Corrective/ Preventive Actions

The Who, What, When, Where, Why, And How Of Implementing An Effective Corrective Action, Preventive Action (CAPA) Process

Who needs a CAPA process?

- **Any** organization that wishes to improve their performance and prevent making the same mistakes over and over again.
- Organizations that have chosen to implement a comprehensive Quality Management System. They quickly learn that implementing an effective CAPA process is fundamental to continuous improvement.
- Organization striving to meet ISO (International Standards Organization) standards such as ISO 13485. They are required to implement an effective CAPA process.

What is a CAPA process?

Process: A series of actions or operations conducing to an end (Merriam Webster)

Nonconformance: A deviation from a specific procedure, standard, stated process or system requirement.

Corrective Action: Action taken to eliminate the cause of a nonconformance that has occurred, and prevent reoccurrence of the nonconformance. (In this case a nonconformance has already occurred)

Preventive Action: Action taken to eliminate the cause of a potential nonconformance and prevent the nonconformance from occurring. (In this case a nonconformance has not yet occurred)

CAPA Process: Business process established and resources provided by an organization's management with the objective of systematically preventing occurrences or reoccurrences of defects within the organization's products and services.

When should a company implement a CAPA process?

There needs to be a sense of urgency within the organization about solving problems permanently. It is ineffective to implement a CAPA process without the minimum required resources and the necessary commitment to improving the performance of the organization. The "How" section of this paper will help define the necessary resources required for an effective CAPA process implementation.

Where within the organization does the CAPA process operate?

The CAPA process can be utilized across all functions of the organization. Management must determine the scope of implementation based on available resources and the level of commitment to change. Frequently the initial implementation is limited to business process defined by standards such as ISO 13485. The administration of the CAPA process is typically assigned to the part of the organization that acts as the change agent. The CAPA coordinator will be management's representative for implementing a culture of improvement and should have a contempt for the cycle of repeating past mistakes.

Why must you invest time and effort to implement and manage a CAPA process?

- **Customer Perspective:**

◊ Increase customer satisfaction
◊ Provide closed-loop feedback

- **Financial Perspective:**

◊ Reduce cost of rework
◊ Reduce returned material
◊ Prevent loss of revenue

- **Process Perspective:**

◊ Meet ISO 13485 Requirements:
8.5.2 Corrective Action: Action must be taken that will remove the cause of a nonconformance to prevent it from occurring again. The action taken should be appropriate to the impact of the nonconformance on the organization.
8.5.3 Preventive Action: The Action must be taken that will remove the cause of a potential nonconformance to prevent it from occurring at all. The action taken should be appropriate to the impact of the potential nonconformance.

◊ Stabilize processes through systematic improvement
◊ Sustain improvement gains

- **Learning Perspective:**

◊ Avoid "reinventing the wheel" for every

problem
◊ Maintain history of organizational change

How should a CAPA process be implemented?

The following steps are necessary for an effective CAPA Process:

1. **Record Potential or Actual Non-conformance**
2. **Assign and Manage Request**
3. **Investigate Root Cause**
4. **Design Corrective Action**
5. **Implement Corrective Action**
6. **Follow-Up on Corrective Action to Assure**
7. **Effectiveness**

1) Record Potential or Actual Non-conformance
The person observing a potential or actual non-conformance initiates the process and often is called the "Requestor", because they are requesting the CAPA process be applied to the potential or actual non-conformance they have observed. The "Requestor" will typically provide the following information:
Request or CAPA number
Requestor Name:
Request Date:
Problem Description:

2) Assign and Manage Request
The CAPA Process administrator, sometimes referred to as the CA Coordinator, ISO Representative or Management Rep will route the request to the appropriate people in the organization to assure the necessary action is taken in a timely manner.

3) Investigation and Root Cause Analysis
A detailed instigation of the circumstances that created the problem is required. The elimination of the actual root cause of the problem is the only means to prevent the problem from reoccurring. Many problem solving techniques have been developed to help in this phase of the process. The most popular are:

- Brainstorming
- Fish Bone Analysis
- Window Analysis
- Process Mapping
- The Five Whys

The investigation is typically assigned to an individual who has the skill of tapping into the expertise of the people within the organization to identify real root cause.

4) Design Corrective Action

Once an accurate understanding of the root cause of a problem is established, the action(s) required to prevent a reoccurrence of the problem can be determined. These actions frequently involve changing documented processes, conducting additional training, or even improving tooling, equipment or materials. Systemic problems may require changes in management policies.

5) Implement Corrective Action
Installing the changes into the system in a way that assures consistent compliance to those changes is critical to avoid reoccurrences of the problem. This is where many organizations fall short. Without a consistent and controlled process, it is impossible to see a continuous improvement of outcomes, better product or services.

6) Follow-Up on Corrective Action to Assure Effectiveness
Follow-Up includes confirming the corrective/preventive action has been taken and determining the effectiveness of the action taken. This critical step closes the loop on the CAPA process. If the actions taken are effective, the CAPA process is complete; if ineffective the CAPA process repeats itself. This can be done by opening a new CAPA request or continuing to managing the current CAPA request.

More on "How"

The administration of the CAPA process is critical to its effectiveness. Auditors typically report the following issues:

- Corrective actions closed without verifying effectiveness
- No due date assigned for the closure of corrective action
- Corrective actions not completed by the due date
- Management has not provided the necessary resources to properly administer the CAPA process.

The most important resources are the people involved in administering and executing the process. They must have the skills, organizational credibility, knowledge and tools to perform the required task.

Recommended Links

The FMEA Investigator
Root Cause Analysis With Corrective Action