5 Steps to a Reliable CAPA Process

*Maintain compliance and achieve operational excellence
in your corrective and preventive action process*

1. Document the CAPA process

A strong CAPA program requires proper planning and organization. It sounds simple, but lack of CAPA process documentation is a frequent reason for FDA 483 citations, which can damage your brand reputation and even lead to a shutdown. Many details need to be documented prior to implementing a CAPA workflow including processes to be monitored, people to involve, potential failure modes, severity levels and actions to implement best practice CAPA.

2. Leverage trends to pinpoint risk

Despite intense regulatory pressures, not every deviation, complaint, audit finding, or supplier defect should trigger a CAPA. Trend analysis and risk management can help to avoid the costly and time consuming "Everything is a CAPA" syndrome. Paying close attention to trends revealed through analysis determines if the deviation is an anomaly or part of a greater concern that might trigger a CAPA process. Trending can also reveal minor problems before they become riskier issues and help you prioritize nonconformance for further investigation.

3. Solidify root cause analysis

An effective CAPA process hinges on your team's ability to understand the true cause of each problem you encounter. A well-defined root cause analysis process is essential to a CAPA system's effectiveness. Corrective and preventive actions cannot be effective without understanding the fundamental reason for the problem.

The goal of root cause analysis in not only to fix the problem at hand. It is to understand why the problem occurred so the right actions can be taken to correct and ultimately prevent that problem from reoccurring. A root cause needs to be specific, and it also needs to be something that can be changed with action.

4. Maintain involvement

A CAPA process is not effective or compliant without management commitment. Managers who understand CAPA procedures and conduct management reviews of CAPA data and records, keep the CAPA process in compliance and reduce their risk of 483s. And forward thinking managers are beginning to leverage best practice CAPA as a tool to increase efficiencies, improve customer satisfaction and protect their corporate brand.
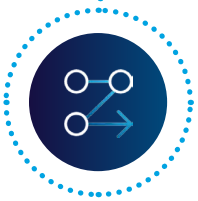
5. Take action

Change is a natural output of the CAPA process; in fact, change is the purpose of the CAPA regulation. Managing corrective and preventive actions keeps you in compliance and also contributes to continuous improvement initiatives. Tying CAPA-related changes back to specific root causes ensures that your action plans are focused on finding the most effective solution to each nonconformance you encounter. This ensures that appropriate changes are implemented

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