***CELL AND GENE THERAPY COMPANY*, NEW JERSEY**

CASE STUDY

Streamlined Deviation Process Flows

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Streamlined Deviation Process Flows

Why CAI?

A leading cell and gene therapy company needed to stabilize site operations and optimize site improvement activities. Specifically, the site sought to improve its deviation management program while reducing the time to release its critical product to patients. Due to previous engagements and successes with the client as well as demonstrated expertise in human performance, CAI was the best partner to lead this project.

Project Overview

CAI was tasked with improving deviation management, with a specific focus on aligning turnaround times with site objectives. Our approach began with a thorough assessment of the existing deviation process, coupled with operational oversight for the teams responsible for deviation management, initiation, and documentation. During this initial assessment phase, CAI's experts carefully examined the different stages within the deviation lifecycle, collaborating closely with stakeholders from relevant departments. This collaborative effort resulted in a clear outline of necessary data, actions, content, and responsibilities, ensuring adherence to procedures and regulatory mandates.

Through detailed process mapping, the CAI team uncovered communication gaps, identified redundant meetings, pinpointed avoidable bottlenecks causing delays, and evaluated the balance between value-added and non-value-added activities.

This analysis provided the CAI team the insight to develop an innovative workflow designed to expedite the resolution of low-level deviations, within a 24-hour timeframe. To ensure seamless integration, we conducted extensive training sessions, involving over 600 personnel, acquainting them with the new workflow and aligning their efforts with the overarching site objective.

CLIENT:

Confidential

LOCATION:

New Jersey, USA

TIME FRAME:

7 months

CONTRACT SIZE:

$1,575,620

Streamlined Deviation Process Flows

In the weeks that followed the implementation of the new workflow, we achieved a remarkable 73% reduction in the overall cycle time for low-level deviations. This substantial progress represented a significant stride toward realizing the site's ambitious goals. Simultaneously, streamlining workflows freed up valuable resources and shifted their focus to solutions that have a higher impact on patient safety.

Project Challenges

The project encountered a variety of intricate challenges requiring innovative solutions. These challenges included:

- Diverse Stakeholder Groups
- Misaligned Expectations Across Departments
- Unnecessary Process Steps and Workarounds
- Large Deviation-Writing Groups
- Conflicting Priorities
- Inexperienced Workforce

Addressing these challenges required a comprehensive approach that not only resolved process inefficiencies but also involved thorough training, clear communication, and efficient resource management to successfully implement improvements within the complex pharmaceutical environment.

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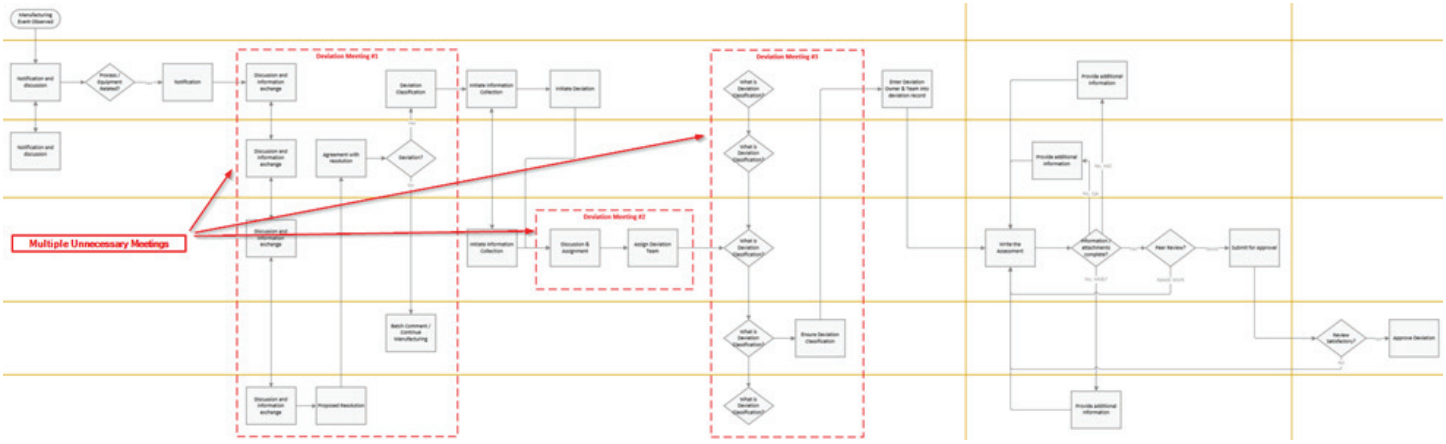
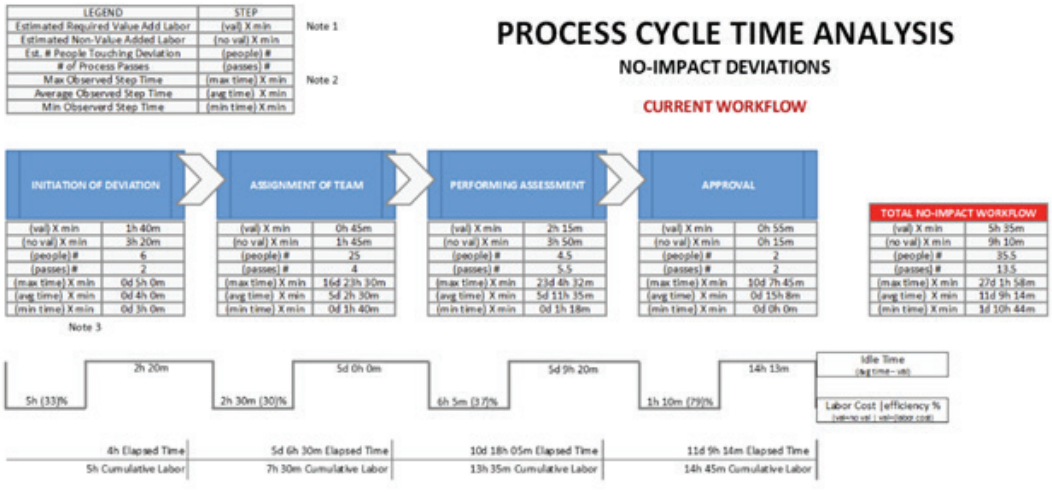
CAI Solutions

