GLOBAL HEALTHCARE COMPANY, *CHICAGO, IL*

CASE STUDY

OPERATIONAL IMPROVEMENTS

Integrated Solutions

WHEN YOU NEED TO MEET A HIGHER STANDARD®

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Overview

CAI was brought in to help the site with on-time batch release. Due to our experience and expertise, our team knew that we could **help the client not only understand their issues,** but we could also **provide methods to resolve the issues.** CAI brought in a small team of experts to work alongside the client's team to collect, trend, and understand the error rates and deviation data. CAI's knowledge of quality, production process, and human performance proved to be a valuable asset, and our team stayed on site for an additional four months to sustain the implemented practices for long- term operational improvements.

Challenge

The critical issue this mature client faced was the timely release of product. While **release delays prevented them from reaching organizational and financial goals, the product was on the FDA's Drug Shortage List,** which raised the stakes and increased urgency for production and release. The client had an idea of where they needed to improve and brought us in to help with specific issues. Our team of experts captured and analyzed batch data to identify areas where the client's established process and communication flows prevented them from viewing the entire scope of challenges. Their areas of concern were a part of the overall problem, but they were unable to view the "big picture" to realize the process and organizational issues that needed to be addressed.

Solution

A holistic approach to this project was vital, so CAI provided experts from different backgrounds to address the root-cause issue with a multi-faceted approach.

REAL RESULTS

Achieved and sustained a threefold increase in on-time batch release, from 17% to 63%

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Our team evaluated the issue through three lenses: *quality, process, and human performance*. We weren't promising to simply help close deviations; we were going to collect data, analyze it, and trend it to determine what the deviation and error rates were truly illustrating. This allowed our team to uncover the deeper root-cause issues mentioned previously. Once we understood the data, we worked with the client to remedy the issues and create long-term action plans to prevent future issues in these same areas. After reviewing every batch record to create an extensive database, we then utilized heat maps to highlight troubled areas visually.

> *Heat maps represent data in the form of a graph or diagram in which data values are represented as colors. The variation in colors gives obvious visual clues to how the data clusters.*

We then viewed the heat map data by department, process, shift, and error type to understand the most pressing issues. Our team trended the data week over week, month over month, to see what the trends were illustrating both short- and long-term. After analyzing the data, several objectives were identified to help the client meet their goals. Primary goals included reducing the unreleased Batch Record backlog and then achieving a 40% on-time Batch release rate, at a minimum.

Our team identified three major areas for improvement to achieve this:

- Remove or reduce process and Batch Record flow bottlenecks through process and documentation changes
- Accelerate Manufacturing Quality Assurance (MQA) Batch Record reviews
- Reduce Batch Record error rates

To reduce error rates, our team:

- Coached manufacturing area supervisors and operators on on-floor GMP and operations
- Provided on-floor MQA supplement, process improvement, and coaching
- Delivered human performance best practice tools and training

BENEFITS FOR ALL

Helped the client meet their FDA commitments and realize an initial financial return of about $575,000 per month

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Our team helped deliver these solutions on the production floor, shoulder to shoulder with quality and manufacturing. We helped establish processes, training programs, a Continuous Improvement program, communication routine, and more. We introduced a "campaign mindset" to the site that included providing materials and training geared toward a specific goal. For example, the site needed a reset on how to review their work, so our team conducted training and practice that focused on this topic, educated supervisors on accountability, and created and posted flyers around the site with tips for reviewing work. This method for campaigns provided a framework for how to make a sustained change moving forward.

Result

Batch record backlog was reduced from over 200 and growing to a manageable, rotating level requiring investigation. The client achieved and sustained a threefold increase in on-time batch release, improving from 17% to 63% – consistently exceeding the 40% goal. The Manufacturing error rate of batch records reaching MQA was reduced by more than 60% and sustained at this reduction. Our team helped complete over 20 changes to process and documentation and implemented a cross-functional Continuous Improvement workshop routine. We also developed and implemented standards for shift routine, ongoing training, and coaching for continuous error control and accountability. The site saw behavioral change in Manufacturing and MQA demonstrating a GMP culture that can sustain timely productivity and release levels. Not only did this help the client meeting their FDA commitments, but the initial financial return was about $575,000 per month.

SOLUTIONS

Reduced batch record backlog from over 200 and growing to a manageable number requiring investigation

Completed over 20 changes to process and documentation