The 5 Building Blocks of a CAPA Solution

Managing Corrective Actions/Preventive Actions

Sparta Systems

Introduction

In today's increasingly regulated business environment, the need to investigate and track quality related events remains a crucial factor in the day-to-day manufacturing operations of organizations. With the multitude of regulations being imposed by government bodies from FDA Food Safety Modernization Act (FSMA) and ISO 9001 to Hazard Analysis & Critical Control Points (HACCP), the needs of manufacturing organizations to track quality issues and actions is becoming a critical job – not to mention an increasingly difficult one.

To date, the most widely-used and effective process for ensuring safety and quality management is a closed-loop corrective action and preventive action system (CAPA).

Successful CAPA management ensures that any quality control issues that appear unexpectedly in the manufacturing process can be addressed quickly and efficiently, with new or revised processes implemented to ensure that these issues are minimized and corrected elsewhere where the same conditions may exist. This allows organizations to anticipate any future issues with regulatory bodies that may arise, and saves enormous time and resources that can impact the ability to generate revenue from the clean manufacturing process.

The concept of CAPA management will likely be nothing new to the average quality assurance professional. This is a notion that has existed for years in various permutations across industries and is one that is generally viewed as an efficient way for dealing with any quality issues that arise in the manufacturing process.

But the truth of the matter is that many organizations have yet to adopt an effective closed-loop CAPA management process, and even fewer have implemented a system for addressing the quality of the processes in place to track and report CAPA issues.

Many, in fact, are still using rudimentary tools like spreadsheets, databases and paper-based systems to track their CAPA issues and efforts. So why are organizations so reticent to adopt effective CAPA management, and why are those that have so far behind in the methods they're using?

This e-book will explore the needs and effectiveness of correct CAPA control, how to implement a successful system.

Tackling Quality Issues & Incidents

While the needs of different quality professionals and departments may vary across industries – be it personal care, semiconductor, food processing, or other manufacturing – the goal of most of these industries is often the same: to manufacture and ship product as efficiently as possible and to do so with minimal detrimental impact on the manufacturing environment.

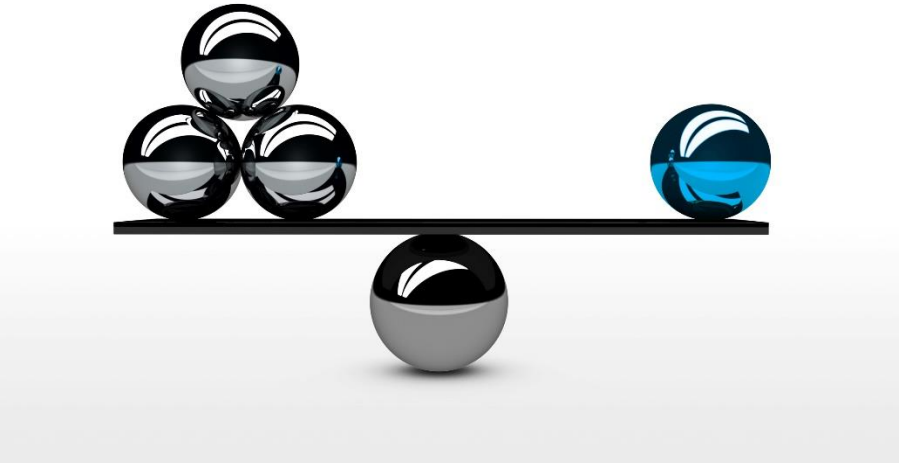
This means that whatever the industry, professionals must always maintain a manufacturing environment that is free of any potentially damaging pollutant, contaminant or impurity that may result in a flawed or even harmful product.

Quality issues and incidents can become even more of a challenge when government regulations are introduced.

With new recalls making headlines almost daily and companies being made and broken based on their ability to maintain a compliant environment, the need for effective quality management processes in the manufacturing environment takes on an entirely new importance.

