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White Paper:

Simplifying CAPA: Seven Steps to a Comprehensive CAPA Plan

1. Introduction

Troubleshooting problems and attempting to identify and prevent potential problems is a typical activity for most businesses. Problems impact on a company financially and the ability to correct existing problems or implement controls to prevent potential problems is essential for continued customer satisfaction and efficient business practice.

The missing element in this process is often adequate documentation of the actions taken. Properly documented actions provide important historical data for a continuous quality improvement plan and are essential for any product that must meet regulatory requirements demanded by FDA and ISO. This is the reason for the implementation of a formal Corrective Action / Preventive Action (CAPA) program. CAPA is a major area of concern for both the FDA and ISO 9000. They have recognized that maintaining and monitoring quality systems is the key to success and effectiveness.

Their risk-based CAPA requirements demand determination of root causes of non-conformances, system failures and process problems. For these 'issues' (known or suspected) companies should follow three basic rules:

- Identify the problem
- Correct the problem
- Prevent the problem

A Quality System must identify why something went (or why it may go) wrong and ensure it does not happen again.

CAPA can be a powerful management tool. This guide provides a simple step by step process for capturing, managing, tracking and trending corrective and/or preventive actions. This will satisfy regulatory requirements and form the basis for an effective continuous improvement plan for any company.

This white paper defines corrective and preventive actions and discuss the seven distinct actions for which companies doing business in regulatory environments should develop thorough plans and procedures. Specifically, a comprehensive CAPA process is comprised of the following procedures that must be meticulously conducted and tracked:

1. Identification
2. Evaluation
3. Investigation
4. Analysis
5. Action Plan
6. Implementation
7. Follow Up

2. Corrective Actions

Corrective actions are reactions to problems, complaints and/or other nonconformities. The main reaction here is to fix the issue. The process for 'fix' includes:

- Reviewing and defining the problem or nonconformity
- Finding the cause of the problem
- Developing an action plan to correct the problem and prevent a recurrence
- Implementing the plan
- Evaluating the effectiveness of the correction.

3. Preventative Actions

Preventative actions are detection of potential problems or nonconformance's and eliminating them. The process includes:

- Identifying the potential problem or nonconformance
- Finding the cause of the potential problem
- Developing a plan to prevent the occurrence
- Implementing the plan
- Reviewing the actions taken and the effectiveness in preventing the problem

4. Differences

The processes used for corrective actions and preventive actions are very similar and the steps outlined in this white paper are applicable to both. However, it is important to understand the differences and also be aware of the implications involved when performing and capturing information for each.

A corrective action is a reaction to a problem that has already occurred. It assumes that a nonconformance or problem exists and has been reported by either internal or external sources. The actions initiated are intended to: a) fix the problem and b) modify the quality system so that the process that caused it is monitored to prevent a reoccurrence. The information captured for a corrective action provides evidence that the problem was:

- Recognized
- Corrected
- Prevented from recurring

For example, in a clinical trial environment the Investigator's CV was missing from the trial file. In this situation a problem exists and has been identified. The corrective action would be to locate the CV and file accordingly.

A preventive action is initiated to stop a potential problem from occurring. It assumes that adequate monitoring and controls are in place in the quality system to assure that potential problems are identified and eliminated before they happen. If something in the quality system indicates that a possible problem exists or may develop, a preventive action must be implemented to avert and then eliminate the potential situation. The documentation for a preventive action provides evidence that an effective quality system has been implemented that is able to anticipate, identify and eliminate potential problems.
For example, it has been noted on several occasions that the Investigator's CV is not available in the trial files for a particular study. On investigation it was noted that these sites had the same monitor. Several causes might be investigated to determine the reason for this repeat issue. Such causes could be monitor training, supplemental checklist (with missing check-point). etc. If this were a training issue one possible preventative action could be to improve the specific training program.

An effective, reliable Corrective and Preventive Action program adds value to a quality system by identifying potential problems and effectively correcting them when they do occur.

5. CAPA Procedures

Implementing an effective corrective or preventive action program that is capable of satisfying quality assurance and regulatory documentation requirements can be achieved as follows:

1. Identification of the potential or actual problem, nonconformity, or incident
2. Evaluation of the extent of the problem and potential impact on the company
3. Availability of an Investigation procedure that includes responsibilities
4. Analysis of the problem with appropriate data capture
5. Creating an Action Plan that lists all tasks to be completed in order to correct and/or prevent the problem.
6. Implementation of the Action Plan.
7. Follow up with verification of the completion of all tasks, and an assessment of the appropriateness and effectiveness of the actions taken

6. 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.

Source

The specific origin of the information that initiated this action is recorded. 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.

