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White Paper

Complete Guide to Building an Effective CAPA Plan

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When faced with an issue, you will need a well-built and effective CAPA Plan.

CAPA is a corrective and preventive action plan. It is a quality management strategy used to identify systematic issues to solve and ensure that reoccurrence is unlikely.

If you have a production, manufacturing, distribution or testing industry you will need a CAPA Plan.

Below you will find your guide to help you build the most effective CAPA Plan. It is easy to implement and allows you to spend less time solving issues that occur as well as save money.

Why do you need a CAPA Plan?

Imaging receiving a bunch of customer complaints on a product. At first, you will try to deal with them the way you have been taught.

But suddenly, you find yourself lost in between not knowing where to start, and what is the main issue to solve. Implementing a CAPA system can help in finding resolutions easily without the extra stress, time, and money. If you have a well-structured CAPA plan you will know your roots back to compliance smoothly.

You should know that the FDA reviews CAPA systems during inspections. In 2016 alone, the FDA issued more than 300 citations to medical device manufacturers for inadequate CAPA procedures. In addition, many ISO standards recommend implementing a CAPA process.

What are the criteria for a good CAPA Plan?

First, there are two fundamental features of a CAPA system:

1. The experience and wisdom of the employees conducting the processes: employees should have prior experience with the CAPA system to give an effective result.

2. The process: The CAPA process requires critical thinking and an effective determination to come up with proper solutions

For your CAPA Plan to be considered adequate, the FDA is looking for an effective and useful process that will address defects.

The plan should indicate owners and timelines, be clearly written and should take into consideration to whom it is addressed and how much knowledge they have.

Below we will tackle 8 guidelines:

1. Identifying the issue
2. Evaluating the criticality of an issue
3. Investigating the root cause of an issue
4. Developing a resolution plan
5. Implementing the resolution plan
6. Measuring efficacy
7. Updating and recording procedural changes
8. Communicating CAPA information

An issue should be evaluated by personnel before moving to the CAPA process to anticipate the severity of the issue.

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1. Identifying the issue

The first step is to identify the problem. Problems could be anything from a complaint, a non-conformity report, internal audit findings or any other issue needing corrective action. So how should you proceed when you have an open CAPA? You start by reviewing then investigating the issue, check the effectiveness of the product, process, and/or system, then take preventive actions.

You have received a complaint and you are trying to collect more information about it. An issue typically occurs when someone notices a defect in a product, process, or system. Complaints can be made internally or can come from an external resource such as customers.

If your review and complaint processes are effective, a good amount of information should be available and documented.

Here are some questions that can assist in identifying the issue:

- What is involved? (Equipment – product – process)
- What is the expected result?
- Where did it happen?
- When did it happen?

2. Evaluating the criticality of an issue

At this stage you should be able to recognize if the problem requires a CAPA plan to resolve the issue, or if it needs a minor resolution.

You cannot treat every issue as a CAPA issue, you will be overwhelmed, and the process in turn will become ineffective. It's a waste of time, energy, and resources. Also not treating any issue as a severe one and worth being handled with a CAPA Plan will be harmful to your employees and customers.

Evaluation is key to identifying the severity and complexity of each issue. The evaluation will determine if you need to adopt the following CAPA steps or not.

CAPA is always used for systemic issues where complaints are repeatedly reported. One complaint rarely requires a CAPA response unless it is dangerous. For example, if a customer is injured due to the product usage, this should be taken seriously.

Two factors should be taken into consideration, the quantity of complaints and their severity to determine the CAPA necessity.

Questions to consider:

- Is the safety of the customer or the employee is affected?
- How many times has the issue occurred?
- Does this impact the product design or performance?
- Does this impact regulatory documents?

Asking these questions will help you classify the issue as low, medium, or high risk. If the issue is determined as low risk there is no need for a CAPA intervention, if it is medium to high risk then you should proceed with the next steps.

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3. Investigating the root cause of an issue

The root is the source of the problem, and it is crucial to find it so that reoccurrence does not happen.

Not being able to identify the root cause of a problem will lead to wasted time on false causes and will not fix the issue.

It is not an easy job to do especially when you need to know which of the causes is the main one.

Below are 3 ways to help identify the root cause:

A. The 5 Whys

It is quite simple; continually ask 'why' questions until you address all avenues of an answer and eventually you will get to the root of the problem.

B. The Fishbone Diagram

Start by drawing a fish. Where the head would be, write out the problem or defect. Then, label the bones using the major categories of potential causes (machines, methods, materials, measurements, nature, manpower…) for manufacturers (policies, procedures, people, technology…) or for service industries. Under each fishbone write down all possible causes related to the problem from the category. Continue with this method until you have determined the root cause.