A company with a highly developed culture of quality spends, on average, **$350 million less** annually fixing mistakes than a company with a poorly developed one.[1]

1 Harvard Business Review, "Creating a Culture of Quality", April 2014



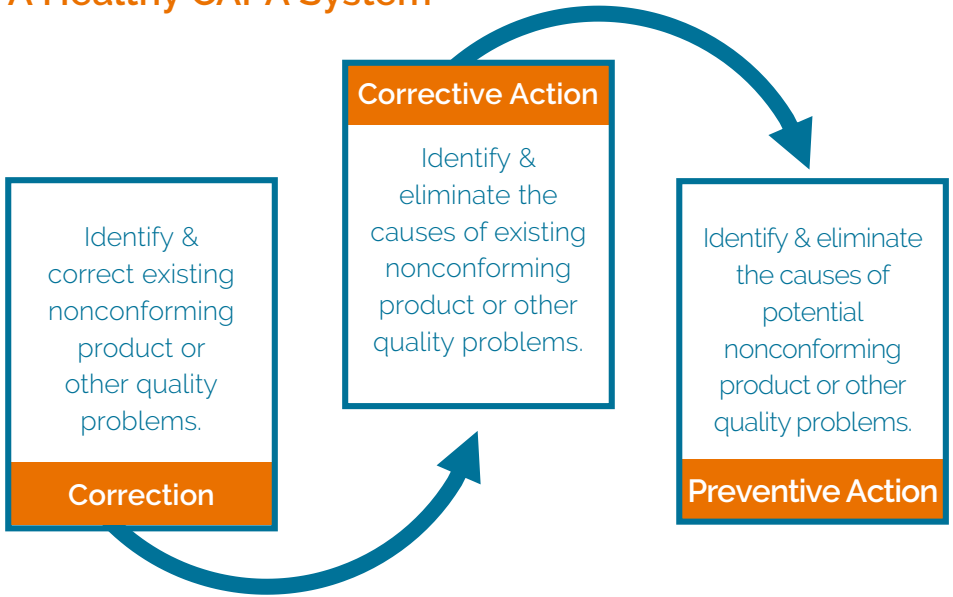
The importance of minimizing risk and ensuring compliance with regulatory issues while upholding an efficient and profitable operation is a balance companies continue to seek, and many are able to do so.

But despite organizations' best efforts to implement processes and systems for maintaining control over the manufacturing environment, it's frankly impossible to ensure that incidents never happen. When these incidents do inevitably arise, it's vital that companies be prepared to deal with them as quickly as possible.

This is where CAPA management comes into play and emerges as an essential process. In theory, CAPA management should be the hub of an organization's quality management initiatives. It should allow them to log events and problems, investigate them to determine root cause, propose corrective and preventive action plans to ensure that issues are anticipated and become a non-issue for the future, and measuring the effectiveness to ensure the root cause has been eliminated.

This kind of system usually involves an approach that includes a holistic quality management solution for tracking all of the aforementioned issues and allowing for efficient handling of them.

A Healthy CAPA System



Five CAPA Building Blocks

When implementing a closed-loop CAPA management system, the most important thing to remember is that these systems have been proven to effectively reduce organizations' quality issues. Proper CAPA management can aid in reducing costs that would feasibly be spent on supporting quality initiatives within other organizational departments.

Step 1: Create a centralized CAPA system

The first step is to make certain that your CAPA system is centralized and controlled, thereby consolidating operations and eliminating overlap between departments.

Whether the location for this centralized system is an office in the facility or the organization's headquarters, conducting CAPA management from the centralized system will avoid confusion when incidents do occur and serve to minimize the cacophony of voices and e-mails sent between departments all claiming that they know what went wrong and how to correct it. It also fosters knowledge sharing across multiple sites and helps prevent issues from recurring elsewhere in the organization.

The Benefits of an Automated CAPA System

- Manage all quality processes – including CAPA – in a centralized database for improved visibility & efficiency
- Initiate CAPA automatically when an incident, deviation or other quality event occurs, ensuring consistency & reliability
- Provide seamless traceability to related quality processes, such as change control and training
- Create an automated workflow, reducing investigation cycle time while improving root cause analysis
- Capture quality process data to improve quality trends and management reports

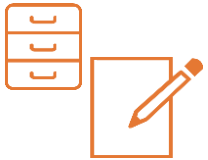
Step 2: Implement electronic incident tracking

The next step is to generate an effective system for tracking all incidents and events that occur. This should be electronic, and should rely again on a centralized system that may be accessed by as many valid users as possible, to ensure visibility and provide one source of truth.

Often companies will use databases or spreadsheets to serve as their tracking system, while some are still tracking issues manually via paper document-based solutions. In a day and age that has become so sophisticated with new electronic quality management solutions readily available from a number of different vendors, this should really no longer be an option – centralized quality management systems for tracking of incidents should be the de facto solution for any organization regardless of size.

