



ARE YOU READY?

VALIDATION AS A SERVICE MODEL

CASE STUDY: DIGITAL TRANSFORMATION
AND HARMONIZATION



Validation as a Service Model

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 especial reason to maintain a robust validation program.

By deploying Kneat, CAI was able to establish an in-house program 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.

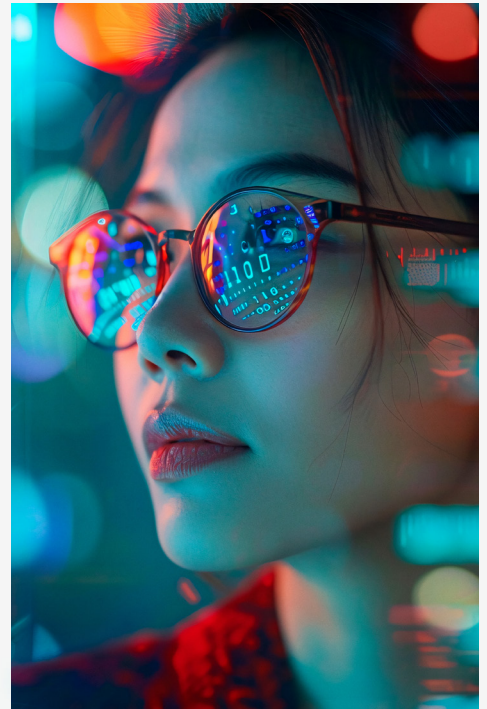
THE CHALLENGE

Slow and Difficult Project Initiation

Often when working with small companies and startups, there exists little or nothing in the way of what validation professionals are accustomed to existing a priori of project initiation. Large established drug companies have global validation groups with detailed standards and procedures for how to do this work, while small and medium sized companies usually have much less, or even nothing, in this regard. As a result, every project requires the development of a new project plan, approach, protocol templates, etc. Even when the project team starts with existing examples or templates, first contact with customers usually results in significant changes and several rounds of review before executable documents are available.

COMPANY PROFILE:

- Over 800 employees worldwide
- Supports thousands of life sciences projects each year
- Around \$160M USD Annual Revenue
- Kneat partner since 2022





WHY KNEAT GX?

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

Kneat'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. 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:

- Kneat 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.
- Kneat is easy to understand by the intended audience
- Access can be granted quickly without a significant training hurdle

RESULTS: SUCCESSFUL PROOF OF CONCEPT

Application of the Validation as a Service Model to a Small CDMO

The Validation Plan took minimal time to generate, as it simply referenced CAI's pre-approved program and identified the equipment in scope. In addition, for controlled temperature chambers, CAI's program allowed field execution of standard off-the-shelf protocols immediately upon approval of the validation plan, with minimal document development cost.

By virtue of a fully vetted internal program, with deliverables pre-approved by internal Quality, Compliance, and Regulatory specialists, the customer was able to treat CAI as a "fire and forget" solution, allowing their staff to focus on their other duties and minimize distractions during the project timeline.

Major Win

**30% Reduction
in Project Budget**

CAI was able to immediately begin field execution, which resulted in the rapid identification of several equipment issues that needed to be addressed. In particular, a series of freezers were found to be unable to consistently achieve the required temperature range. This required long-lead corrective action that could not have been accomplished within the project schedule if execution had been delayed.

Project Results

- CAI was able to minimize document development costs, saving roughly 20-30% of project budget as compared to traditional approaches.
- CAI completed its scope of work under budget and ahead of schedule: Other firms NOT using Kneat quoted over \$400k for this project's scope. However, CAI quoted 220k, and all work was completed for under \$170k.
- Original schedule called for work to be completed in January 2025. Once execution began and the customer saw the potential for schedule advancement, they asked if all work could be completed by the end of August 2024. Field work was substantially completed by mid-July 2024, with document closeout and punch items being addressed by early August. This included delays for calibration, equipment failures, and late asset deliveries.

Kneat empowered CAI to exceed customer expectations on price and schedule, identify and resolve issues early, and achieve operational readiness.





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