To The Point
Introduction to Corrective and Preventive Actions (CAPA)

According to the U.S. Food and Drug Administration (FDA), corrective and preventive actions (CAPA) aims to collect and analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent recurrence. As the name suggests, CAPA is about problem-solving and it is a two-step process. When something goes wrong, a CAPA is executed to "correct" the immediate issue and then "prevent" it from reoccurring with an improvement that addresses the cause.

The Difference

Corrective actions are reactive, while preventive actions are proactive. Although these two actions use similar processes and similar analytical tools, they are not necessarily used together.

- **Corrective Action:** Elimination of the cause(s) of an existing nonconformity or undesirable situation to prevent recurrence.
- **Preventive Action:** Identification and elimination of the cause(s) of potential nonconformities to prevent occurrence.

Effective CAPAs are the backbone of a quality management system, acting as the mechanism for fixing problems and optimizing processes.

The FDA regularly inspects life sciences companies, which also frequently undergo third-party audits, including those for International Organization for Standardization (ISO) accreditations. Scrutiny of the CAPA process is not limited to the FDA or other regulatory inspections. A company's CAPA program is also consistently evaluated during ISO notified body audits.

FDA Inspection vs. ISO Audit

While it might seem like semantics, people often confuse the terminology used by the FDA and ISO. The FDA conducts an inspection whereas ISO conducts an audit.

FDA inspectors are badge-carrying members of a law enforcement agency responsible for ensuring that the law is upheld and that life sciences companies are compliant. An ISO audit is conducted by a registrar to verify that a company complies with ISO standards, such as ISO 13485 for medical device quality systems, as well as similar requirements for other life sciences companies. During an FDA inspection or third-party audit, the CAPA process will always be evaluated.

The FDA reports data from inspections[1] and companies may receive FDA 483 inspectional observations for "Insufficient corrective and preventive action procedures". CAPAs have consistently topped the list of the most common FDA inspectional observations since the fiscal year 2010[2], and the number one reason medical device companies receive FDA Form 483s is due to CAPA. Other segments of life sciences including biologics, drugs and tissue risks are also frequently cited for shortcomings with CAPA.

Triggering CAPA

The need to initiate Corrective and Preventive Actions may arise from any of the following events.

- **Non-Conformity:** Non-conformance or deviation refers to the failure to fulfill mandated requirements. This can occur at both the product level and the process level. Such events may be the result of negligence on the employee's end or due to defective equipment.
- **Customer Complaints:** Instead of identifying the problem during the manufacturing process, customer complaints reveal deficiencies after the products have been introduced in the market. The defect may pertain to the packaging, the inability of the product to produce desired results, or severe, undocumented side effects.
- **Audit Findings:** Audits, both external and internal are conducted to verify whether existing procedures and systems are aligned with the established parameters. Irrespective of the type of audit, any discrepancy found normally furnishes enough evidence for initiating CAPA.

The purpose of CAPA here is to mitigate the problem and take desirable and appropriate steps in an effort to prevent re-occurrence. It provides a structure for finding the root cause of problems, solving those problems, documenting the conditions and solutions for the future, and looking for other potential problems and solutions.

These events can also draw unwanted attention and impact product liability defenses in the event of a claim or suit. For example, having a strong CAPA program can help identify an issue early, correct it, and prevent it going forward which can be a positive. Not having a proper CAPA program can lead to a delay in identifying a problem or not correcting it properly leading to increased liability risk.

CAPA Program Requirements

There are many components to CAPA, and it's easy to see why it would be a focus for FDA inspections. Ensuring that corrective and preventive actions are taken where necessary is crucial for product safety.

The FDA requires all life sciences manufacturers to have clearly documented procedures for corrective and preventive action in the following areas.

1. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodologies should be employed where necessary to detect recurring quality issues.
2. Investigating the causes of nonconformities relating to product, processes, and the quality system.
3. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems.
4. Verifying or validating the corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device
5. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.
6. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.
7. Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

CAPA is part of the overall Quality Management System (QMS). While the immediate compliance threats are obvious, less obvious are those that leave companies vulnerable to serious quality system issues that can develop under the radar of their quality management system, putting patients at risk and increasing their liability exposure.

Tips for Effective CAPA Implementation

Companies must implement an effective CAPA process from the beginning to comply with the FDA and other third-party audit entities, as well as to identify, correct, and prevent issues with their products or processes that could cause injury or damage to customers. Remember the common citations such as, "lack of adequate documentation" and "lack of adequate procedures." These both should be addressed as early as possible.

Here are a few tips for better CAPA implementation:

- Create the CAPA process early, following recommended guidelines.
- Keep data centralized (such as with a CAPA Management software system) for better control.
- Keep the process as lean as possible to keep it easy to follow.
- Implement risk management within the first stage of a CAPA process.
- Clearly distinguish symptoms from causes. A clear definition of the problem ensures getting to the root of it.

A robust and modern approach to CAPA is about shifting from reacting to situations and events to being proactive to address potential areas of concern before they become reality.

By addressing problems at their root cause, CAPA can prevent minor issues from snowballing into major ones. Additionally, by taking proactive steps to prevent future problems, CAPA can help organizations avoid disruptions, maintain high levels of product quality, and ensure compliance with regulatory requirements.

Resources

US Food and Drug Administration (FDA), www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/corrective-and-preventive-actions-capa

The FDA Group, www.thefdagroup.com/blog/definitive-guide-to-capa

Greenlight Guru, www.greenlight.guru/blog/corrective-action-and-preventive-action-capa-medical-devices

Learn More & Connect

For more information on protecting your business, contact your local risk engineer, visit the Chubb Risk Consulting Library, or check out www.chubb.com/riskconsulting.

1. FDA Inspection Observations, www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations
2. FDA Warning Letter & Inspection Observation Trends, www.thefdagroup.com/blog/2019-fda-warning-letter-inspection-observation-trends