Integrated Quality Systems

Simplify CAPA Management, Mitigate Risk and Maintain a High Level of Compliance

WHITE PAPER
Cincom In-depth Analysis and Review
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Summary

In today’s volatile climate of increased regulatory oversight, media scrutiny and widespread recalls, even the hint of a product’s failure or a procedural error is enough to damage a company’s reputation and negatively impact its bottom line.

Manufacturing and service companies are especially vulnerable to these risks, given the nature of their products and the intense regulatory burdens under which they operate. Failure to meet government and industry regulations can result in punitive events—namely audits, fines, warnings and lawsuits—that adversely affect a company’s productivity and ability to conduct business.

Due to the nature and scope of manufacturing enterprises, their quality systems must encompass the majority of their company’s processes, making quality systems organization as difficult as it is paramount. Most firms have pieced together quality management systems using several disconnected programs, overlapping databases and even manual pen-and-paper processes. CAPA (Corrective Action and Prevention Action) oversight is typically not prioritized across the entire enterprise and built into Standard Operating Procedures (SOPs). The end result of these piecemeal systems is inefficiency, loss of productivity and repeated citations for the same nonconformance.

To meet mounting regulatory pressure and media scrutiny, to preserve the reputation and good name of their organization and to avoid costly delays, bad publicity and repeat errors that could lead to recalls or lawsuits, many companies are incorporating a closed-loop, system-wide CAPA program as part of their overall robust and reliable quality management system.
CAPA—It’s the Key

Corrective action is taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation to prevent recurrence. Undertaken in a timely and thorough manner, corrective action can repair customer satisfaction after a complaint, build additional customer confidence in the responsibility of the industry, curtail negative public commentary about a particular deficiency and reduce financial losses caused by the noncompliance.

Preventive action is taken to eliminate the cause of a potential nonconformity, defect or other undesirable situation in order to prevent an initial occurrence and improve quality trends. This action impacts the bottom line the most since plainly avoiding defects or other noncompliance saves money. In addition, preventive action reduces the potential for liability, warranty claims, fines and negative publicity. This is an area where many organizations that have implemented CAPA-wide systems fail to make progress.

Taken together, corrective and preventive action is the expected response when deficiencies are reported. In fact, companies have been cited for failing to suggest both corrective and preventive actions and for failing to establish adequate quality management controls.

Finally, effective CAPA management is more than just an important regulatory requirement. It is a good business practice that brings many benefits. As previously stated, a strong CAPA program can reduce liability, improve customer satisfaction, prevent major financial losses and strengthen a company’s reputation. In addition, CAPA is an integral part of an Enterprise Compliance and Quality Management (ECQM) strategy. The ability to quickly identify and address deficiencies and zero in on the sources of potential problems and prevent them, drives a company’s continual improvement efforts and helps it achieve operational excellence both in product and process. And that translates to increased performance and greater revenue.

Key CAPA Definitions

- **Nonconformance (NC)**
  Any noncompliance with the requirements of the Quality System.
  NCR = Nonconformance report

- **Correction**
  Repair, rework or adjustment related to the disposition of an existing nonconformity. Corrections are typically one-time fixes.

- **Corrective Action (CA)**
  Action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

- **Preventive Action (PA)**
  Action taken to eliminate the cause of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence and improve quality trends.
Obstacles to Achieving Integrated CAPA Compliance

To achieve the maximum benefits from CAPA compliance discussed above, CAPA must be part of an integrated Enterprise Compliance and Quality Management system that collects data on existing and potential problems, investigates and analyzes the data, digs down to the root cause, addresses the issue, institutes specific procedures to avoid similar problems in the future and documents the entire process. CAPA is most effective when it is part of the culture of a company, pervading every organizational level and department.

In the typical manufacturing organization, there are many obstacles to achieving a truly integrated quality management system. They include:

Disparate systems:
Even if CAPA compliance is included in a company’s SOP, it is difficult to achieve with the systems that most companies have in place. Different programs that don’t interface with each other, homegrown systems that lack universal application and even manual pen-and-paper processes inhibit the flow of information, delaying the resolution of quality issues and clouding the compliance picture.

Lax documentation:
Without centralized control, the documentation chain required by regulatory agencies is often broken. Procedures are not always well documented and required steps are not always completed. And, if companies do not document their own CAPA procedures and fixes, regulatory agencies like the FDA will not know that CAPA requirements have been fulfilled.

Communication barriers between cultures and specialties:
Employees of the same organization don’t always speak the same language, literally. Many complex manufacturers are multinational with different languages spoken among their employee population. In addition, the terms that an engineer would use to describe a quality issue may be different from what a compliance officer or marketing manager would use.

Lack of training:
For as much specialized training as some receive, it is rare for the majority of employees across a company to be trained in compliance issues. As a result, employees don’t always know, understand or embrace their role and responsibility when it comes to quality management.

Disconnect among business units or product lines:
It is common to find that CAPA management is seen as a job for the quality department only, not a concern in which the production, R&D, marketing or other departments should be involved.

Non-collection of trending data or data not readily available to appropriate personnel:
Unless an integrated ECQM system is in place, most departments track and trend their own data on their own systems, making it hard for management to see the whole compliance picture across the company in real time. Without this vision, key personnel cannot predict and prevent possible deficiencies and meet CAPA regulations.

Seeking a quick fix versus seeking to correct the root cause:
Companies tend to address product and material issues without reaching below the surface to identify and address potential process or quality concerns. The result is that they focus on product problems and ignore systemic issues that might lead them to correct a root problem. Getting to the root of the problem is a key CAPA priority.