This information may come from many possible sources. For example, situations that require corrective actions may come from external sources such as customer concerns or service requests. Internal quality audits, staff observations, quality assurance inspections, trending data, and management review are all examples of possible internal sources of information.

Examples of sources that lead to preventive actions may include:

- Service Request
- Internal Quality Audit
- Customer Complaint / Concern
- Quality Assurance Inspection
- Staff Observation
- Trending Data
- Risk Assessment
- Process Performance Monitoring
- Management Review
- Failure Mode Analysis

Other sources are certainly possible and are dependent on specific circumstances.

7. Evaluation 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.

Evidence

List the specific information available that demonstrates that the problem exists. For example, the evidence for a product defect may be a high percentage of service requests or product returns. The evidence for a potential equipment problem may be steadily increasing downtime.

Corrective/Preventive Action Request form

A sample form is provided "Corrective/Preventive Action Request" that can initiate a CAPA action and collect preliminary information.

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.

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.

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. For example, a problem that presents a serious risk to the function or safety of a product may be assigned a high priority and require immediate remedial action. On the other hand, an observation that a particular machine is experiencing an increasing level of downtime each month may have a lower priority.

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. If remedial actions are necessary, the actions and the resources required are listed. The steps that must be taken immediately to avoid any further adverse effects are explained. The actions taken are documented. This documentation will become part of the 'Action Implementation' and 'Follow Up' sections of the CAPA action.

In some instances it may be determined that the remedial action is all that is needed. In that case, a rationale is written for that decision, appropriate follow up is done (see "Follow Up" section), and the CAPA closed out.

Remedial Action form

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

8. Investigation

In this step of the process a procedure is written for conducting an investigation into the problem. A written plan provides assurance 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.

Objective

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."

Investigation Procedure

A set of specific instructions are created that outline what must be done to determine the contributing and root causes of the problem. The investigation procedure will vary depending on the circumstances, but must incorporate a comprehensive review and analysis of all of the circumstances related to the problem. Consider equipment, materials, personnel, procedures, design, training, software, and external factors.

9. Responsibilities and 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 are also identified and documented. For example, specific testing equipment or external analysis may be required.

Investigation Procedure form

A sample "Investigation Procedure" form 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.

10. 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.

Note: There are many formal methods of performing root cause analysis. A discussion of specific methods is beyond the scope of this document.

11. Possible Causes/Data Collection

A list of all possible causes is created. This will form the basis for collecting relevant information, test data, etc. For example, consider the situation where a large batch of parts from a CNC Mill were discovered to be out of tolerance. There are many possible causes for this condition including: operator error, incorrect software, a dull or broken tool, an incorrect or obsolete print, a material problem, a design problem, etc. By considering all possible causes, appropriate information and data can be collected that will be ultimately be used to determine the root cause of the problem.

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.

12. Root Cause Analysis

Determining the root cause often requires answering a series of 'why?' questions and digging deep until the fundamental reason for the problem is found. For example, in the out of tolerance parts situation described earlier, the investigation revealed that the operator had not been properly trained and had forgotten an essential step in the machining process. The improperly trained operator is the immediate cause of the problem, but may not be the root cause. Why was the operator not trained properly? Are the existing training programs adequate and are they being implemented properly? Further investigation revealed that the operator was on vacation when the training was given and, therefore, did not receive the training when other operators did. The root cause of the problem was a lack of follow up in the training program. No mechanism existed to cross check training records to assure that a missed training session was rescheduled.
The root cause of the problem is documented. This will be essential for determining the appropriate corrective and/or preventive actions that must be taken.

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 can be attached.

13. 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. The plan should include, as appropriate: the items to be completed; document changes; any process, procedure, or system changes required; employee training; and any monitors or controls necessary to prevent the problem or a recurrence of the problem. The action plan should also identify the person or persons responsible for completing each task.

14. 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. For example, in the training situation described

earlier, the root cause was a flaw in the training program. One of the actions that must be taken is to review all previous training records to determine if this problem resulted in any other employee not receiving necessary training.

Document or Specification changes

List any documents that will be modified and describe in general terms what the modifications will be.

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.

15. Employee Training

Employee training is an essential part of any change that is made and should be part of the action plan. To assure that the actions taken will be effective, any modifications made to documents, processes, etc. must be effectively communicated to all persons or departments that will be affected.

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.

16. Action Implementation

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.

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.

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.

17. 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:

1. 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?)

2. Have all recommended changes been completed and verified?
3. Has appropriate communications and training been implemented to assure that all relevant employees understand the situation and the changes that have been made?
4. 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.

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.

