Compliant. Connected. Complete. ™

master™ CONTROL

White Paper:

Does Your CAPA System Need a CAPA: Automating Corrective and Preventive Actions in FDA Environments

Conceptually, performing corrective and preventive actions (CAPA) sounds like a very good idea. It makes sense to want to improve your business processes – improved quality improves your bottom line by increasing customer satisfaction and reducing scrap, rework, recalls, and warranty claims.

Implementing an effective CAPA system, however, can be a challenge. Most employees were not hired to do corrective actions. Many of them may view it as a task that takes away from their real work and that it is the job of the quality department. This perception results in a lack of buy-in and accountability from the very employees that are key pieces to the CAPA puzzle.

Additional challenges include:

- Deadlines for closing CAPA are routinely missed
- Issues that were addressed with previous corrective actions seem to continually reappear
- Quality data is spread out in many different areas or repositories
- Forms are not filled out correctly
- The process is not followed consistently
- Lack of management review and/or support
- Failure to verify effectiveness

Why CAPA?

Given the challenges of maintaining an effective CAPA process, an organization may question whether the investment of time and money is worth it. There are numerous reasons to implement a CAPA program, two of the most obvious are:

- Regulatory Requirement

For companies pursuing ISO certification, ISO 9001:2000 Clause 8.5.2 states, in part, ”the organization shall take action to eliminate the cause of nonconformities in order to prevent reoccurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.” Similarly, clause 8.5.3 outlines the need for preventive actions.

CAPA requirements for medical device companies regulated by the FDA are stipulated in 21 CFR Part 820.100, which states “each manufacturer shall establish and maintain procedures for implementing corrective and preventive action.” Medical device companies have the added incentive in that under quality system inspection technique (QSIT), an FDA inspection will always include an inspection of a company’s CAPA system. Similarly, CAPA requirements for pharmaceutical companies are outlined in 21 CFR Part 211.

- Improve Product Quality

Even more important than being a regulatory requirement, an effective CAPA process should have a direct impact on improving product quality. An effective corrective action process takes into account all the potential sources of a quality issue and provides the feedback mechanism to product processes that prevent the particular issue from reoccurring.

An effective preventive action process will minimize the number of quality deviations from occurring in the first place. Taken together these two processes should reduce product returns, recalls, scrap, and warranty claims.

CAPA Solutions
The procedures and tools used in the CAPA process are the primary factors that will determine the success or failure of the system. Many companies follow an evolutionary path to develop the correct set of procedures and tools required to maintain an effective corrective and preventive action system.

Initially, companies will create a paper-based system primarily due to the low start-up cost and flexibility a paper-based system provides. Next, they move to a paper/electronic hybrid system in an attempt to improve upon their paper-only system. The next step is to either create a custom application that is completely electronic or purchase a third-party software application.

The Paper Approach
Many companies have implemented and continue to use a corrective action process that is completely paper-based. Paper-based systems have two primary advantages over most electronic systems:

- The initial implementation cost is low
- They are very flexible and can be customized to meet almost any CAPA process

The initial low cost of a paper-based system is quickly outweighed by the on-going costs required to maintain an effective system. Most of these costs are hidden. Unless the necessary analysis is performed to quantify them, the true cost is unknown. A few of these costs and issues are:

- Extensive follow-up is required to determine status and ensure the CAPA is progressing
- The process is difficult to execute consistently due to a lack of control
- Incomplete forms and/or mistakes in completing the forms
- Reporting and analysis is very labor intensive
- Difficult to determine the bottle-necks in the process
- Lack of buy-in and accountability from employees due to lack of management visibility

Eventually, enough problems occur that an enterprising employee creates (either independently or directed by management) an electronic tracking mechanism using a spreadsheet or simple database.

The Hybrid Approach
The paper/electronic hybrid solution combines the flexibility of paper-based forms with some electronic tracking and reporting capabilities. The electronic capabilities of a hybrid solution usually range from a simple spreadsheet that tracks some subset of the data on the form to a database application that enables electronic entry of CAPA data.

Like a paper system, a hybrid solution usually has relatively low start-up costs. However, it only helps to resolve a few of the issues inherent with paper-based systems and so the majority of hidden costs still remain.

The hybrid solution reduces the labor required to report and analyze corrective action data. Depending on how sophisticated the system, it may also help reduce issues surrounding incomplete or inaccurate forms.

However, this type of solution rarely resolves the extensive follow-up challenges and buy-in and accountability problems. This is mainly due to the system's lack of ability to electronically distribute and track tasks.

The Electronic Solution
The next step companies will take is to either create a custom application or more commonly, purchase a package from a software vendor. There are a variety of packaged software products that offer varying capabilities.

