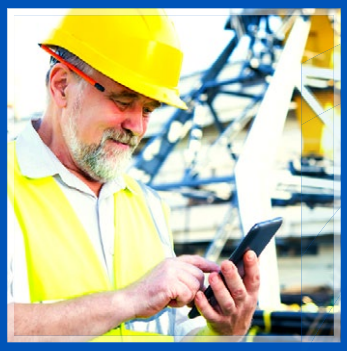

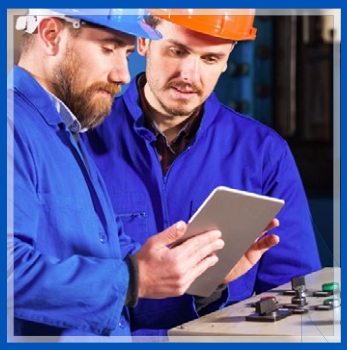

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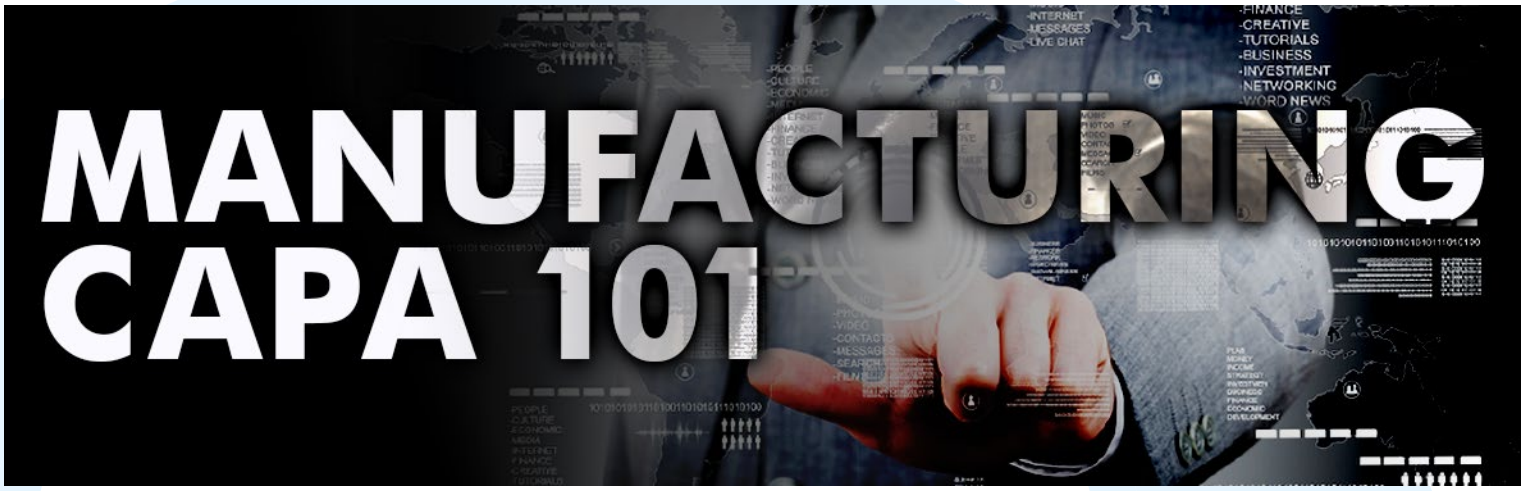

WHAT IS CAPA & WHY YOU NEED IT

To understand how to achieve greater quality in manufacturing, you need to know that corrective and preventative actions (CAPA) are essential elements of quality management, continuous improvement and process discipline. Indeed, you cannot achieve compliance to ISO 9001 and myriad other quality standards - particularly if you are a quality professional and operate in a federally regulated industry, such as life science - without strong, consistent CAPA processes. To give an introduction into the basics of CAPA from a general manufacturing point of view, this paper defines CAPA from a high level and also delves into why you need it to lift quality to new heights.

What is CAPA?

Since CAPA is such a commonly used tool in quality management, you should remember that this process for identifying and mitigating nonconformances and deviations, both internal and external, consists of two key elements: corrective actions and preventative actions. When used together effectively, these two aspects of CAPA complement and reinforce one another to improve quality.

