level of risk that is associated with the problem may affect the actions that are taken[1].

Remedial Action

Based on the outcome of the impact and risk evaluations above, it may be determined that immediate remedial action is required to remedy the situation until a thorough investigation and a permanent solution is implemented.

The actions that are taken are documented. This documentation will become part of the 'Action Implementation' and 'Follow Up' sections of the CAPA action[1].

Remedial Action form

A sample "Remedial Action" form is included. This form should be used to explain the steps that must be taken to avoid any further adverse effects[1].

Investigation

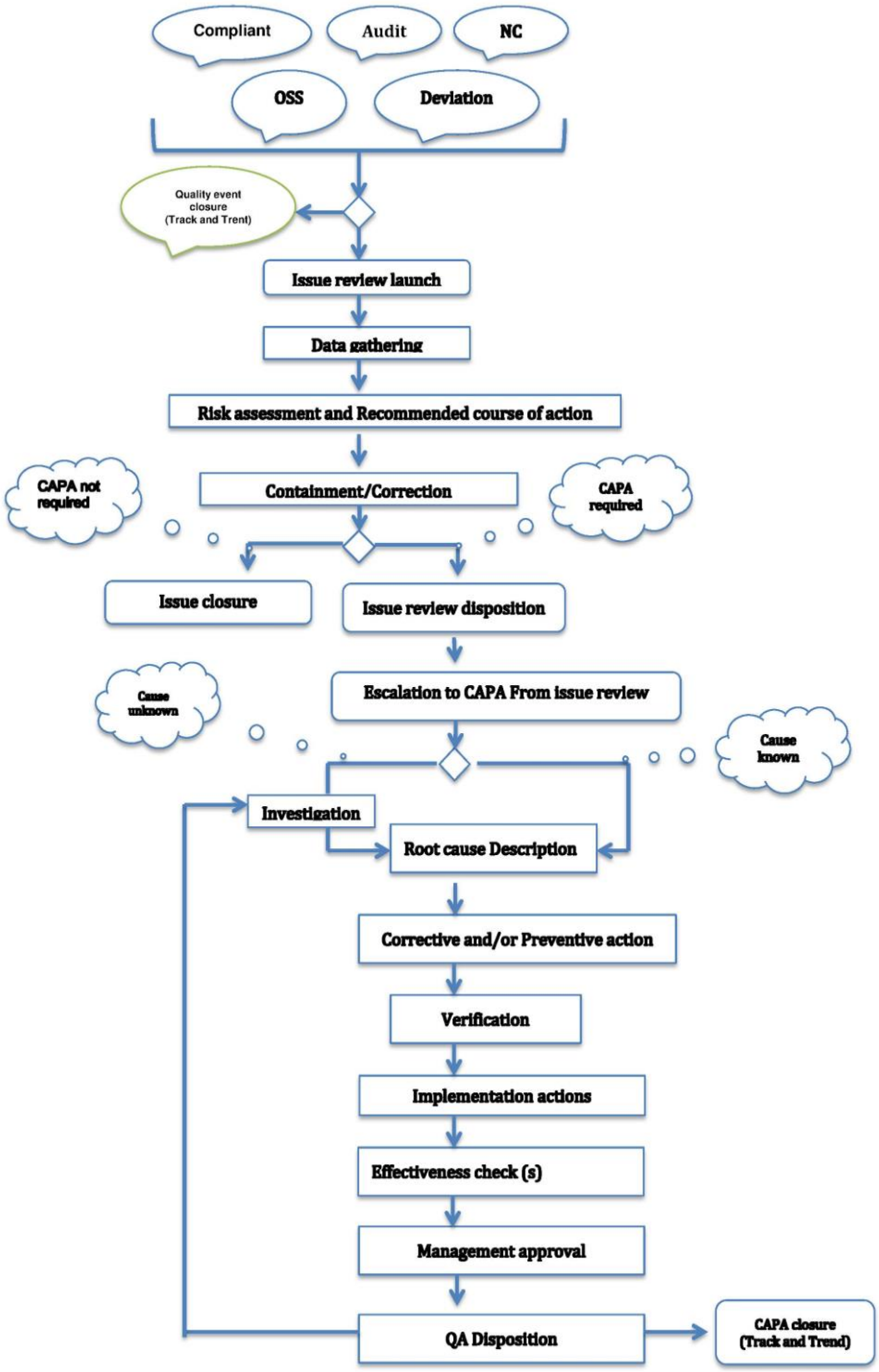
In this step of the process a procedure is written for conducting an investigation into the problem. A written plan helps assure that the investigation is complete and nothing is missed. The procedure should include: an objective for the actions that will be taken, the procedure to be followed, the personnel that will be responsible, and any other anticipated resources needed[1].