18. Additional Comments

It is always a good idea to add any additional information or other appropriate comments concerning the problem, investigation, actions, or follow up that may be helpful in understanding anything that has been done for a CAPA action. 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. When the Follow Up is complete, there should be a formal indication that it has been completed (such as a checkbox and date.) A review and approval signature by authorized personnel is also recommended.

A Corrective / Preventive Action policy is essential!

Troubleshooting problems and attempting to identify and prevent potential problems is a typical activity for most businesses. The reason is obvious: Problems have a financial impact on the company. The ability to correct existing problems or implementing controls to prevent potential problems is essential for continued customer satisfaction and efficient business practice.

However, the missing link in this process is often adequate documentation of the actions taken. Properly documented actions provide important historical data for a continuous quality improvement plan and are essential for any product that must meet regulatory requirements demanded by FDA and ISO. This is the reason for the implementation of a formal Corrective Action / Preventive Action (CAPA) program. CAPA is a major area of concern for both the FDA and ISO 9000. They have recognized that the maintenance and tracking of a quality system is critical to its effectiveness. Their risk-based CAPA requirements demand a well documented system that determines the root cause of nonconformances, system failures, or process problems, and that the system 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 white paper has provided a simple step by step process for completing and documenting corrective or preventive actions. Following the steps outlined here should result in a complete, well documented investigation and a solution that will facilitate regulatory compliance to FDA and ISO requirements.

19. Examples of Forms

Corrective / Preventive Action Request

Date: _____ ☐ Corrective Action ☐ Preventive Action
Request Source
☐ Service Request ☐ Internal Quality Audits
☐ Customer Compliant / Concern ☐ Quality Assurance Inspection
☐ Staff Observation ☐ Trending Data
☐ Risk Assessment ☐ Process Performance Monitoring
☐ Management Review ☐ Failure Mode Analysis
Description of the Problem
Evidence Observed
Preliminary Assessment of Potential Impact and/or Risk
Action initiated by _____

Corrective / Preventive Action
Remedial Action Required

CAPA Action #:_____
Date: _____ ☐ Corrective Action ☐ Preventive Action
Description of the Problem
Evidence Observed
Potential Impact of the Problem
Remedial Actions Required
Actions Completed Date_____ By_____

Results

Corrective / Preventive Action
Investigation Procedure

CAPA Action #:_____
Date: _____
Objective of the Action
Instructions
Investigation Assigned to _____
Expected completion date _____
Approved _____ Date _____
_____ _____

Corrective / Preventive Action
Problem Analysis

CAPA Action #:_____
Date: _____
List of Possible Causes and Supporting Data:
Analysis Results and Data

ĺ Supporting Documents Attached

_____

Root Cause Determination
ĺ Supporting Documents Attached

_____
Analysis Complete Date _____ By _____

Corrective / Preventive Action
Action Plan

CAPA Action #:_____
Date: _____
Actions to be completed
Document changes required
Procedure, Process, or System Changes required
Training required
Action plan assigned to _____
Expected completion date _____
Approval By _____ Date _____
_____ _____

QAAD™

Corrective / Preventive Action (CAPA) Made Easy !

QAAD™ is an integrated software solution that manages the entire Corrective / Preventive Action process. Using a very logical and intuitive approach, the program guides the user through the initiation, investigation, resolution and documentation of corrective or preventive actions. It provides a powerful tool for implementing and maintaining an effective corrective / preventive action program for any organization.

Some of the features and benefits of QAAD™ include:

- Comprehensive management of existing and potential problems resulting from quality assurance concerns, customer complaints, audits, process problems, etc.
- Simple step by step process for completing and documenting corrective or preventive actions.
- Navigation is simplified through the use of a "wizard" style interface, tabbed pages or via menu selections
- Allows thorough documentation of the CAPA process from identification of the problem through verification and validation of the resolution
- Encompasses all essential elements of a compliant CAPA system including: identification, investigation, analysis, implementation, and follow up.
- Complete documentation of the Action
- Export reports in PDF, MS Word, MS Excel or text formats

If you are interested in receiving more information about QAAD, please call us at +44 118 981 2838 or email us at contact@amgit.com.

"QAAD supports a complete, well documented corrective and/or preventive action process that will satisfy regulatory requirements and form the basis of an effective continuous improvement plan."

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MasterControl Inc.

USA
6322 S. 3000 E. Suite 110
Salt Lake City, UT 84121

P. 800.825.9117
F. 801.942.7088
www.mastercontrol.com

Europe
7200 The Quorum
Oxford Business Park North
Garsington Road
Oxford OX4 2JZ
United Kingdom

P. +44 (0) 1865 481481
F. +44 (0) 1865 481482
www.mastercontrolglobal.co.uk