CAPA is so integral to quality management and compliance that it is a fundamental aspect of compliance standards and Good Manufacturing Practices. As such, CAPA is applicable across several fields aside from industries that are heavily regulated domestically and abroad. Here is a closer look at each element of CAPA, because there are key distinctions you should understand to gain a firm grasp on the overall concept.

Defining Corrective Actions

Corrective actions are the processes you initiate to respond to an identified nonconformance through root cause analysis, which can take any form, whether it be a supplier defect, an uncalibrated gauge, or fabricating a part based on an obsolete specification. Corrective actions begin by acknowledging that a nonconformance exists, assigning the right personnel to mitigate it, finding the root cause and creating an executable plan for correcting the nonconformance. Analyzing the impact of an identified nonconformance to assign follow-up actions and validating the implementation of the corrective action are two additional key facets to remember.

Defining Preventative Actions

There is a common misconception that preventative actions merely represent the follow-up steps to corrective actions. Remember that preventative actions are a separate, albeit very closely related, activity to corrective actions. Essentially, preventative actions seek to avoid a potential nonconformance from occurring in the first place,

which could adversely affect quality at a future date. As such, there is a predictive element to preventative actions. Preventative actions follow a process that includes identifying the potential nonconformance, assigning the right personnel to further investigate the preventative action, developing an actionable plan, and validating that the action has worked by averting the potential nonconformance.

Why You Need It

The manufacturing industry needs CAPA for a few reasons. First, CAPA processes afford the benefit of identifying current and potential quality issues as early as possible during production. It is a well known mantra in quality management that cost of quality rises as defects surface closer to the customer. CAPA gives you a tool to prevent costly mishaps from reaching the consumer.

Today, CAPA is so essential to quality that many enterprise quality management software (EQMS) have automated traditionally manual, spreadsheet-based CAPA processes into a holistic quality system. In fact, CAPA is one of the most frequently automated processes by EQMS, which shows how important it is to quality management from an enterprise perspective. You need CAPA simply because it has been proven time and again to be an effective tool to mitigate nonconformances, or prevent them from occurring altogether.

Remember that CAPA consists of two separate activities: corrective actions and preventative actions. Without CAPA, you will not be able to manage cost of quality and will not reap the benefits of such a proven quality process.

CHALLENGES WITH CAPA

As you might expect achieving CAPA excellence is easier said than done in the real world - and even more difficult to get right the first time. To dive deeper into CAPA and common pain points related to its implementation, this chapter outlines the top three challenges with CAPA.

1. CAPA is (still) a very time-consuming process:

You may not know that not too long ago CAPA - and all quality management processes for that matter - were wholly based upon manual, paper-driven processes. If you worked as a quality professional before the advent of information technology, you would literally have printed paper document after paper document just to keep up to date on the status of one particular quality process. Today's technology, however, has made it easier to move away from manual quality systems, but at the end of the day, CAPA remains a time-consuming process without the right automated technology in place.

Why? The answer revolves around the fact that CAPA touches so many different aspects, from engineering to production and beyond. CAPA can have a profound impact on the deliverables that are typically associated with its successful implementation, such as engineering change orders, control plans and rework orders, just to name a few. In short, you should remember that CAPA can touch many additional quality processes, often in ways that are far from apparent and only reveal themselves upon implementation and validation testing.

2. Difficulties in defining CAPA scope & context internationally:

You should know that CAPA, consisting of two separate but very related processes, are not one dimensional, flat quality processes. To put it succinctly, plant-level CAPA can have a very different scope and context than enterprise-level CAPA, which may not necessarily share the same point of view. Consider the example of an in-line production process deviating from specification. On the shop floor, this

issue would need immediate attention, but would C-suite executives really need to know about one minor issue at one particular plant on one particular day?
As such, one of the main challenges with CAPA is defining its scope and context within a large company. If you work for a global manufacturer, one plant site may literally speak a different language than another plant site, but this comparison is also applicable internally, too. One department may use a different vernacular than another department, which can introduce unnecessary complexity into CAPA. Likewise, it is not uncommon to find different software tools in place within the same company to manage the same quality process, which only makes it more difficult to achieve consistent CAPA internally when scope and context remain amorphous and undefined.

3. Finding the right CAPA software:

As you might expect, there are many different point solutions and custom software available to manage CAPA. Some CAPA software are simply modules for enterprise resource planning systems or product life cycle management (PLM) solutions; some are stand-alone solutions that require their own IT resources. Nonetheless, the important lesson you can take away is the fact that the CAPA software market is dynamic, which can make choosing the right software difficult.

