# Understanding CAPA:

## Elements of CAPA, Pitfalls and Challenges, and Essentials for Success

MERIT SOLUTIONS

# Content

# 1. Introduction

The Life Sciences industry is facing more pressure than ever before, fromgovernments and regulatory bodies, supply chain partners, and end consumers. Today's executives are continuously challenged to focus on and improve quality – while at the same time reducing costs, streamlining processes, and increasing profits.
Corrective and Preventive Action (CAPA) software is one way that Life Sciences companies can achieve these objectives. Two events that keep executives up at night are upcoming audits, 483 observations and warning letter citations. (See FDA Inspections, Compliance, Enforcement, and Criminal Investigations for statistics.)
This makes an effective CAPA system extremely important, for the following three reasons:

1. CAPA can identify quality problems early in the cycle before problems become severe.
2. CAPA can provide reassurance to regulatory agencies that the company is capable of resolving issues.
3. CAPA can convince regulatory bodies and clients that identified problems have been resolved.

A CAPA system is essential for any regulated company.
However, many CAPA systems have been implemented with very few tangible benefits. One of the most common reasons for these disappointing results is the failure to connect and fully integrate CAPA systems and processes with corporate strategies and policies – and / or other enterprise business systems.
While CAPA is handled differently at almost every life sciences company, best practices for handling complaints and investigations revolve around certain core activities, a basic process and, more often than not, some enabling technology.

# 2. What is CAPA?

The FDA defines the purpose / importance of CAPA as:

*The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.*
*Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures.*

One of the most important quality system elements is the corrective and preventive action subsystem.

Currently, there are five different types of information sources that can trigger the CAPA process:

1. Complaints from supply chain customers or consumers
2. Process deviations because of a manufacturing inconsistency or production failure, or an engineering non-conformity
3. Laboratory investigations
4. Audits – either internal or from regulatory bodies
5. Internal employees (for example, an engineer who notices a spill)

Now that we understand how the FDA defines CAPA – what makes a CAPA?

## 3. What Makes a CAPA?

ISO 9001 standards identify three distinct actions that are critical to understanding how to effectively maintain CAPA systems and processes:\

- Correction – Any action that is meant to eliminate a detected nonconformity.
- Corrective Action – Any action to eliminate the cause of a detected nonconformity.
- Preventive Action – Any action to eliminate the cause of a potential nonconformity.

Many Life Sciences companies fall short when defining these three actions. Traditionally, companies have thought it was necessary to have a correction, corrective action, and preventive action on the same issue. But when you review the ISO definitions, you can see that is not the case. For example, not all situations require a preventive action be taken.

Typically, the first thing companies fail to address in their CAPA program is determining when a deviation or non-conformance should be escalated to CAPA status - and then delegating the appropriate responsibility to employees to resolve the issue. There are many reasons for this failure - and the lack of documented SOPs for CAPA processes makes it more difficult for life sciences companies to ascertain which issues should be escalated.

This confusion is partly because the FDA relies on each company and their executives to ensure that their CAPA programs will incorporate the necessary processes, actions, and controls to effectively resolve any issues. This lack of guidance often results in companies escalating too many routine deviations to CAPA status - or too few severe ones - and maintaining insufficient documentation for regulators to properly discern whether issues have been resolved correctly and within the right time frame.

A good rule of thumb is that CAPAs should be prioritized on the severity of the risk and take into account the frequency with which a non-conformance might occur - meaning events deemed severe enough to result in a negative impact on consumer safety should be escalated to CAPA status.

## 4. What Does the FDA Need?

Now that we've covered the high level CAPA basics, let's consider what the FDA expects to see when documenting CAPA programs.
The responsibility for ensuring CAPA compliance ultimately lies with company executives, and failure to adequately and sufficiently document CAPA processes can result in 483 observation or a warning letter from the FDA.
That's why it is extremely important to document CAPA processes in a way that provides the following elements to the FDA:

- A structure for directing current and future activities.
- The history explaining how the company complied with the requirements to correct a nonconformity and employed reasonable measures to limit the risk to its consumers of being exposed to unsafe or ineffective products.

When documenting CAPA programs, it is critical to articulate the timeline for when non-conformances occur, when each step was taken to resolve them, and which employee(s) were assigned to deal with each individual CAPA record. Companies should include as much detail about the steps taken through the process so that FDA is left with little question about when the incident occurred, when and how it was corrected, and how quickly the loop was closed.
Sufficiently documenting CAPA processes is crucial to ensuring compliance and avoiding warning letters from the FDA. Don't overlook the importance of understanding exactly how much data needs to be captured during the entire CAPA process.