To overcome the numerous challenges in improving the deviation management program and optimizing the critical product release process, CAI introduced a comprehensive set of solutions based on industry best practices.

- **Process Refinement:** CAI began with a rigorous assessment of the existing deviation process, performing detailed process mapping to identify bottlenecks, communication gaps, and redundant meetings. This analysis served as the foundation for process refinement.





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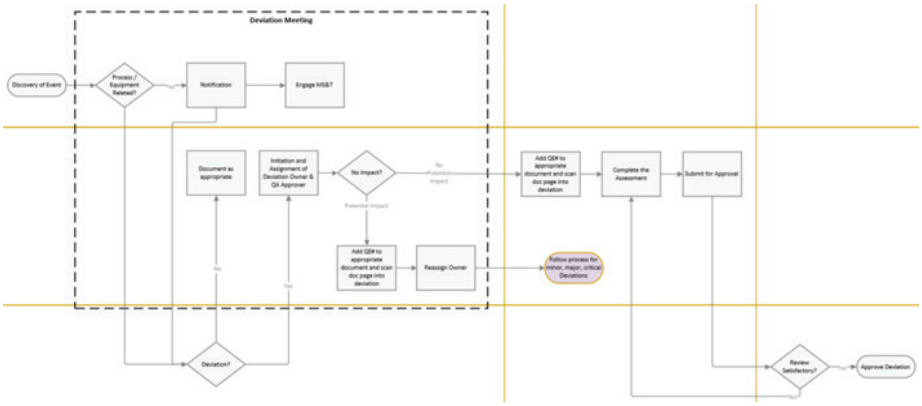
- **Innovative Workflow:** We devised an innovative workflow tailored to expedite the resolution of low-level deviations within a stringent 24-hour timeframe. This workflow not only enhanced efficiency but also bolstered compliance with regulatory requirements.



- **Stakeholder Alignment:** Recognizing the diverse stakeholder groups with distinct work expectations, CAI implemented a nuanced approach to process mapping. We worked closely with each group to align their expectations and streamline processes, fostering operational unity.
- **Coordination Enhancement:** Managing large deviation-writing groups was a complex endeavor. CAI introduced coordination mechanisms to ensure effective communication and collaboration within these sizable teams, overcoming logistical challenges.
- **Priority Management:** Conflicting priorities among organizational units were a recurrent issue. We implemented a prioritization framework to resolve scheduling clashes and facilitate productive discussions.
- **Training & Knowledge Enhancement:** Acknowledging the inexperienced workforce, CAI conducted extensive training sessions involving over 600 personnel. This comprehensive training not only addressed knowledge gaps but also ensured adherence to industry standards and cGMP regulations.

Project Success

The innovative new workflow produced a 73% reduction in the overall cycle time for low-level deviations following implementation. This substantial improvement expedited the resolution of deviations and aligned seamlessly with the overarching site objectives of reducing product release timelines. This marked a substantial leap towards achieving the site's ambitious objectives and enhancing the company's competitive position within the industry.

Streamlined Deviation Process Flows

One of the key successes of the project was the enhancement of compliance. CAI's solutions not only improved operational efficiency but also elevated compliance with regulatory requirements. The meticulous process refinement, coupled with the innovative workflow, ensured that deviations were not only resolved swiftly but also in a manner that adhered rigorously to industry regulations. This substantially reduced compliance risks, providing the company with a robust framework for maintaining the highest quality standards.

A critical aspect of the project's success was the significant improvement in stakeholder collaboration. By addressing the challenge of diverse stakeholder groups with distinct work expectations, CAI was able to foster an environment of operational unity. Stakeholders across the organization were now aligned in their approach, and processes were streamlined to accommodate their specific needs. This not only improved deviation management but also contributed to overall operational efficiency and cohesiveness within the organization.

Effective priority management was another noteworthy achievement. Conflicting priorities among various organizational units had been a recurring issue, leading to scheduling clashes and unproductive meetings. The implementation of a prioritization framework resolved these conflicts, resulting in more efficient scheduling and more productive discussions. This streamlined the deviation resolution process, further contributing to the project's success.

Moreover, the thorough training sessions brought about a profound transformation in the workforce. Numerous employees, who had limited prior exposure to the pharmaceutical sector and a less comprehensive understanding of current Good Manufacturing Practices (cGMP), experienced a substantial increase in their knowledge. This not only streamlined the implementation of changes but also guaranteed the long-term commitment to industry regulations.

CAI's holistic approach, rooted in process refinement, innovative workflows, stakeholder alignment, coordination enhancement, priority management, and comprehensive training, resulted in a successful project marked by substantial achievements. These successes aligned seamlessly with the client's site objectives, enhancing both operational efficiency and compliance within the intricate pharmaceutical landscape. The project exceeded expectations, positioning the cell and gene therapy company to enhance not only efficient deviation closure but also address various business aspects by leveraging the innovative tools and methods provided by CAI.