In the absence of a concerted strategy to streamline CAPA, it is easy to choose a software that may not be the best solution based on your needs. Often, CAPA software is used as an extension of PLM because many manufacturers have invested very heavily in these systems, so it makes sense to manage CAPA in this manner. However, you do not necessarily need to manage CAPA through PLM; there are many, many other possible deployments. The accurate and timely flow of information is the key – and with the integration abilities of specialized software systems today, you have choices.

Certainly, the challenges with CAPA are numerous, but these are the most common pain points. The key lesson you can take away is that CAPA does not have to be a lengthy, manual quality process if you define scope, context and deploy the right software.

BENEFITS OF CAPA

By reading the first couple of chapters in this paper, you learned about the essential elements of corrective and preventative actions (CAPA) and the top three challenges related to their implementation. Next, you will discover the benefits of CAPA to balance out the previously discussed pain points. To show why manufacturers use CAPA, here are the top three benefits of CAPA and how EQMS can help manage them more effectively.

1. CAPA is a key facet of continuous improvement processes:

CAPA is important to continuous improvement processes, which are fundamental elements of quality management in manufacturing. Quality professionals use corrective actions to tackle reported nonconformances and propose a method to address these deviations, too, but preventative actions address potential deviations and take concerted steps to avoid them in the first place.

When combined, it is easy to see how these two quality processes can create great value if implemented well. To enable continuous improvement, you need to be able to feedback quality-related data from suppliers, international manufacturing sites and customers to engineering processes early in the production cycle. By doing so, you can enable the next benefit of CAPA.

2. CAPA can help lower the cost of quality:

It may surprise you to learn that despite the breadth of software solutions available companies still struggle to measure and address cost of quality, but why? The answer relates to the sheer complexity of the task at hand. As you might expect, more complexity usually entails higher cost of quality.

However, with robust CAPA and quality processes, you can bring order to data chaos to pinpoint quality issues as early as possible in the production cycle. Since cost of quality rises substantially as defects come to light closer to the customer (e.g., global recalls), another benefit of CAPA is the ability to capture quality issues early in production, thus helping to reduce cost of quality with synergistic processes.

3. CAPA can improve the number of products in compliance when automated with EQMS:

As you might expect, there are many different point solulf you work as a quality professional, you already know how difficult it is to manage myriad regulations domestically and abroad, too. In fact, if your company still struggles to satisfy the most basic standards, such as the ISO 9001 series, you are not alone. However, when implemented well, CAPA can actually make managing compliance easier when automated in a holistic system, such as enterprise quality management software (EQMS).

As further evidence, you can turn to the experts at LNS Research for data on where CAPA is most effective. In an annual survey of quality management professionals and executives, LNS Research revealed that CAPA can improve the number of products in compliance substantially when automated with EQMS. Specifically, automated CAPA can raise the number of products in compliance from 96% to 99%, which in the world of quality management is a big improvement that can equate to a major improvement in cost of quality.

What EQMS can do is give you a powerful tool to move away from manual, paper-driven CAPA to an automated system with real-time quality data. The potential synergies are numerous and vary from industry to industry, but the key takeaway is the same: The more you automate CAPA with EQMS the easier it will be to manage quality from an enterprise point of view. Without EQMS, achieving this goal will be very challenging.

In short, the three benefits of CAPA are better continuous improvement processes, lower cost of quality and a greater number of products in compliance. As such, you need the right tool to enable these benefits, so EQMS is precisely the right tool for the job.

AUTOMATED CAPA WITH EQMS

1. Audit all currently deployed software & quality systems:

Your company most likely shares many of the same pain points as other global manufacturers. Complexity is at the root of the issue when it comes to redefining CAPA and managing these processes in a holistic software solution. In short, the task is easier said than done for a number of reasons previously discussed in part two of this blog series, such as difficulties defining CAPA scope and context - even internally.

To begin automating CAPA, you have to start by auditing the IT systems that currently exist, with particular attention

paid to the applications used on a daily basis to manage nonconformances and subsequent CAPA. You may discover that certain elements of your nonconformance processes are essentially still paper-driven, which remains an all-too-common mistake. Certainly, enterprise business productivity software has changed the way manufacturers operate and communicate on a global scale, but far too often, employees simply end up printing out spreadsheets and manually disposition issues (i.e., manually emailing documents back and forth).

