



ARE YOU READY?

OPTIMIZED OUTCOMES

ACHIEVING FASTER TIMELINES AND COST
SAVINGS THROUGH DIGITAL VALIDATION

CASE STUDY: DIGITAL TRANSFORMATION
AND HARMONIZATION



Optimized Outcomes

CAI works with many companies in early phase clinical trials for whom speed to patient is of the utmost necessity. Often such companies don't need a large internal validation department, and no special reason to maintain a robust validation program.

By deploying Project Ready, CAI was able to establish an in-house program for a Contract Development and Manufacturing Organization (CDMO) with standardized procedures and off-the-shelf content that can be immediately deployed on a project-by-project basis. For common systems, pre-approved templates can be used without even waiting for pre-execution review. As a result, projects can be initiated more rapidly, with document development times reduced or even eliminated in some cases. Using Project Ready on this project, CAI was able to achieve a 25% reduction in budget compared to traditional methods and accelerate the timeline for project completion.

PROJECT READY APPLICATIONS

- Commissioning & Qualification (C&Q)
- Equipment Validation

THE CHALLENGE

Slow and Difficult Project Initiation

Initiating projects within emerging companies and startups often presents unique challenges due to the lack of established validation processes that validation professionals typically rely on. Unlike large, established pharmaceutical companies, which have comprehensive global validation groups equipped with detailed standards and procedures, smaller entities frequently possess limited or no predefined validation frameworks. Consequently, each project necessitates the creation of a new project plan, approach, and protocol templates from scratch. Moreover, even when initial templates or examples are available, initial engagements with customers commonly lead to substantial modifications, necessitating multiple rounds of reviews before finalizing executable documents.

25%
Reduction in
Project Budget

COMPANY PROFILE:

- Emerging Contract Development and Manufacturing Organization (CDMO)
- Expertise in small to mid-scale commercial production
- Partners with innovative biotech and pharmaceutical companies



WHY PROJECT READY?

Easy to Implement, Easy to Understand, Easy to Use, Easy to Standardize

CAI's Project Ready harnesses the power of Kneat Gx, the leading digital validation platform, to enhance our service offerings. Our strategic partnership with Kneat not only enables us to swiftly implement robust, scalable validation processes that adhere to the strictest regulatory standards but also streamlines documentation and approval workflows. Through a dedicated Kneat instance, CAI provides customers with their own pre-validated workspace, complete with CAI's comprehensive template library, facilitating efficient project completion and delivering a seamless electronic turnover package.

Project Ready's ability to compartmentalize information and user access allowed CAI to develop standardized templates for common project functions and apply them on a project-by-project basis. This optimization facilitates quicker project initiations and enhances operational efficiency.

The following standardized content was approved by CAI quality before ever setting foot on the customer site:

- Pre-approved SOP for commissioning and qualification of new equipment.
- Pre-approved work instruction for how to do this for controlled temperature chambers (CTCs)
- Pre-approved verification checklists for the disposition of CTCs
- Controlled templates built around SOP for application to other systems.

Customers audit CAI's program and have no trouble adopting it because:

- Project Ready is powered by Kneat which is a well-established provider for its eVLMS platform
- The platform is acknowledged by the broader industry to comply with all relevant regulations for data integrity and electronic signatures.
- Easy to understand by the intended audience
- Access can be granted quickly without a significant training hurdle

RESULTS: SUCCESSFUL PROOF OF CONCEPT

Streamlining Validation for Enhanced Efficiency and Cost Effectiveness

CAI's implementation of its validation plan showcased remarkable efficiency by leveraging its pre-approved program, which quickly delineated the scope of equipment needing validation. This streamlined approach was particularly effective for controlled temperature chambers, where CAI's program allowed field execution of standard off-the-shelf protocols immediately upon approval of the validation plan, with minimal document development cost. This process significantly reduced the necessity for extensive document development, thereby lowering associated costs.

The foundation of CAI's method lies in its internally fully vetted program, pre-approved by in-house Quality, Compliance, and Regulatory specialists. This pre-approval meant that the customer could rely on CAI to manage the validation autonomously, enabling their personnel to remain focused on other critical duties without the distraction of ongoing project management issues. This efficiency was pivotal when it came to the field execution phase, where CAI's team promptly uncovered and addressed several critical issues with the equipment. Notably, multiple freezers were discovered to be unable to maintain the required temperature range. Identifying these problems early allowed for timely corrective measures that were essential for keeping the project on schedule.

FINANCIAL IMPACTS

From a financial perspective, CAI's utilization of Project Ready significantly impacted the financial and operational aspects of the entire project. CAI's approach yielded substantial savings, cutting document development expenses by nearly 25% compared to traditional validation methods. By utilizing Project Ready, CAI completed the project with a budget that was 57% less than competitor firms, demonstrating significant cost efficiency and value.

The timeline for completion was also significantly accelerated. Initially scheduled for completion in January 2025, the swift progression of the project led the customer to request an expedited finish by the end of August 2024. Despite facing potential delays from calibration issues, equipment failures, and late deliveries of assets, CAI completed the main field work by mid-July 2024. The remaining tasks, including document closeout and the resolution of minor pending issues, were finalized by early August 2024.

Through this project, CAI not only demonstrated its ability to execute validation plans efficiently but also affirmed its capability to manage complex projects under tight deadlines and budget constraints. Using Project Ready, CAI was able to exceed customer expectations on price and schedule, quickly identify and resolve issues, and achieve operational readiness. This approach ensured client satisfaction and underscored CAI's commitment to delivering high value and robust performance in every aspect of their service.





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