Whatever the system in place, implementation of an automated quality management system will allow organizations to log and manage all issues and incidents that have occurred, which will ensure that they reach the desired conclusion when it comes time to correct issues, determine the causes and take the necessary steps to prevent future occurrences.

Manual vs. Automated Systems



Manual Entries — Hand-written entries, edits, & signatures take time.

Poor Visibility — Multiple systems & sources makes tracking CAPA status difficult.

Delayed Process — Time lags due to reviews/approvals, one person at a time.

Standard Process — Structured forms, fields & workflows, with e-signature capabilities.

Transparency — One centralized process across all functional groups.

Optimized Process — Concurrent access, review & approval of information.

Step 3: Discover, define and execute corrective action

The next step is to effectively evaluate quality events or incidents, and ensure the needed corrective actions are carried out. These incidents can be related to factors such as equipment or process failures, or due to customer complaints. While simple corrections of minor problems do not necessarily require a full CAPA process, they should be recorded; if these problems constantly recur, then a CAPA may be warranted.

For this process to be managed effectively, incidents need to be reported quickly to minimize the response time. Once reported, the CAPA process follows a regimented workflow that typically begins with a risk analysis to determine the impact of the incident. Then one or many investigations are initiated regarding the incident by all business units that may have caused or been affected by the event. Once the investigations are complete, a root cause analysis determines the origin(s) of the incident.

Leveraging an enterprise quality management solution to manage this process helps ensure that this workflow is followed consistently and efficiently, ultimately resulting in faster responses.

What this also entails is that escalation procedures are applied so that the right people are notified of incidents and these occurrences don't become recurring problems.

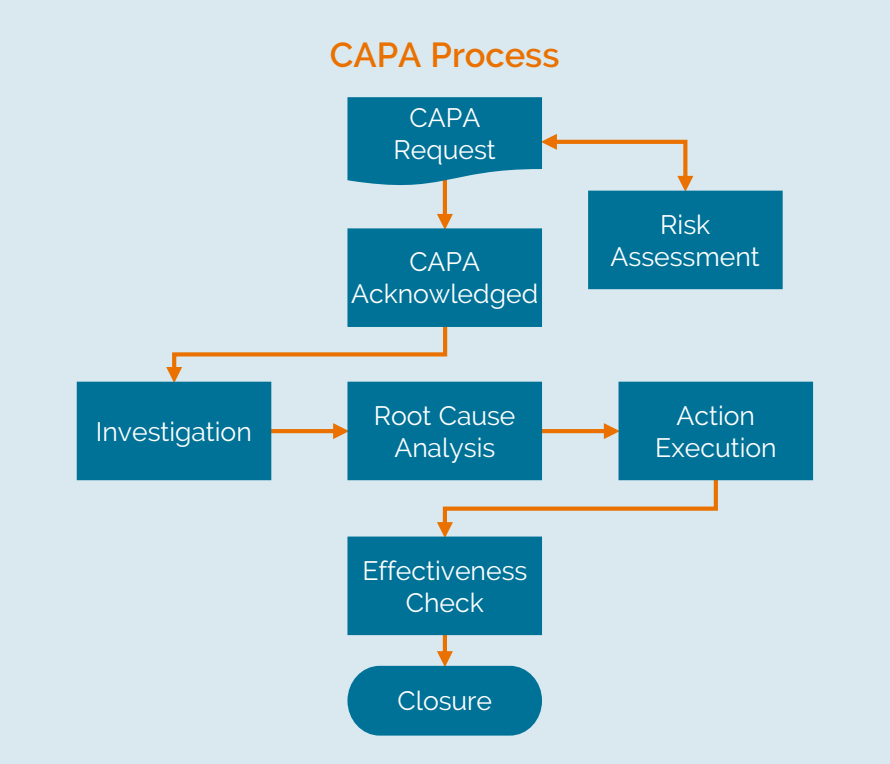
It is absolutely essential that organizations take the time to map out a CAPA workflow and an effective escalation procedure plan that tracks and manages individual actions, while it measures the effectiveness to ensure that the expected improvements actually happened. As soon as a corrective action has been efficiently enacted and the problem dealt with, then the preventive action can begin.

Step 4: Using CAPA for continuous improvement

In a CAPA process, the corrective action is the activity or activities performed to correct the quality incident that happened and keep it from recurring.

