ARE YOU READY?

WHEELER BIO, *OKLAHOMA CITY, OH, USA*

CMO VALIDATION AS A SERVICE MODEL

CASE STUDY: DIGITAL TRANSFORMATION AND HARMONIZATION

CMO Validation as a Service Model

PROJECT OVERVIEW

In 2023, CAI helped Wheeler commission and qualify its OKC CDMO facility. The facility was completed on time and on budget, and was a finalist for the 2024 ISPE Facility of the Year award.

In early 2024, Wheeler issued a Request for Pricing on CQV services around a set of special equipment needed for a specific campaign. The budget and timeline were tight, and controlled by the client's end customer. CAI presented an approach that was aggressive on cost by using its Validation as a Service (VaaS) model as a basis, which offered a price point that was roughly 50% of any competitor and offered the opportunity to accelerate the timeline.

The scope of work included a Project C&Q Plan and qualification of a series of CG&T process equipment including single use bioreactors, freezers, incubators, a cold room, and floor centrifuges. The objective was to have all equipment qualified for use on a Phase 3 Clinical production campaign scheduled to begin in the first quarter of 2025. Field verification activities were substantially completed five months ahead of the original project schedule.

CLIENT:
Wheeler Bio

LOCATION:
Oklahoma, OH

TIME FRAME:
~3 months

CONTRACT SIZE:
~$200K USD

CLIENT CHALLENGES

This project required an extremely lean but compliant approach. Wheeler operates on extremely low overhead with no internal validation group, and needed a team they could trust to do the work correctly without significant oversight. In addition, much of the equipment was owned by Wheeler Bio's end customer. CAI had to demonstrate our abilities, not only to Wheeler, but also the owner of the assets with whom CAI had no direct contact.

CAI was able to minimize or zero out normal document evelopment costs, save roughly **20-30%** of project budget as compared to traditional approaches, and start field testing **immediately!**

CAI SOLUTIONS

CAI executed the project using the VaaS model which included the application of existing CAI SOP's, approved by CAI internal QA, as a basis for execution. CAI's program was audited by Wheeler and accepted as a basis. As a result, the Validation Plan took minimal time to generate, as it simply referenced that 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 zero document development cost.

By virtue of a fully vetted internal program, with deliverables pre-approved by internal Quality, Compliance, and Regulatory specialists, the client 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.

PROJECT SUCCESS

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, the freezers were found to be improperly assembled by the vendor in some cases, and in all cases 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.

Once execution began and Wheeler Bio saw the potential for schedule advancement, they asked if all work could be completed by the end of August 2024. Despite various delays for calibration, equipment failures, and late asset deliveries, field work was substantially completed by mid-July 2024, with document closeout and punch items being addressed by early August.

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