You may also discover that your company uses different software to manage the same nonconformance process at different plant sites. This issue introduces unnecessary complexity and redundancy into any quality management system. IT sprawl is an all-too-real problem in the world of enterprise IT. You may not even be aware that your company has more software than you truly need to manage CAPA, so as a starting point, it is critical to audit the software tools you currently have in place for nonconformances.

2. Redefine the nonconformance management in an EQMS:

IAs a quality professional, you already know that effective CAPA begins with sound nonconformance management. You may use disparate databases to reference customer accounts, original equipment manufacturers (OEM) and customer complaints. Each of these areas can potentially initiate CAPA once a nonconformance has been identified and assigned a disposition.

EQMS automates nonconformance management by integrating previously disparate software and data sources into one intuitive workflow and provides process visibility into where the nonconformance or defect record (which may have originated from one inspection lot several weeks ago) first appeared. EQMS allows you to attach all relevant information and data to any nonconformance record. For example, you may need to upload a digital photograph of a defective part, but the software you currently use to assign CAPA dispositions may not even allow such a simple, yet extremely helpful, feature.

3. Redefine CAPA workflow in a single system:

Once you have redefined nonconformance management, you can move on to redefine CAPA in a holistic, automated system that integrates into your quality system seamlessly. As a basic CAPA workflow, you want to configure a quality system to:

- **Define the problem**
- **Contain the problem**
- **Perform root cause analysis**
- **Identify permanent planning procedures**
- **Record notes on CAPA implementation**
- **Identify preventative measures**
- **Validate/follow-up on CAPA processes.**

One of the biggest benefits of an EQMS is the ability to streamline communications among suppliers and OEM to automate follow-up processes with reminders and periodic notifications. Today, you can rely on the automation features inherent to EQMS to make your job easier and more efficient.

Automating CAPA begins by auditing your current systems, redefining nonconformance management and redefining CAPA workflow. By taking these three basic steps, you can begin to reap the benefits of EQMS faster than you may expect.

with EQMS the easier it will be to manage quality from an enterprise point of view. Without EQMS, achieving this goal will be very challenging.

DEVELOPING CLOSED-LOOP CAPA PROCESSES

So, how do you take automated CAPA to the next level and develop what industry gurus call "closed-loop quality processes"? Each chapter in this paper has led up to this discussion on closed-loop quality processes, with a particular emphasis on closed-loop CAPA. Indeed, CAPA automation is one of the most widely deployed features of EQMS. Here's how you can enable closed-loop quality processes by automating CAPA management.

Integrating Quality Processes with Business Processes

Your experience as a front-line quality professional is indispensable when it comes to integrating quality processes with business processes. Surely you have encountered the all-too-common frustration of spending a lot of time completing CAPA that have to be repeated due to incomplete record keeping or poor communication. In all likelihood, you have encountered several situations where the old adage "the left hand does not know what the right hand is doing" rings very true.

Closed-loop quality merges quality processes with business processes to bolster quality management throughout the value chain, from engineering to distribution and beyond. Each facet of the value chain has a stake in quality, but in previous eras, disconnect remained and "gaps" in quality systems led to serious oversights and defective products reaching the open market, where quality issues are devastatingly costly to address. The recent Takata recall is a prime example of how a relatively simple quality oversight can cascade out of control into a major global recall.

When you close the loop on CAPA management, you feed-back data to enable cross-functional collaboration by merging business systems with quality management systems. For example, a sound EQMS would allow you to create a central hub of quality data that integrates with your enterprise resource planning (ERP) system and your product life cycle management (PLM) solutions in concert. Furthermore, in a large global enterprise it is not uncommon to find more than one ERP instance, which only introduces more complexity; EQMS manages this complexity in a single solution to close the loop on CAPA management.

Which closed-loop quality processes yield the most benefits?

You may have read that, according to LNS Research, CAPA automation is the most widely deployed function of EQMS. However, you can enable synergies in other processes as well, not just CAPA. You should understand that merging quality with each step in the value chain is the essence of closed-loop quality management. Aside from CAPA, you can leverage EQMS to integrate software that oversee:

- **Supplier management**
- **Risk management**
- **Complaints**
- **Compliance**
- **Audits**
- **Product part approval processes**
- **Statistical process control**
- **Advanced product quality planning**

In short, you can tie each facet of quality management to one another in a single solution that integrates seamlessly with your current application portfolio.

