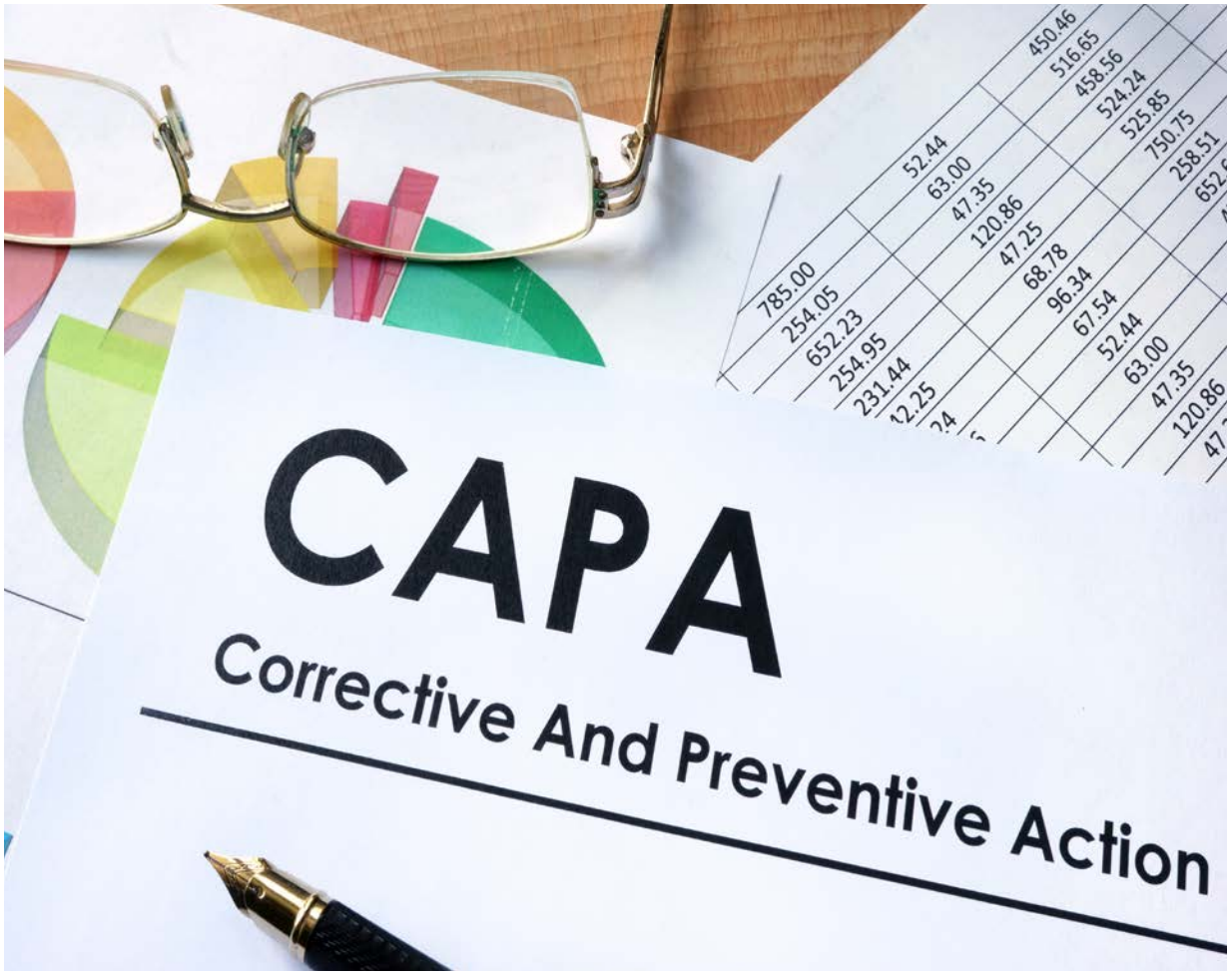
Pharmaceutical MANUFACTURING
RESEARCH REPORT

Exploring Pharma's CAPA Challenges

Industry survey indicates a need for an integrated, systematic approach to corrective and preventative action



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Maintaining high levels of quality is of critical importance in the pharmaceutical industry. Often considered the core of a company's quality management system, a corrective and preventive action (CAPA) process investigates and solves problems, identifies causes, and takes action to prevent recurrence. Yet, despite an increased emphasis on quality management, many pharmaceutical manufacturers continue to struggle with quality problems because of ineffective corrective and preventive action processes.

Pharmaceutical Manufacturing recently partnered with Verse Solutions to survey 163 pharma and biopharma professionals regarding their opinions on how their companies handle CAPA processes. The survey was inspired by a previous survey partnership that found over 50 percent of pharma/biopharma respondents pinpointing CAPA processes as their organization's biggest quality/compliance pain point.