A preventive action is put in place as a continuous improvement to prevent the same or similar problem from happening at any location within the organization that may have the same or similar processes in place. This allows organizations to reduce the amount of time and resources “fighting fires”, and focus on proactively making products better.

As part of the preventive action process, accountability needs to be maintained, assigning responsible parties to investigate and review potential quality issues before they can occur.



Active participation by these parties (e.g. improvement teams or customer satisfaction teams) is essential to ensure feedback and investigation results are captured in a timely manner – otherwise, it's possible that the correct solution will never be reached.

Quality Management System (QMS) software can automate this process and alert executives of deadlines and ongoing investigations, providing increased visibility to the C-level and ensuring accountability across departments.

Over time, the goal of leading consumer product companies should be to get to the point where preventive actions outnumber corrective actions to ensure that quality issues are minimized.

Step 5: Measure and Report

The final piece of the closed-loop CAPA process for quality control is tracking of effectiveness checks, or the measure of how well the CAPA is working postimplementation.

When these checks are streamlined and tracked effectively, the correct personnel are assigned and are committed to testing the success of the CAPA.

This will essentially “close the loop” on the CAPA process and provide executives with the tools they need to ensure that compliance with regulatory bodies is maintained, by anticipating and preventing future trouble from these bodies.

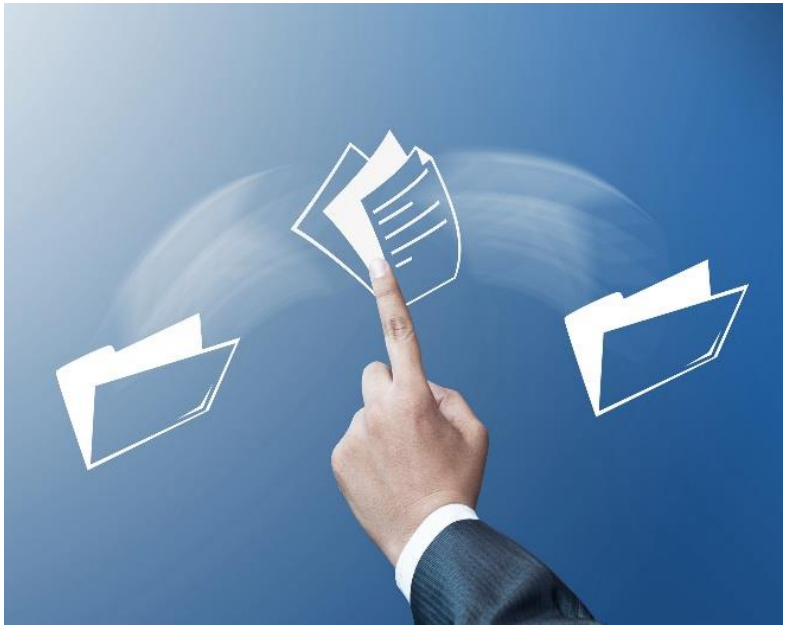
CAPA: It's a Journey

With these building blocks in place, organizations can detect and remediate quality issues early in the manufacturing process, and eventually allow the organization to spend more time on continuous improvement. This in turn allows company executives to trust that quality is actually instilled within their corporate culture, and because of this, they are delivering safe and effective products to market. This approach not only improves total quality, but also creates efficiencies that save companies measurable operating expenses.

A consolidated CAPA management system has been proven time and again as the most efficient system for preventing future occurrences, with minimal drain on the time and resources that companies generally view as impediments to profitability.

Successfully implementing a CAPA management system as part of an overall quality management initiative can ultimately reduce costs and resources, and provide organizations with the tools they need to anticipate future emergencies and maintain business growth for years to come.

Resources



Implementing a CAPA system as part of the broader enterprise quality management solution improves the tracking and trending of key quality drivers and resulting actions.

To learn more about strategies to implement a successful QMS to address quality processes and incidents, please visit www.spartasystems.com or check out the following resources:

eBook: 3 Steps to Quality in the Cloud

eBook: 4 Best Practices to Improve Quality in the Supply Chain

Video: TrackWise Digital Quality Suite

Founded in 1994, Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the solutions, analytics, and expertise that speed up quality and compliance. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta.

1.888.261.5948 | 1.609.807.5100 | sales@spartasystems.com | www.spartasystems.com

Sparta Systems