C. The Fault Tree Analysis

It is a tree topped with the main issue and underneath it is many possible causes. Below each cause try to break it down furthermore to create a diagram. This tree is a deductive diagram, it helps determine the sequence of faults that caused the issue.

4. Developing a Resolution Plan

After gathering all the information needed about the problem and its cause(s), it is time to plan the best resolution.

There are three categories of resolutions:

A. Correction: the main purpose is to find a temporary solution while more permanent actions can be explored

B. Corrective actions: the main purpose is to prevent reoccurrence from happening by addressing the root cause

C. Preventive actions: is a form of risk management, it helps prevent the occurrence of the problem

- What is the difference between corrective and preventive actions?

Corrective action is when you react to a problem that already occurred, while preventive is a proactive action on a problem that might occur or is expected to happen.

- What are the ISO standards for preventive actions?

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Before the release of ISO 9000:2015, preventive actions were mandatory procedures required by ISO 9001. Companies had to keep records on nonconformities and preventive actions taken.

However, a new problem occurred on how to define the potential problems and where to look for them.

Experts explained that preventive actions concerned risk and directed practitioners to ISO 9004, "…managing for the sustained success of an organization — a quality management approach…" which was considered a reference point to what preventive action modules should address.

ISO 9000:2015 eliminates the requirement for predefined procedures for both corrective and preventive action. Preventive actions are now considered to be a part of good planning and risk management.

5. Implementing the Resolution Plan

To implement corrective actions, after identifying the issue, it might be sudden and quick but it is an important step in correcting and resolving an issue. Sometimes you just need to act quickly!

From an employee's perspective, corrective actions are warnings, leave with or without pay, or any measure related to disciplinary behavior.

From a production perspective, corrective actions can be an alert, redesign, and/or process modification, etc.

Keep in mind that corrective actions should be taken immediately, and remember they often are temporary solutions.

Preventive actions are actions based on predictions, to help keeping the issue from happening. They can be most commonly reviewing or auditing suppliers, implementing alarms, risk analysis, disaster recovery plans, etc.

6. Measuring efficacy

After implementing your solution, whether it was a corrective or preventive action, you should document its effectiveness. Measuring effectiveness is a crucial step that will determine if your proposed solution resolved the problem and kept it from reoccurring..

There are many ways to report on effectiveness, depending on the measures you chose to implement.

For example, you can test errors before and after you implement the corrective action, as well as conduct surprise audits to further measure effectiveness.

7. Updating and recording procedural changes

After documenting the entire process, it is important to keep records updated of any changes that occur for future inspections. By continuously updating and evaluating documentation, users can ensure that the implemented solution has resolved the problem for good and the possibility of reoccurrence is unlikely.

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After the first use of the plan, ask if it was easy to follow and implement. Writing the process correctly is critical to the CAPA procedure, it will ensure the plan is clear and easy to use.

You can also make training sessions on the draft of the plan to test how easy it is to understand and implement. And afterward take the feedback into consideration and update your plan.

8. Communicating CAPA Information

After investigating information, implementing changes, evaluating, and documenting the CAPA plan, you should communicate all changes that occurred during the process to any involved or will be involved employee to prevent any further problem that could occur from misunderstanding or lack of knowledge.

One last useful advice, develop key performance indicators (KPIs) they are very important to communicating the effectiveness of your CAPA system to the organization management. KPIs help find non-conformity and reveal areas that require in-depth investigation. They help prevent problems and take anticipatory actions.

Misconceptions about CAPA

Even though quality regulations require organizations to document CAPA processes and following them, some tend to have some doubts and misconceptions about it:

- Employees will be punished because something went wrong: this is untrue, eventually someone must implement the CAPA process. Training a team to do so will help destigmatize the CAPA system and its purpose.
- It is hard work: when everyone in the company is a part-time investigator, the extra work remains undone. The solution is to have a review board with people trained in appropriate roles so that CAPA becomes a regular responsibility.
- Training is too expensive: In terms of longevity, CAPA processes will save time and money by thoroughly treating the issue once, rather than multiple times throughout time.

Software Solutions for CAPA

CAPA's have many details and documents necessary for a good quality management system; having a strong platform can help track the many updates that should be added to assorted documents. With a web-based system, authorized users will have access to a central of information to get all the documents they need and stay updated on any amendment.

Improve CAPA Procedures with Work Management in Intellect QMS

Empower your employees with a developed flexible platform that matches their needs and adapts with their changing ones.

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The Intellect QMS platform makes everything much easier. It will help plan, capture, manage, and report on work from anywhere, as well as manage your team to become more productive and effective.

When everything is communicated clearly to your team, you can consider the job done. There will be no need to ask how much more they can accomplish in less time.

Demo Request