STEPS TOWARDS A RISK-BASED CAPA PROCESS

BEST PRACTICE

MUNICH - BERLIN - ROSTOCK - PHOENIX – WASHINGTON, D.C.

CAPA, also known as Corrective and Preventive Action, is a way to establish and keep a company's compliance in a holistic and sustainable way. Just a few measures can sometimes eliminate unforeseen situations caused by non-conformities. CAPA as a concept falls under several ISO business standards and Good Manufacturing Practices and is a common paradigm for the pharmaceutical industry.

The fundamental idea of CAPA is to get down to the root causes of specific problems and the risks associated with them. The completion of this process includes preventive actions so that a particular problem does not reoccur in the future. Companies can create a risk-based CAPA process and comply with the latest ISO standards. Follow the arivis steps towards a risk-based CAPA process.

1. DETERMINE THE COMMON INPUTS

There are many inputs to CAPA that are the crux of the Quality Management System (QMS). This is because it helps you solve any problem. It's important to know that authorities expect these inputs to be varied and not just from a single source. For this reason, the CAPA process is considered the core of the Quality Management System and also indicates how effective the QMS is in general.

If an internal audit is an input, you should be aware of your peers and what they use as inputs. This internal benchmarking helps you in understanding patterns of issues that have occurred somewhere in the organization. Shared process knowledge assists you in understanding your own CAPA. This is when corporate culture turns into collaborative success, which enables your organization to implement preventive actions even before an actual problem occurs. The 5D platform is entirely data-driven and quality processes with implemented arivis5D Compliance give you the necessary predictive models for your smart decisions. This helps not only in internal audits but also helps to survive inspections effectively.

2. DESIGNING A GREAT FORM

Creating well-designed forms seems like a no-brainer, but the reality is that it takes a long time to eliminate technical bugs and create something that is logical and chronological in nature. Designing a great CAPA form helps to improve the effectiveness of your CAPA process. Beyond that you will reduce usage errors and improve the efficacy of the whole process. The forms ensure completeness and should include all the mandatory elements for a robust CAPA, but also can have individual configurations for your organization.

3. LEARNING TO ANALYZE CAPA

Learning from solved issues in the past is a must. Further analysis of process-related quality problems lets you change views in a predictive mode before they compromise the compliance of your organization. Any of these, of course, might have undergone the process and required corrective actions. Organizations actually should not just sit on data but should turn into predictive mode by regularly analyzing their quality patterns. A retrospective analysis should include data and information from all inspection findings, complaints, issue tracing, and quality records.

Predictive models involve, determine and analyze acceptance criteria. See related patterns to document types, process phases, artifacts in-process, and completed tests. Further quality data from quality audits, implementation reports, lawsuits can also be included and added to models, and be analyzed. An efficient way to explore quality patterns is to watch the facetted navigation and interactive browsing and reporting in arivis5D Compliance – a completely new paradigm for meta-data driven quality reports.

4. UNDERSTANDING "RISK-BASED"

What sounds like a NASA aerospace attitude is mainstream for life science corporations as well. Pharmaceutical quality management analyzes the risk associated with a particular process as well. Risk management should be an underlying feature for all phases and parts of the QMS system. Risk management as an integrated function of QMS has strategic relevance. One evaluates risks at both conscious and subconscious levels. If your system is capable of capturing risks, making them part of decisions and being evaluated, machine learning can take your future corrective and preventive actions to the next level, because some patterns are subliminal and sometimes just informal.

5. THE RISK MANAGEMENT PROCESS

Updating the Risk Management System is important to keep an organization aligned with the current situation. By deploying a Risk Management System, new actions can be developed to reduce the identified risks in the organization.

Machine learning, automation and data-driven software as arivis 5D Compliance not only helps you with the implementation of quality processes or CAPA conform procedures but also with a risk management process that translates. A smart system will easily distribute the designated actions of the CAPA to tasks of the respective people. It also helps in tracking the effectiveness and adoption of the implemented actions.

6. RISK AS FILTER AND PRIORITIZATION TOOL

The decision to open a CAPA should depend on a classification system where issues of significance and severity gets properly coded. Knowing when to open a CAPA reduces half of the stress. If a company is facing an issue of delayed response, one may open a CAPA to understand the cause. However, sometimes, the risk management system can detect the cause even without a CAPA.

Nevertheless, any incident leading to significant harm should trigger an immediate CAPA; but you will also have issues that do not fall under this category. There is no simple "three times" rule given by FDA guidelines that indicates what is eligible for a CAPA. It needs some more elaborate rules and coding.

7. PLANNING AND DOCUMENTATION

The guidelines of the FDA under 13485:2016 do not have any major changes for corrective and preventive actions. However, planning and documentation is something that is still needed. The FDA requires your planning as far as CAPA goes. Hence, documentation and strategy planning must be included in the CAPA processes.

8. CONTAINMENT AND CORRECTION

While finding proper corrective and preventive actions should be your primary concern, one should also be ready to run containment to stop an actual issue from occurring while you're still investigating the root cause. During the process correction, an auditor may find a few granting factors to the issues that need to be corrected. The FDA may issue a 483 observation which may require you to go over the past 2 years' data. That is potentially a lot of data that needs correction.

9. HAVING RISK CONTROLS IN PLACE

There are a few risk controls that need to be set in place.

- Inspection: They are used for getting metrics for data analysis and are commonly used for the containment method. Factors such as depth and frequency of inspection need to be risk-based decisions.
- Process Validation - This is a proactive approach that determines how capable our organization is in terms of inspection readiness. Once you use data from the process validation, you can utilize patterns to determine a risk-based approach of further management.

Overview

With upcoming technology, the CAPA process has taken a risk-based and practical approach to resolving issues. In the transition from a retrospective data analysis to a more predictive and risk-based quality management system, new technology and software play an important role in standardizing the whole quality system.

One such software that facilitates the automation process for CAPA is arivis 5D. This software can be customized for your organization. arivis 5D is a data-driven quality software that helps streamline the quality management system.

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