So why does CAPA continue to challenge the industry? The new survey found that over 57 percent of manufacturers are not getting a comprehensive view of how quality management applies across their entire organization. What much of the industry appears to be lacking is an integrated, systematic approach to corrective preventative action.

Because CAPA is compulsory for compliance with cGMP regulations, there's a tendency to treat it as another box to check for compliance. But beyond compliance, an efficient corrective and preventive actions process is a powerful tool that can significantly improve quality systems and process understanding across an entire enterprise.

CAPA CHALLENGES

When asked to pinpoint the biggest challenges associated with current CAPA processes,

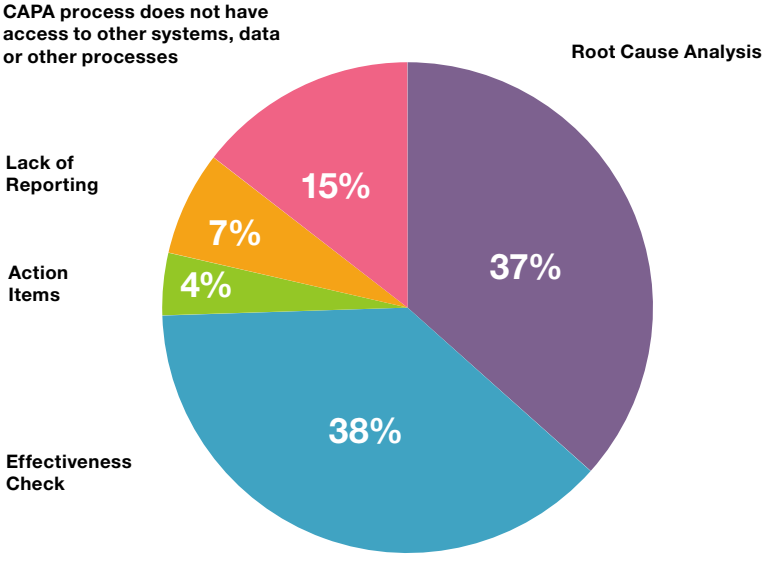
the number one concern was root cause analysis (38 percent), followed closely by effectiveness checks (36 percent).

Root cause analysis (RCA) is a problem-solving process for conducting an investigation into an identified incident, problem, or nonconformity. As a common tool used to identify the source of a good manufacturing practice deviation, the root cause investigation process is paramount to the success of the CAPA process, and yet continues to challenge the industry. This struggle is supported by regulatory audit findings; inadequate RCA continues to be one of the most frequent FDA audit issues. Determining RCA takes up resources and time, especially as companies struggle to distinguish between the observed symptoms of a problem and the fundamental/root cause.

Effectiveness checks are used to determine if the corrective action has (or has not) fixed the problem. This action serves to close the loop between identifying the root cause of problem and completing the actions to solve a problem.

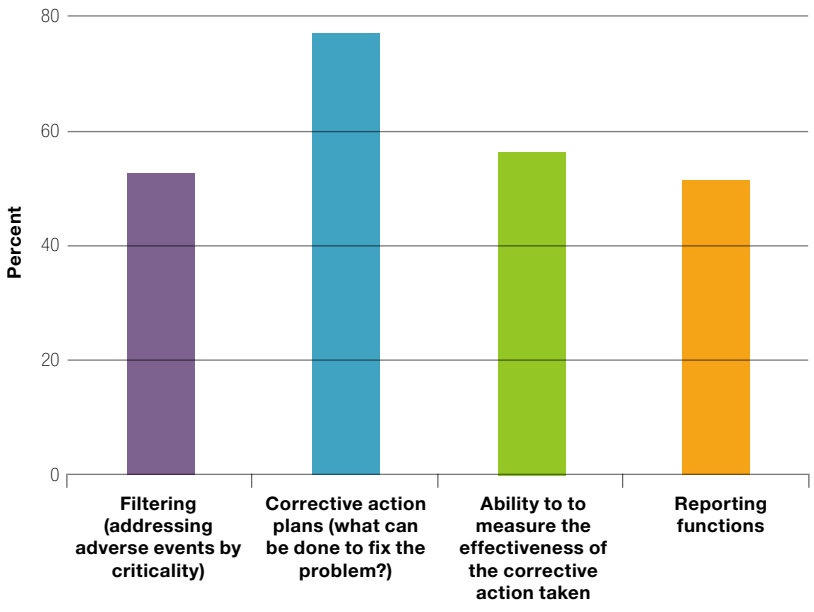
It is not surprising that the two biggest CAPA challenges are

WHAT DO YOU BELIEVE IS THE BIGGEST CHALLENGE OF YOUR CURRENT CAPA PROCESS?



closely related to each other. When companies can't determine the actual root cause of a quality event they end up addressing the same event over and over again within their corrective action process. It is often the case where companies begin fixing problems before properly determining the problem's root cause. Logically, it is then difficult to assess the effectiveness of a corrective action if the actual cause of the issue was not properly determined.

