

Implementing a Risk-Based Approach to Corrective and Preventive Action (CAPA) Management

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1. Background

In 2021, Mayo Clinic Comprehensive Cancer Center (MCCCC) implemented a new Corrective and Preventive Action (CAPA) management system, which focused on a streamlined approach to assist with implementation of CAPAs and adding CAPA effectiveness checks.

Despite the benefits of this approach, there were still components that did not meet the requirements of a true effective Quality Management System (QMS). Additionally, this approach placed an operational burden on the MCCCC Compliance and Quality Unit (CQU), due to information not provided by the original requestors.

In 2023, the CQU and QMS re-evaluated the CAPA management process.

2. Goals

To ensure that MCCCC CAPAs maintained the highest quality, met QMS standards, remained objective, and provided real-time automation, the CAPA process was enhanced to:

- Enable front-line staff to input all the necessary information into the CAPA system to facilitate:
 - Natural flow of information
 - Eliminating back-and-forth between study team/departments and CQU
- Create a risk-based algorithm to determine whether a CAPA plan is required
- Eliminate subjectivity caused by the variability of the CQU reviewer
- Update the REDCap system to:
 - Include risk-based algorithm
 - Automated communication alerts (i.e., CAPA determination)
 - Provide trend reports
- Reduce timelines

3. Solutions and Methods

To achieve an effective CAPA Management system and to conform with ISO 9001:2015 requirements, a 5x5 risk matrix, developed by the Department of Defense (DOD), was adopted. This system empowers the requestor to identify if reported issues should be escalated to a CAPA. The resulting risk matrix allowed quantification of frequency of occurrence and severity of harm.

- Requestor will submit a CAPA plan request using REDCap Matrix
- Impacted groups immediately notified of request and determination (i.e., CQU and requestor)
- Identifies CQU's priority and review frequency

4. Outcomes

The implementation of the new CAPA Management process has vastly improved:

- CQU CAPA reviewers' confidence that CAPA requests meet the MCCCC CAPA plan requirements
- CAPA reviewers' effort as it allowed the requestors (i.e., study teams/department) to provide more information upfront

- Human error and subjectivity from the CAPA reviewers

The new process has also:

- Increased study teams' awareness
- Provided instantaneous determination and notification
- Promoted tracking of all CAPA requests
- Enabled reviews to determine trends and systematic glitches
- Standardized CAPA timelines
- Decreased hands-on time

5. Lessons Learned and Future Directions

To identify process improvements and educational opportunities, CQU and QMS will develop a satisfaction survey to be sent to teams. This will allow CQU to obtain feedback.

The REDCap system provides a PDF export documenting the entire review process and associated outcomes. This will allow for consistent messaging between study teams and sponsor inquiries.

CQU plans to build dashboards to visually identify trends.