## 5. How to Collect CAPA Data?

Life Sciences companies typically collect and manage CAPA data in one of three ways: via manual, paper-based processes; in entry-level electronic systems such as Excel; or enterprise quality management software (QMS).
Almost every Life Sciences company started with paper-based processes – which is by far the longest-used process. Unfortunately, paper systems have little upside in their ability to accurately capture, manage, and quickly report CAPA data. Paper documents are a hassle to manage, and they often end up collecting dust in filing cabinets or on individuals' desks for long periods of time. This results in failures to meet project deadlines or, worse yet, an inability to track and trend issues across the enterprise.
Beyond these reasons, paper-based processes are also generally poor at capturing essential data such as incident and resolution timelines.
Basic electronic systems like Excel and Access are a lot better than paper based CAPA systems, allowing companies to manually input any required CAPA data directly into spreadsheets and databases, while administrators can set access privileges by administering passwords to ensure only authorized users have the ability to manipulate the data. However, these applications also present several significant challenges to Life Sciences companies. First, like paper processes, they offer limited visibility into the full scope of how CAPAs are initiated and resolved or the full timeline of who performed what actions and when. Second, because of the manual nature of entering data and managing these tools, they are enormously prone to error, with very little

ability to identify and correct inconsistencies that arise during data entry. And finally, because of their disconnected nature, these systems often result in major process inefficiencies and frequent miscommunication for global organizations that typically have multiple sites and hundreds of users all requiring access to the same system.

The third most common way organizations manage their CAPA processes is through enterprise systems like QMS applications. There are many advantages to these systems as most are designed specifically to manage CAPA documentation processes along with a host of other quality and compliance functions.

With these QMS systems, Life Sciences companies can prioritize incidents that occur during the manufacturing process based on risk, determine which incidents need to be elevated to CAPA status, and assign the right personnel to initiate the CAPA. Once a CAPA is initiated, companies can then centrally manage and streamline the processes of resolving CAPAs across any number of sites, setting user access privileges as necessary and setting up e-mail alerts to ensure the right personnel take the required action efficiently and effectively. Finally, and perhaps most importantly, as many such systems feature templates configured in an FDA-ready format, QMS systems prove especially adept when it comes time to extracting data from the system to track and trend across departments and demonstrate compliance to third parties.

## 6. Understanding CAPA Systems

Taking into account the systems and processes above, we believe it is essential that any FDA-regulated company that wants to become an industry leader needs to have an effective electronic CAPA system.

Unfortunately, companies are often at a loss as to what an effective CAPA system should look like, so they err by enforcing either too much control or not enough control. At its core, an effective CAPA system should be a closed loop system, ensuring evaluation of quality input, implementation of corrective actions and evaluation of the results of the changes.

The basic functions of a CAPA system include:

- Identification of possible issues
- Categorization based on severity and impact
- Recognition and acceptance of the issue
- Investigation and root cause analysis
- Defining corrections
- Implementation of correction
- Verification of implementation and problem resolution
- Close the corrective action record
- Management reporting

Companies must ensure that they monitor all sources of potential quality information, including inspection records, customer complaints and service records. Once the company has identified a potential issue, they must scope the issue using the “Five Ws” to determine the severity and impact. The “Five Ws” are:

1. Who
2. What
3. When
4. Where
5. Weight or severity

Correctly identifying the "Five Ws" leads to a sixth "W": Why. The "why" represents the root cause of the issue which must be identified before there can be any assurance that corrective actions will resolve the issue. Once the company knows the root cause, they can identify correction and containment actions that resolve the issue. Before the final corrective action is in place, the company may choose to implement containment actions that prevent further damage from the issue, but which may not entirely solve the underlying quality problem.

The company should use a variety of problem-solving techniques to identify the root cause and potential solutions. The most successful approach is to use investigation and deductive reasoning to identify the root cause, possibly supplemented with tools such as fish boning or trial and error experiments.

Whatever approach they choose, the company must be sure to document the reasons for the choice and all of the procedural changes. The company must implement all procedural changes in a timely fashion as defined in the CAPA process itself, and the authorized parties must sign off on all the changes.