CAPA are traditionally stand-alone processes managed in point solutions. As such, silos of valuable information may remain dormant within your company. Truly, you may not even know the value of your data when it comes to CAPA management until you begin to close the loop on quality.

Depending on your particular manufacturing segment, automating CAPA with EQMS can enable synergies across the enterprise by providing visibility into supplier management issues, for instance. If you work in automotive manufacturing or aerospace, you already know how critical it is to pinpoint supplier defects as early as possible when you have multiple tiers of suppliers to manage.

Closing the loop on quality is most effective when you include CAPA data earlier in the value chain. As such, it is easy to see why so many companies have automated CAPA with EQMS.

A CAPA SUCCESS STORY

In the final chapter of this paper on corrective and preventative actions (CAPA), we have highlighted a truly unique success story, showcased by the LNS Research paper "How to get started with quality performance management" (available on www.iqs.com for download). In this paper. we have covered different elements of CAPA and what you can do to rework your CAPA processes with integrated, holistic enterprise quality management software (EQMS). Here is a recap of the chapters and how one manufacturer was able to take a different approach to CAPA and cost of quality.

Paper Recap

WHAT IS CAPA & WHY DO YOU NEED IT?

CAPA consists of two separate elements:
Corrective actions and preventative actions. It is a myth that preventative actions are merely the follow-up steps to corrective actions. Both aspects are distinct and key to identifying and mitigating nonconformances. Without sound CAPA, your company would not be able to pinpoint quality issues as early as possible during production.

TOP CHALLENGES WITH CAPA

In short, you have three primary challenges with CAPA:

- **CAPA is a time-consuming process**
- **CAPA scope and context**
- **Implementation of CAPA software**

Certainly, you can count on encountering many more pain points along the way, but these are the problems that you will have to address immediately if you want to build robust quality processes.

BENEFITS OF CAPA

Once you know the CAPA challenges you are likely to encounter, you can reap the benefits of reinvented quality processes. Overall, your company will benefit from retooling CAPA processes because:

- **CAPA is key to continuous improvement processes**
- **CAPA can help lower cost of quality**
- **CAPA can improve compliance metrics with EQMS**

In fact, by automating CAPA, you can increase the number of products in compliance from 96% to 99%, according to figures from the trusted experts at LNS Research.
How to automate CAPA

HOW TO AUTOMATE CAPA

Automating CAPA entails:

- **Auditing current software and quality systems**
- **Redefining nonconformance management**
- **Redefining CAPA workflows in a single system**
- **The main idea to remember is that EQMS is the enabler of all three facets of CAPA auto mation.**
- **Developing closed-loop CAPA processes**

You should always remember that closed-loop CAPA entails bolstering quality processes with business processes from end to end. With integrated EQMS, it is possible to "close the loop" on CAPA as well as auditing, complaint handling and supplier management. Truly, you need the capability to manage CAPA in a single system.

ACCURIDE: A CAPA SUCCESS STORY

When you integrate all aspects of CAPA with EQMS, you can reveal substantial benefits -- and novel approaches to quality like the automotive manufacturer and supplier Accuride. Accuride's approach to quality is so unique that LNS Research dedicated an entire case study to showcasing Jd Marhevko, VP of quality and lean systems, and the effectiveness of her cost of poor execution (COPE) metric. COPE, a metric that includes unplanned losses due to poor execution of quality and operations, has opened new avenues for Accuride, especially with respect to CAPA.

As you have read throughout this blog series, CAPA is key to continuous improvement. To that end, Accuride leverages data collection into actionable intelligence by approaching quality from a more holistic perspective, pioneered by Marhevko. To state the bottom line of the paper succinctly, "it is important to focus on only the data that is usable and relevant ... an effective approach can be to define high loss areas and just start the measures. Redefine them as you go." You can download the LNS Paper directly from the IQS website.

Accuride's success story highlights what is possible when you automate CAPA and all quality processes with EQMS. Indeed, without a holistic approach to quality, CAPA will fall short of the mark, which is why selecting an integrated EQMS is so critical.

CAPA is important to continuous improvement processes, which are fundamental elements of quality management in manufacturing.

You need CAPA simply because it has been proven time and again to be an effective tool to mitigate nonconformances, or prevent them from occurring altogether.

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