



GLOBAL HEALTHCARE COMPANY, CHICAGO, IL

CASE STUDY

CAPA Management Improvement Process

Integrated Solutions



CAPA Management Improvement Process



Project Overview

A client was struggling with on-time batch release, missed CAPA closure deadlines, and a CAPA program that was difficult to manage due to the large volume of deviations and CAPAs being created. CAPA completion delays prevented the client from reaching organizational and financial goals, and product was not released on-time, which impacted their customer relationships and potentially impacted product availability.

Due to our experience and expertise, our team members knew that they could help the client not only understand their issues, but we could also provide methods to resolve the issues. A small team of experts worked to collect, trend, and understand the CAPA generation and completion process. CAI's knowledge of quality management systems, deviations/investigations, CAPA process, life science manufacturing, and human performance proved to be an asset.

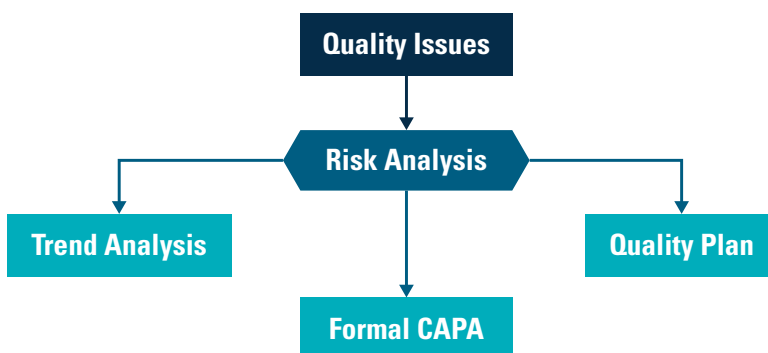
Challenge

The critical issue this client faced was the number of CAPAs that were being generated and the timely closure of each CAPA. The client knew they needed expert assistance and brought CAI in to help. The CAPA completion delays were the result of a larger problem and CAI's analytical approach helped the client view the "big picture" to understand what process and organizational issues needed to be addressed to meet the challenge of timely closure of CAPAs.



REAL RESULTS

Eliminated redundant CAPAs, categorized CAPAs to be able to close minor CAPAs quickly, increased on-time closure of CAPAs, and drove the amount of CAPAs down to a manageable level without compromising quality.



Operational Improvements



Solution

A holistic approach to this project was vital, so CAI experts from diverse backgrounds were utilized to examine the root-cause(s) for late CAPA closure from a multi-faceted approach.

These experts analyzed all open and closed CAPAs within a two-year time frame to categorize them, determine if there were redundant CAPAs, calculate average closure time, and study the client's established process and communication flows.

The analysis was completed through three lenses: *quality, process, and resources*. The data analysis uncovered the deeper root-causes. CAI collaborated with the client to remedy the data-driven issues and create long-term action plans to prevent recurrence in the problem areas.

After analyzing the data, metrics were identified to help the client measure their success in meeting their goals of (1) reducing the backlog of CAPAs, (2) reducing the amount of open CAPAs to less than 100, and (3) achieving a 75% on time CAPA closure, at a minimum.

The CAI team helped deliver these solutions shoulder to shoulder with the client's quality and manufacturing organizations. We helped establish processes, training programs, a scoring rubric, routine communication, and more. We introduced a "campaign mindset" to the site that included accountability, visibility, and training geared toward specific client goals. This campaign method provided a solid framework for sustained change moving forward.



BENEFITS FOR ALL

Reduced the amount of CAPAs generated and increased CAPA on-time closure rate so that production lots could be released on time and financial goals were met.

Operational Improvements



The team implemented the following changes to achieve this:

- Standardized forms for CAPA status updates, extension requests, and closure.
- Deleted or combined redundant CAPAs and eliminated non-value added CAPAs.
- Formal decision-making process for determining when a CAPA is required.
- Daily triage meeting, which was chaired by Quality and included investigators, owning department representatives, and SMEs.
- Transparent CAPA tracking on a company-wide information board.
- Updated CAPA review and approval process with a Quality review scoring rubric.

Results

CAPA backlog was reduced from over 200 and growing to a manageable level at around 100. The client achieved and sustained a greater than 80% on time CAPA closure – consistently exceeding the 75% goal. Our experts helped complete multiple changes to process and documentation. They also developed and implemented ongoing training and coaching for completing CAPAs. The site saw behavioral changes in CAPA owners, demonstrating a GMP culture that can sustain timely completion levels. Not only did this help the client meeting their financial goals, but the completion rate of open CAPAs continued to rise.



SOLUTIONS

Reduced CAPA backlog from over 200 and growing to a manageable number and increased on-time CAPA closure to > 80%