One of the most important parts of a CAPA system is ensuring closed loop effectiveness checking. Once the company implements a corrective action, they must collect and analyze quality data to ensure that the solution actually resolved the underlying issue and did not introduce new problems. Disseminating the information is also a key component of a successful CAPA system. Management reports are important, but all members of the team who might be affected by the procedural changes should also be notified.

The FDA requires that all CAPA information be stored, legible and easily retrieved in case of an audit or a recall. Many companies find that storing paper records is nearly impossible because of the amount of storage space they consume and the difficulty in ensuring legibility and in preventing deterioration. As a result, most companies turn to electronic records to ensure compliance.

## 7. Top Pitfalls and Challenges of CAPA Systems and Processes

Every Life Sciences company needs to have an effective CAPA program in place to minimize risk and ensure compliance with regulations, but maintaining an effective CAPA process can be challenging. Challenges can occur at every step of the CAPA process and it requires vigilance to ensure that they don't derail the process and expose the company to unnecessary or excessive risk.

Here are the top challenges of CAPA systems and processes:

**1. Relying on Experts' Experience**: Historically, Life Sciences organizations have relied upon the experience of a couple internal experts to drive CAPA programs and identify root causes of nonconformances. But since company experts attempt to solve all problems using their experience with past CAPAs - their solution is completely dependent upon and limited by their expertise. If the root cause happens to lie outside the scope of their expertise levels, they are not likely to find it. They will use up an inordinate amount of time and resources running trial-and-error tests that often don't uncover a resolution. This results in high costs for the company – and leads to a lack of confidence from FDA inspectors.

**2. CAPA Silos:** One of the biggest challenge Life Sciences companies find themselves caught with is a silo'd CAPA system (or multiple CAPA systems) in which the data in the CAPA system(s) cannot be effectively shared across the company or cross-referenced with other data. This makes it hard for companies to link related problems – and even harder to generate metrics and perform trend analysis on elements like products, problem types, root causes, costs, and more. These companies need to break down their CAPA silos to achieve a single, managed, integrated and complete view of the process - and enable a common way for them to do trending and put preventive action in place across the company.

**3. Complex Processes:** The first step of effective CAPA systems is to create and document the process. However, companies often make the mistake of trying to build every potential exception condition or possible incident into the CAPA system – which makes it too complex for people to understand and follow. Complex systems lead to slow resolution and aging CAPAs because people are unsure of the next steps. Instead, CAPA systems and processes need to be simple, yet comprehensive – and they need to include a process for escalations and exceptions that provides guidelines but doesn't necessarily dictate specific steps that may not be appropriate in every case.

**4. Lack of Documentation at Every Step of the CAPA Process:** When people are in a hurry to resolve an issue before it escalates, they naturally tend to focus on taking the action rather than documenting the reasoning behind the action. Part of an effective CAPA process should be full documentation at every step; your people don't need to write a novel before every action, but they do need to record what they are doing and why. Be careful not to let documentation lag the CAPA process because you can lose valuable information; however, employees need to answer the "who, what, when, where, how and why" questions for every step.

**5. Confusion between a Corrective Action and a Preventive Action:** A Corrective Action generates a solution to issues that have already occurred. A Preventive Action looks for solutions to problems that might occur. Don't fall into the trap of thinking that every problem and every process change needs to have a CAPA to justify it. That will bog down your system and critical actions may not get resolved as quickly because of it. Instead, ensure that people understand the distinctions between corrective actions and preventive actions, and that they reserve them for actual or potential incidents.

**6. Imprecise Language:** If people can't state the problem succinctly, the team will be unlikely to resolve the issue or even to measure results of their actions. People often try to jump ahead to possible solutions when defining the CAPA or they get emotional in their description. Neither choice is conducive to rapid resolution, so don't tolerate sloppy problem definitions. Make sure team members are trained in writing simple,
concise problem statements that highlight the difference between the current state and the future state. When people know the starting and ending points, plotting the route and measuring progress are much simpler. It also makes it simpler to determine relative priorities and risk associated with each incident of non-conformance.

**7. Jumping to Solutions:** This is often a direct result of imprecise problem statements. When people jump to conclusions about the solution to the problem before fully defining and investigating the issue, they may make "corrections" that don't correct anything. Instead, companies need to insist that every problem statement answers the "who, what, when, where, how and why," as well as the frequency and severity of the effects of the problem. Don't let panic about compliance cause people to rush through the steps, because you may end up addressing the symptoms rather than the causes of the problem.

