

Why CAPA Still Matters

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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 21 CFR 25 to 40 CFR and ISO14001, the needs of businesses 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 and preventative 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 processes implemented that can make certain that these issues never appear again. 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 in this industry 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? Most importantly, what will it take for companies to realize that CAPA management doesn't need to be as much of a drain on time and resources as they think?

This article will explore the needs and effectiveness of correct CAPA control, how to implement a successful system and examine just why CAPA still matters.

The Issue at Hand

While the needs of different quality professionals and departments may vary across industries – be it biopharmaceuticals, medical device manufacturing or food processing – the goal of most of these departments is often the same: to manufacture and ship product as efficiently as possible and to do so with as little detrimental effect on the manufacturing environment as can be achieved. 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 (in the case of food and pharmaceutical) product.

This becomes even more of a challenge when government regulations are introduced. With new lawsuits 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. 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 companies' 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 Corrective and Preventative Action 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, as it should allow them to log events and problems, investigate them to determine root cause, propose corrective and preventative action plans to ensure that issues are anticipated and become a non-issue for the future, measuring

effectiveness to ensure the root cause has been eliminated. This kind of system usually involves an approach that includes a business intelligence system for tracking all of the aforementioned issues and allowing for efficient handling of them.

So why do some organizations still use inefficient Corrective Action systems?

The irony of companies' failure to implement the proper CAPA processes is that that when CAPA management works correctly as originally intended, it can actually save the time and resources that they are so reticent to employ in implementation. Ideally, a CAPA system that functions as intended should lower costs by consolidating redundant systems, enhancing collaboration between departments and fueling cost-savings in process implementation. Such a system will eliminate costly repeat problems by improving the investigation and root cause of incidents quickly, and will eliminate the potential of lost information by electronically and securely managing all information needed to comply with industry regulations.

This is the promise that many companies have thus far failed to realize. The next step is to examine how to correctly implement a CAPA system that will achieve these results.

Taking Action with CAPA

When implementing a closed-loop CAPA management system, the most important thing to remember is that it is not a magic pill for curing all of companies' regulatory woes. At best, proper CAPA management can aid in reducing costs that would feasibly be spent on aiding in quality initiatives within other organizational departments. But as previously mentioned, CAPA can go a long way to ensuring that actions are taken to solidify the effectiveness of future quality endeavors.

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 company's corporate headquarters, conducting CAPA management from the centralized office 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.

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 as few as possible within the organization are accessing to eliminate confusion between departments. 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.

Once the foundation has been laid for CAPA management via centralized, electronic incident tracking, the company is now ready to effectively deal with incidents and the real work to correcting unforeseen problems can begin. This arrives in the form of corrective action, which translates into the steps that need to be taken at the time of incident occurrence. For this to happen, companies need to be able to close deviations faster and more efficiently than previous processes have allowed, and incidents need to be reported with minimal hesitation so that response time is minimized.

Again, an electronic quality management system is the only way to ensure efficient root cause analysis and incident reporting, 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 more pronounced than they need to be. It is absolutely essential that organizations take the time to map out an effective escalation procedure plan that incorporates quality management that tracks and manages individual actions, while measures the effectiveness to ensure the root cause has been eliminated.

As soon as a corrective action has been efficiently enacted and the problem dealt with, then the preventative action can begin. The most important components of preventative action are investigation and root-cause analysis, both which can once again be accomplished through quality management. Accountability needs to be maintained via assigning responsible parties to investigate the catalyst for the quality control issue, and these parties need to be kept on a strict timeline for concluding what went wrong – otherwise, it's possible that the correct solution will never be reached.

A quality management system can automate this process and alert executives of deadlines and ongoing investigations, providing increased visibility to the C-level and ensuring accountability across departments. Additionally, quality management can serve as an effective way of tracking and determining the progress of root-cause analysis so that the timeline is maintained and conclusions are reached efficiently and correctly.

The final piece of the closed-loop CAPA process for quality control is tracking of effectiveness checks, or the measure of how well the preventative solution is working post-implementation. When these checks are streamlined and tracked effectively, the correct personnel are assigned and are committed to testing the success of the preventative action and correctly identify how well the solution is working. 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, anticipating and preventing future trouble from these bodies.

Not Perfect, But Good Enough

The simple fact is that even when correct CAPA management has been mandated and instituted within an organization, it still won't cure all of the company's compliance ills, or provide complete protection against future incidents. It's just the nature of the beast.

But of the systems available to effectively deal with such quality emergencies consolidated, CAPA management 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.