DOES YOUR CORRECTIVE ACTION SYSTEM OFFER:



WHY THESE STRUGGLES EXIST

In their quest to achieve a single managed view of the process, pharmaceutical companies struggle to break down the silos in which they might have several different CAPA processes being used across different departments and plants. Often, companies have to chase the same complaint at multiple facilities. Consequently, the struggle to resolve issues is compounded because problems are not visible across the entire organization.

Centralized reporting tools are necessary to pull all processes together and provide high-level visibility into what's driving quality performance. Over 50 percent of those surveyed have a CAPA system in place that does not offer reporting functions. This deficiency can largely be attributed to the use of paper-based or spreadsheet-based quality management methods. Among those surveyed, 60 percent are still managing CAPA processes using manual- or spreadsheet-based systems, or software/manual hybrid systems. Regulatory agencies insist that manufacturers maintain consistent procedures across their organizations, embedding regulations into the CAPA process standard operating procedures – and this can be extremely challenging without a standardized automated solution.

The survey also found that only 53 percent of respondents have a CAPA system in place that filters corrective actions by priority. It is often the case that companies will create a CAPA for every adverse event that enters their quality system, resulting in huge bottlenecks and delayed resolutions. A key benefit of many automated quality management system solutions are CAPA applications that have the ability to filter events by severity and risk, to enable companies to take action on those events that have the greatest impact to the organization.

Risk management tools, often built into automated CAPA solutions, apply risk levels to corrective and preventive actions, allowing companies to prioritize them. However, survey results strongly indicate that risk management is not being used effectively and/or not being properly integrated with overall quality management process. Of those surveyed, 30 percent are not using risk management to guide actions and 57 percent claim their current CAPA process leaves them unable to see trends in risk across their entire organization. When it comes to actively managing risks, the process is simplified

when companies have the right tools to enable a systematic and objective means of building risk into all processes.

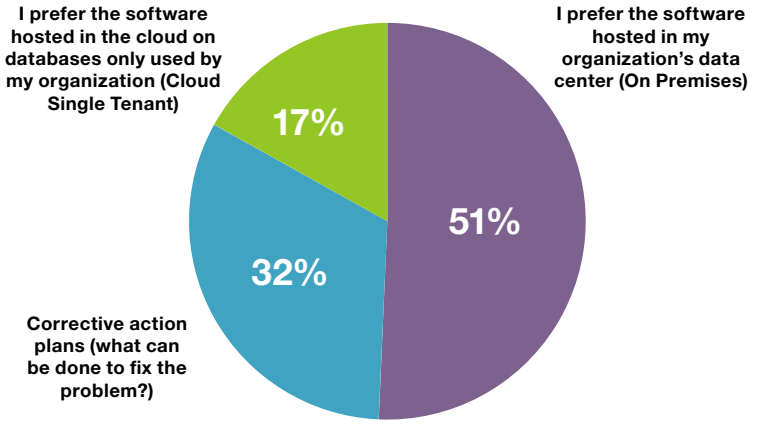
CLOUD BENEFITS

Despite the long-term enterprise-wide benefits associated with quality, the biggest anticipated challenge in implementing an automated CAPA process noted by respondents was building a business case to justify the cost to purchase an automated solution. Additionally, 27 percent were concerned with the time it would take to implement and maintain an automated solution.

Cloud-based software, as an alternative to on-premise software, offers potential advantages that address numerous cost and implementation concerns. Cloud-based solutions are both scalable and flexible, and their virtual nature means that implementation time is greatly reduced – saving time, money and resources. The cloud has made quality solutions more accessible to organizations of all sizes, and using the cloud-based systems to automate quality processes is resulting in more consistent and repeatable processes.

While a majority percentage of those surveyed — 52 percent — still noted a preference for software hosted within their organization's data center, on servers only used by their organization, 48 percent were open to using cloud-based solutions. Of this 48 percent, the majority noted a specific preference for single tenant cloud hosting, meaning the software is hosted in the cloud on servers only used by their organization, as opposed to shared, multitenant enterprise solutions.

WHAT IS YOUR PREFERENCE IN DEPLOYING AUTOMATED SOLUTIONS, SUCH AS CORRECTIVE ACTION?



QUALITY FUTURE

CAPA is often referred to as the "heart" of quality management. An effective CAPA process is a tool that can enable a quality system to bring continuous improvement to all aspects of the business.

But corrective and preventative action struggles persist because many systems in place are disparate and manual-based. CAPA-related data is siloed, preventing enterprise-wide visibility of quality. The CAPA-related challenges and concerns outlined in the survey point to the industry's need for a fully integrated, cloud-based quality management system that offers the ability to automate the corrective action process. This systematic approach to CAPA will bring the industry closer to its quality goals. ◻