A packaged software product can enable a company to overcome many of the challenges of maintaining an effective CAPA system. Some of the key features that should be available are:

- **Distributed task assignment** – a system that enables tasks associated with a CAPA to be individually assigned to employees to facilitate buy-in and accountability. Management also has greater visibility of where the bottlenecks are in the process because they have access to real-time data.

- **Web-based** – the software package should be web-based so that employees from all site locations can access and use the same data repository. Departmental CAPA solutions keep quality data in a silo that can prevent systemic problems from being identified.

- **Built-in Reporting and Analytics** – the system should have robust reporting and analytic capabilities. Each data field tracked by the system should be able to be reported on. On-line charting should be available to enable users to easily trend quality data.

- **Signature Manifestations** – signature manifestations should be automatically appended to each document including the printed name, date, time, and meaning of the electronic signature. ISO-certified organizations promote good business practices by displaying the record approval status at a glance when users view a record.

- **Audit Trail** – the system should have a secure, time-stamped audit trail of all changes made to any record and should be accessible to the appropriate users and departments. This information should be automatically captured and secured.

- **Email Notifications** – real-time notifications should be provided to alert users of specific tasks they need to complete. In addition, unlimited escalation workflow rules should be an option. By ensuring the appropriate users are notified of pending tasks and that tasks escalate when necessary should help reduce turn around times for corrective action processes.

- **Security** – access should be allowed to be individually tailored for each user. Administration tools should exist to easily group users together with the same security rights. Automatic time-out options, minimum password settings, intruder login detection, and SSL (secure socket layer – provides secure internet communication) should all be standard features.

In general, high-quality packaged software solutions do a good job of overcoming many of the challenges of maintaining an effective CAPA system. However, most of these packages have drawbacks that prevent an organization from gaining all the benefits of an electronic system. These are:

- **Lack of flexibility** – most packaged solutions require the company to conform to the software's forms and processes instead of allowing the company the flexibility of recreating their existing

paper-based forms they accustomed to using. Additionally, many CAPA software packages provide little to no capability to extend the software to effectively control other sources of quality incidents, such as nonconforming materials, rework documentation, returned goods authorizations, etc.

- **Disconnected Solution** – most electronic solutions do not tie quality processes together. Ideally, a company could "close-the-loop" and have a completely documented flow from initial non-conformance to corrective action, to document changes, to training, and finally to verification.

The Connected Solution

MasterControl CAPA is an example of a "connected" CAPA solution that also has a flexible what you see is what you get (WYSIWYG) forms capability. MasterControl CAPA is part of an integrated suite of products that enables companies to control their quality data through its entire lifecycle: from initial non-conformance to corrective action, documentation changes, training, and verification.

A connected CAPA solution provides the linkages between processes to help ensure that all the varied activities required to close out a CAPA are performed in a timely manner. In addition, this type of solution allows the process to be completely documented online and can be made available for employees as well as auditors.

Figure 1 - provides an example of how quality data flows through the MasterControl quality management suite.

MasterControl CAPA is a very flexible solution. The software comes with forms and processes that can be used out of the box or easily customized to match an existing process. MasterControl CAPA is built using DCS' powerful MasterControl Forms platform. This platform enables companies to create feature-rich forms using industry-standard PDF forms technology.

The system allows users to take their existing forms and processes and easily configure them to be used within the system as an integrated suite of processes. Form processes can be linked so that all of an organization's quality data can be tied together.

CONCLUSION

Implementing an effective corrective and preventive action system enables organizations to improve product quality while at the same time meeting regulatory requirements. An important element of an effective CAPA system is the tool used to control the process. Having a tool that distributes the tasks to the appropriate people not only streamlines the process, but also promotes greater buy-in and accountability on the part of employees. To gain the full advantages of an electronic system, an organization should look for a solution that can connect all of their quality data and is flexible enough to be configured to match a company's forms and processes.

About MasterControl Inc.
MasterControl Inc. has been at the forefront of providing quality management software solutions since 1993. Hundreds of companies worldwide use MasterControl to help ensure compliance with FDA regulations such as 21 CFR Parts 11, 210-211, 820, 606; ISO quality standards such as ISO 9000, ISO 13485, ISO 14000; and Sarbanes-Oxley Act requirements. In addition to providing off-the-shelf products, MasterControl also offers comprehensive technical and customer support, including product training, implementation, and validation services.

For additional industry white papers about automating quality and regulatory processes, visit www.mastercontrol.com, or call, 800-825-9117.

MasterControl Inc.
6322 S. 3000 E. Suite 110
Salt Lake City, UT 84121

P. 800.825.9117
F. 801.942.7088
www.mastercontrol.com