**8. Insufficient Process Training:** After CAPA processes have been sufficiently defined, companies need to make sure to train employees in the proper steps and procedures. Many companies train people to follow the right steps, but they don't provide training in precisely defining the problem or how to determine the severity of an issue. As a result, the CAPA system bogs down with aging or unnecessary corrective actions and preventive actions that remain open due to either insufficient resources or sheer bafflement about the actual issue. CAPA systems and processes require in-depth employee training, and frequent re-training, in order to remain effective and compliant.

**9. Inconsistency in Applying the Process:** Many companies today have multiple sites, often in multiple countries or regions. This requires extra diligence to ensure that all sites react the same way and apply procedures the same way. One of the worst situations you can have is having each site following different processes or treating equivalent incidents differently. Companies can prevent this problem with extra training (as mentioned above), and by implementing a centralized CAPA system that connects departments and locations. Don't believe any statements that "we're different" unless you investigate and agree that one site should be an exception. If there is a reason for a different process at a facility, document it and make it part of the corporate process.

It requires vigilance to ensure regulatory compliance, but effective CAPA systems and processes should be an important part of your compliance arsenal. When used correctly, your CAPA systems will help you resolve nonconformances quickly and minimize risk.

## 8. CAPA Essentials for Passing Your Audit

Ensuring that your CAPA system and processes meet the FDA requirements can be complex if you rely on guesswork or if you try to memorize all the regulations relating to CAPA that the FDA publishes. Here is a simple 10 step checklist to help ensure that you have covered all the essentials.

**1. Verify that you have documented all procedures.** To prevent misunderstandings or inconsistencies, documentation should include management supported definitions for terms such as:

- Nonconforming product
- Quality audit
- Correction
- Preventive
- Timely

**2. Identify sources of quality data and ensure that you analyze them regularly**
The CAPA system must document all acceptable sources of quality information and make provision for regular analysis of the data. Data sources should include, at a minimum, acceptance information, complaints, service call activities, returned goods information and all quality and non-conformance records. The procedure must define the frequency of analysis, and the team must keep records showing that they performed the required activities.

**3. Ensure that your data sources and analytics would show unfavorable trends if they occur**
Analyzing historical data to ensure that the data would show the need for corrective and preventive action satisfies this requirement, as does the use of statistical process control to capture trends in supplier and process quality.

**4. Verify that the data feed to the CAPA system is timely, accurate and complete**
Verify by sampling records from the various data sources to ensure that the entry of information into the CAPA system occurs as required, and that the data entry occurs within the company definition of "timely."

**5. Validate the statistical methods you use to analyze data and that the results are consistent across all data sources**
It is important that the data sources provide a complete view of the issue. You cannot apply appropriate action until you have identified the full extent of the problem.

**6. Verify that the team follows up and that they apply the right degree of rigor to address the severity of the problem**
Investigation must be comprehensive enough to identify the root cause of any problems, and it must ensure that the company does not continue to distribute nonconforming product.

**7. Confirm that recommended actions have been taken**
Verify that your company has put the recommended actions in place and that they have updated all procedures and the process documentation.

**8. Verify that corrective or preventive actions were effective in resolving the original problem**
This should also include validating that the changes did not adversely affect product quality. In addition, verify the implementation of appropriate design control procedures and calibration records.

**9. Check that the company has implemented and documented all corrective and preventive actions**
Verify that recommended corrective and preventive actions are in place by reviewing equipment and procedures affected.

**10. Disseminate corrective and preventive action information to all involved parties, including management**
Management may be held personally liable for unapplied or improperly applied corrective actions, so it is imperative that they receive frequent, timely reports on the status of all corrective actions. Distribution of quality reports should include production supervisors, quality inspectors, engineering and anyone else who must be aware of the necessary process changes.

## 9. Frequently Asked Questions

Every life sciences company needs an effective corrective and preventive action (CAPA) system in order to meet FDA compliance requirements. It's easy to understand the need for a system, but it's not as simple understanding exactly what the FDA requires from your CAPA system.
FAQs:

**1. Does the FDA require that I use software to support CAPA?**
No. The FDA doesn't mandate that you use software. They do require that your CAPA system, whether manual or software based, be defined and documented. You must also demonstrate that the sources of data that you use are capable of identifying quality trends, that you analyze the data regularly, that your information is complete, accurate and timely and that you have a system in place for regular follow up.