It is important to remember that CAPA compliance is a large process involving many aspects of an organization. True CAPA conformity, being able to quickly identify and correct problems while putting practices in place to prevent future issues, requires the integration and flow of information freely across a company’s various departments and locations.
Five Steps to a Robust and Reliable CAPA System

When preparing to implement a system-wide, integrated ECQM system with CAPA processes, manufacturers would do well to consider the following factors necessary for a robust and reliable system:

• Planning
• Source Error Tracking
• Trending, Analysis and Risk Management
• Employee Involvement
• Change Management

1. Planning
The foundation of a successful quality management program is adequate planning and organization. Prior to implementing a system-wide CAPA process, many details need to be decided upon.

- What are the rules and variances?
- What are the processes and who are the owners?
- What are the failure modes?
- How are the severity levels defined?
- Who will enter the information?

It’s also critical that the quality system and CAPA processes are scalable, simple, risk-based and easily integrated throughout the organization. Identify key personnel to be involved in the CAPA process and the order in which they are involved. Determine how rules and procedures will be enforced across the board, including how to address rules and procedures on a global level.

2. Source Error Tracking
A solid source error tracking process is essential to CAPA system effectiveness. In addition, an important component to developing best practices and ensuring CAPA compliance is to identify any deficiencies in the value chain. Next, make sure that you document the manner in which they are handled. Data collected throughout the organization should be routed to one central location. This allows for big-picture analysis, the identification of root causes, quick access to streamlined, accurate information and continuous process improvement brought about by speedy responses to worrisome data trends.

3. Trending Analysis and Risk Management
Despite intense regulatory pressures, not every deviation should result in a CAPA process. Detailed trending, analysis and risk management will help companies avoid the “EVERYTHING IS A CAPA” syndrome. Paying close attention to trends revealed in the analysis of compiled data can help determine if the deviation is an anomaly or part of a greater concern that might trigger a CAPA process. In addition, trending can help detect minor problems before they become major issues. One way to think of trending is that it monitors the pulse point of an organization’s overall health.

Risk management should also have a high profile in an effective CAPA system. Incorporate risk management techniques into CAPA processes to categorize and prioritize critical deficiencies. Often a company’s risk management team should be involved in critical CAPA processes, especially in the determination of root causes.

4. Employee Involvement
Unless employees are tuned into CAPA elements and processes, it will be difficult to achieve a high level of CAPA compliance. By creating sustainable policies and practices, and with a proper training program, employees can be a vital component of a successful CAPA system. Employees at all levels should be trained in the details and purpose of CAPA processes, sound investigative methods and detailed documentation techniques so that they may contribute to a truly integrated quality management system.

In addition, a CAPA process is not effective without management oversight to ensure proper tasks, actions and ultimately problem resolution. Managers that understand CAPA procedures and conduct periodic reviews of ongoing CAPA events keep the CAPA process and their companies moving smoothly forward toward full compliance and a healthy bottom line.

5. Change Management
Change is a natural output of the CAPA process; in fact, change is the purpose of the entire CAPA regulation. By definition, CAPA processes result in corrective change and/or preventive change. Managing necessary changes revealed by a CAPA event improves a company’s products and processes and contributes to its continuous improvement initiative. Tying the CAPA process to a firm’s overall change management strategy allows more effective responses to issues as they arise, whether the CAPA end result calls for changes to training, document management, equipment maintenance, inspections or audits.
What to Look for When Integrating Quality Management and CAPA Compliance Processes into One System

When a company is ready to integrate their quality management processes and CAPA compliance into one uniform system across their organization, it should look for a vendor that can offer a comprehensive, logical, and relatively easy-to-use solution. Ideally it would be web-based to allow for use across a widespread area without the need for internal networks. It should be secure with numerous levels of access. Also, companies should look for a solution that is user-ready and does not require a huge time investment from a firm’s existing IT department. If a company is a multinational one, it should look for a system that allows for differences in language and culture. Finally, organizations should look to vendors with expertise in the quality management field and a proven customer care and support record.

Cincom’s Enterprise Compliance and Quality Management Suite of Applications

Cincom ECQM Suite of Applications is a comprehensive web-based solution for quality systems management. When fully implemented with SmartDoc™, SmartAudit™, SmartTrain™, SmartComplaints™, Supplier Focus™, Calibration System™ and SmartCAPA™ modules, it offers an out-of-the-box system that does not require heavy reliance on an internal IT department for implementation. The products are integrated with no complicated interfaces and are specifically designed to streamline critical quality processes and provide the bottom-line results that manufacturers demand. Cincom, in partnering with Pilgrim, provides an enterprise-wide solution that addresses the key components of a robust and reliable CAPA system, including detailed source error tracking, trending, analysis, and change management. Cincom’s ECQM platform is the answer to fragmented and pieced-together quality management systems, providing one integrated solution that takes all areas of the compliance picture into account.

Together, Cincom and Pilgrim are dedicated to research and development and incorporating industry best practices into their products. Built on leading open-architecture standards, Cincom’s expertise in implementing enterprise-wide compliance solutions limit the need for extensive training, saving their customers implementation time and labor costs. On average, Pilgrim systems achieve ROI within one year.

About Cincom Systems

For nearly 40 years, Cincom’s software and services have helped thousands of clients worldwide simplify the management of complex business processes. Cincom specializes in the areas of business where simplification brings the greatest value to managers who want to grow revenue, control costs, minimize risk and achieve rapid ROI better than their competitors. Cincom serves thousands of clients on six continents including Siemens, Rockwell Automation, Trane, BMW, Boeing, Ericsson, Penn State University and Milacron.

For more information and additional resources, contact Cincom at 1-800-2CINCOM (USA only) or visit the company’s website at www.cincom.com/ecqm.