Objective of the investigation

The first step in the investigation is to state an objective for the action. In the "Identification" section the problem was defined and the current situation stated. The objective is a statement of the desired outcome of the corrective or preventive action. State what the situation will be when the action is complete. This may be a statement in the form of: "the problem will be corrected, all effects of the problem identified and rectified, and controls will be in place to prevent the situation from happening again[1].

Investigation Procedure

A set of specific instructions is created that outline what must be done to determine the contributing and root cause of the problem. The investigation procedure will vary depending on the circumstances[1].



Responsibilities / Resources

An important part of the investigation procedure is to assign responsibility for conducting each aspect of the investigation. Any additional resources that may be required is also identified and documented. For example, specific testing equipment or external analysis may be required[1].

Investigation procedure form

A sample "Investigation Procedure" forms is included. This is a written plan of action for the investigation into the problem. It should include the overall objective and the instructions for conducting the investigation. The person or persons responsible for the investigation and an expected completion date should also be entered[1].

ANALYSIS

The investigation procedure that was created is now used to investigate the cause of the problem. The goal of this analysis is primarily to determine the root cause of the problem described, but any contributing causes are also identified. This process involves collecting relevant data, investigating all possible causes, and using the information available to determine the cause of the problem. It is very important to distinguish between the observed symptoms of a problem and the fundamental (root) cause of the problem[1].

Possible Causes / Data Collection
A list of all possible causes is created. This will form the basis for collecting relevant information, test data etc.

RESULTS AND DATA
The results of the data collection are documented and organized. This may include a combination of testing results and/or a review of records, processes, service information, design controls, operations, and any other data that may lead to a determination of the fundamental cause of the problem. The resulting documentation should be complete and address all of the possible causes that were previously determined. This information is used to determine the root cause of the problem[1].
Root Cause Analysis
Determining the root cause often requires answering a series of 'why?' questions and digging deep into the situation until the fundamental reason for the problem is found. Root cause analysis is basic link to corrective action, without an effective Root Cause analysis, it is impossible to come up with good corrective action[1].

METHODS
For the analysis of nonconformity, appropriate statistical and non-statistical techniques can be applied.
Examples for statistical techniques are:
Statistical Process Control (SPC) charts
Pareto analysis
Data trending
Linear and non-linear regression analysis
Experimental design (DOE – Design of Experiments) and analysis of variance
Graphical methods (histograms, scatter plots, etc.)
Non-statistical techniques are for example:
Management reviews
Results from quality meetings
Safety committees (internal/external)
Failure Mode and Effect Analysis (FMEA)
Fault Tree Analysis (FTA)[2]
Failure Mode Effects Analysis (FMEA)
FMEA depends on product and process understanding. It methodically breaks down the analysis of complex processes into manageable steps. It provides evaluation of potential failure modes for processes and their likely effect on product performance. It can be applied to equipment and facilities and might be used to analyses a manufacturing operation and its effect on product or process.
Fault tree analysis (FTA)
This tool assumes failure of the functionality of a product or process. The results are represented pictorially in the form of a tree of fault modes. This can be used to investigate complaints or deviation in order to fully understand their root cause and ensure that intended improvement will resolve the issues and not cause any other different problem[3].
Ishikawa
The Ishikawa diagram (also called the Fishbone diagram) is a tool for identifying the root causes of quality problems. The Fishbone diagram is an analysis tool that provides a systematic way of looking at effects and the causes that create or contribute to those effects. Because of the function of the Fishbone diagram, it may be referred to as a cause-and-effect diagram. Some of the benefits of constructing a Fishbone diagram are that it helps determine the root causes of a problem or quality characteristic using a structured approach, encourages group participation and utilizes group knowledge of the process, identifies areas where data should be collected for further study[4].
Problem Analysis form
A sample "Problem Analysis" form is included. This form is optional but is intended to be used for recording information related to the analysis of the problem. The form can be used as a collection point for the information discovered during the analysis and any supporting data or documentation could be attached[1].
Action plan
By using the results from the Analysis, the optimum method for correcting the situation (or preventing a future occurrence) is determined and an action plan developed[1].
Actions to be completed
List all of the activities and tasks that must be accomplished to either correct the existing problem or eliminate a potential problem. For a CAPA program to be effective, it is very important to take a very global approach. Make sure to identify all actions that will be required to address everything related to the situation[1].
Document or Specification changes
List any documents that will be modified and describe in general terms what the modifications will be[1].
Process, Procedure, or System changes
If any changes to processes, procedures, or systems must be made they are described. Enough detail should be included so that it is clearly understood what must be done. The expected outcome of these changes should also be explained[1].
Employee Training
Employee training is an essential part of any change that is made and should be part of the action plan[1].
Action Plan form
A sample "Action Plan" form is included. This should provide a set of written procedures that detail all of the actions that must be done to resolve the problem and prevent it from recurring. This includes corrective and preventive activities, document changes, training, etc. The person or persons responsible and an expected completion date should also be entered on the form[1].
Action implementation
Proposed corrections / corrective and preventive actions that require changes to process, ways of working, procedures or equipment must be implemented using the approved change control system.
The corrective / preventive action plan that has been created is now implemented. All of the required tasks listed and described in the action plan are initiated, completed, and documented[1].
Implementation Summary
All of the activities that have been completed as required in the "Action Plan" should be listed and summarized. This section should contain a complete record of the actions that