**2. What statistical methods does the FDA mandate we use to identify quality issues?**
The FDA does not mandate the use of any specific statistical algorithm. The only requirement is that you prove that whatever method you have chosen to use is capable of identifying quality issues from the data you monitor.

**3. Is it acceptable to use only after sale support data in my CAPA?**
No. The FDA requires that you use several streams of data so that you capture the true quality trends. Support records are one valid source, but you should supplement that information with complaints and acceptance data as well as in-house testing, to ensure that you have accurately addressed all possible sources.

**4. Isn't CAPA purely a quality assurance team concern?**
No. FDA guideline CFR 820.20 calls out management's responsibility as it relates to CAPA. Management responsibilities include:

- Establishment of a QA policy and objectives and for ensuring commitment to them.
- Establishment of an appropriate organization structure to support the stated quality objectives.
- Provide everyone who can affect quality with both the responsibility and the authority necessary to ensure that quality objectives are met.
- Ensure that adequate resources are available to support quality objectives.
- Appointing a member of management to have authority over and responsibility for quality

**5. Must the person responsible for the quality system be a QA manager with no other responsibilities?**
No, if the person has adequate resources and authority, the management designee responsible for the quality system can have other responsibilities as well.

**6. How often must I do quality audits?**
There is no required frequency for quality audits, if the planned frequency is documented and adhered to. You may be required to show documentation regarding the planned audit frequency and the dates when audits occurred. In practice, most companies do quality audits at least annually.

**7. How many people am I required to assign to the CAPA system?**
There isn't a specific or minimum number of people required. The only requirement is that there be enough to ensure that the system performs as documented, and that the people assigned have adequate training, experience, skills and education to ensure that all the requirements are performed.

**8. What must I do if I identify non-conforming product?**
CFR 820.90 for Nonconforming Product mandates that the company have procedures in place to control non-conforming product. Control includes:

- Identification of the affected product.
- Documentation of the non-conformance.
- Evaluation of potential remedies.
- Segregation of non-conforming product.
- Disposition of nonconforming product.
- Determination of the necessity for an investigation.
- A process for notifying anyone responsible for the nonconformance.
- Documentation of the product evaluation and investigation

**9. How can I prove that my corrective or preventive action resolved the issue?**
The company must be able to demonstrate that the corrective action resolved the issue through test data and appropriate analysis. They must also be able to show that they adhere to the principles of design control and production and process control as defined in CFR 820.30 and CFR 820.70(b).

**10. How long must I store records?**
The FDA mandates that all records must be stored for at least two years beyond the expected life of the product. Records must be legible and readily
available to FDA inspectors. You must have a backup for all electronic records. Since the volume of records can easily grow quite large, manual management of paper records can be cumbersome, costly and error prone. As a result, most companies turn to automated CAPA systems to simplify storage and retrieval. While almost every life sciences organization understands the benefits of effective CAPA systems, it is hard to find ways to meet market demands while maintaining compliance with CAPA requirements.

## 10. Conclusion

Using a systematic approach to correcting and preventing issues, measuring the outcome and continuously monitoring the system can ensure that a company is compliant, effective and efficient. And, having a well-thought-out CAPA Incident Management system can result in successful audits, fewer investigations, less product loss, better customer satisfaction, and an increase in overall operational efficiencies. One factor of effective CAPA programs is an investment into people. Companies need to properly train internal investigators to master the CAPA process quickly and effectively. Once a team is trained and in place, they anchor the logic behind all investigations and problem solving.

Equally critical, though, is selecting a software solution that enables consistent, thorough, documented and effective CAPA investigations. The overall goal is to utilize systems that streamline and reinforce a repeatable, standardized, and end-to-end process that can improve quality and ensure compliance.

ITo resolve quality issues, every Life Sciences company must be able to investigate, identify root causes, and implement effective corrective and preventive actions in a timely manner. And they must be able to quickly and convincingly demonstrate this ability to the FDA and other supply chain partners.

Life Sciences organizations have to account for a lot of moving parts when trying to ensure they have a future-proof infrastructure. Maintaining and simplifying regulatory compliance, enhancing operations both digitally and by weeding out inefficiencies, and taking the steps necessary for growth – these are all steps which require a highly coordinated approach.

Thanks to Merit's industry leadership, Life Sciences strategic partnerships, and delivery methodology, we feel confident we are the right partner to support you on your path toward success.

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