were taken to correct the problem and assure that it will not recur. This includes changes, preventive measures, process controls, training, etc[1].

Documentation

All documents or other specifications that have been modified are listed. Typically, the documentation would be attached to a final printed report of this CAPA action. This will facilitate verification of the changes for the follow up[1].

Follow up

One of the most fundamental steps in the CAPA process is an evaluation of the actions that were taken. Several key questions must be answered:

Have all of the objectives of this CAPA been met? (Did the actions correct or prevent the problem and are there assurances that the same situation will not happen again?)

Have all recommended changes been completed and verified.

Has appropriate communications and training been implemented to assure that all relevant employees understand the situation and the changes that have been made?

Is there any chance that the actions taken may have had any additional adverse effect on the product or service?

Verification Results

The implementation and completion of all changes, controls, training, etc. must be verified. The evidence that this has been done must be recorded. Appropriate information should have been entered to document that all actions have been completed successfully[1].

Results / Effectiveness of the Actions

Another important aspect of any CAPA action is to make sure that the actions taken were effective. A thorough evaluation must be done to make sure that the root cause of the problem has been solved, that any resulting secondary situations have been corrected, that proper controls have been established, and that adequate monitoring of the situation is in place. This evaluation must also include an investigation to determine if the actions taken could result in any other adverse effects. This investigation and the results should be documented.

Documenting the complete process involved in a corrective or preventive action from identifying the problem to a successful completion is important for all companies, but absolutely essential for meeting current regulatory requirements. Following the steps outlined in this document will provide a complete, well documented CAPA action that will meet regulatory requirements and can significantly improve the quality process in an organization[1].

Application of Corrective Action and Preventive Action System Throughout the Product Lifecycle

Pharmaceutical Developments: Product or process variability is explored. CAPA methodology is useful where corrective actions and preventive actions are incorporated into the iterative design and development process.

Technology Transfer: CAPA can be used as an effective system for feedback, feed-forward, and continual improvement.

Commercial Manufacturing: CAPA should be used, and the effectiveness of the actions should be evaluated.

Product discontinuation: CAPA should continue after the product is discontinued. The impact on product remaining on the market should be considered, as well as other products that might be affected[5].

Change Management System

Corrective action and preventive, to evaluate, approve, and implement these changes properly; a company should have an effective change management system.

The change management system ensures continual improvement is undertaken in a timely and effective manner. It should provide a high degree of assurance there are no unintended consequences of the change.

The change management system should include the following, as appropriate for the stage of the lifecycle:

Quality risk management should be utilized to evaluate proposed changes. The level of effort and formality of the evaluation should be commensurate with the level of risk.

Proposed changes should be evaluated relative to the marketing authorization; there should be an assessment to determine whether a change to the regulatory filing is required under regional requirements. However, from a pharmaceutical quality system standpoint, all changes should be evaluated by a company's change management system.

Proposed change should be evaluated by expert teams contributing the appropriate expertise and knowledge from relevant areas (e.g., Pharmaceutical Development, Manufacturing, Quality, Regulatory Affairs, and Medical) to ensure the change is technically justified[5].

CAPA Quality System – More than Just Corrective Action

A CAPA Quality System is absolutely essential in some format for a complete quality management program.

The corrective action, preventive action program is the means by which unforeseen issues are addressed, remedied, and eliminated from ever happening again. A CAPA quality system is a required part of ISO compliance, and is a vital part of TQM practices if a company ever expects to reach its goal of zero defects.

Preventive Actions can be anything, but some typical ones are: Write a new procedure and train everyone on it, documenting the training, inspect every other machine that performs a similar function at the facility to ensure it does not have a similar issue, Perform periodic maintenance inspections etc.

In a true CAPA system, there is a formalized process to "close the loop" to make sure all of the corrective and preventive actions were completed, that they perform as they were intended to perform, and the organization can be assured that it will never have to deal with this same issue again.

The CAPA system is one of the best ways to find, fix, and eliminate defects from the process. Fixing it once and ignoring the root cause guarantees that the issue will return. And every time it comes back, it will be as costly as it was the first time to fix[6].

List of Abbreviation

SOP, CAPA, QMS

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