ARE YOU READY?

GLOBAL HEALTHCARE COMPANY, *CHICAGO, ILLINOIS*

LABORATORY EQUIPMENT QUALIFICATION PROCESS

CASE STUDY: COMPLIANCE & REGULATORY ISSUES

Laboratory Equipment Qualification Process

PROJECT OVERVIEW

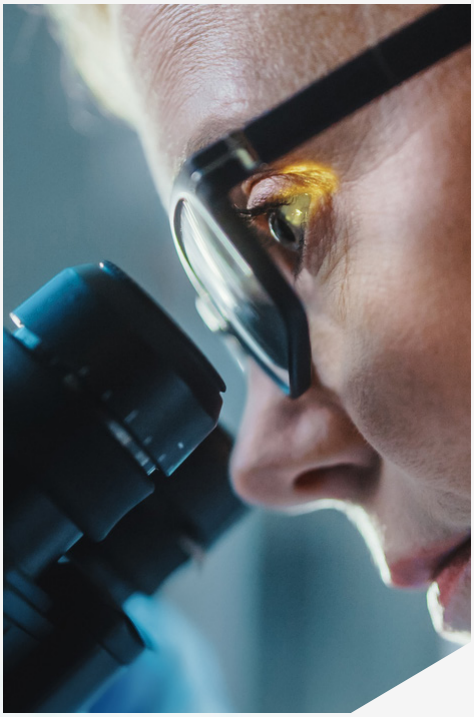
A client was upgrading their laboratory for a new product release. Due to CAI's experience and expertise, our team members knew that they could not only help the client determine what laboratory equipment was needed for their process, but we could also provide resources for the equipment qualification and to create the required operational and maintenance procedures, all in a timely manner. A small team of experts worked with the client to assess the types of required testing for both in-process and final release, and then determine the necessary types of equipment needed with the appropriate precision. CAI's knowledge of laboratory equipment and regulatory standards for validation and testing were pivotal in this situation.

CHALLENGES

The critical issue this client faced was generating the appropriate documentation to determine what equipment was needed and the required accuracy and precision. Once that was completed, the lab equipment were ordered. The client knew they needed expert assistance to help coordinate and execute all the laboratory equipment deliverables and brought CAI in to help. Our team of experts managed the project from start to finish, identified the deliverables, and scheduled all the work to be completed in a timely manner.

REAL RESULTS

This project was managed and Executed from start to finish CAI, on timeand within budget, which allowed the client to focus on other needs.



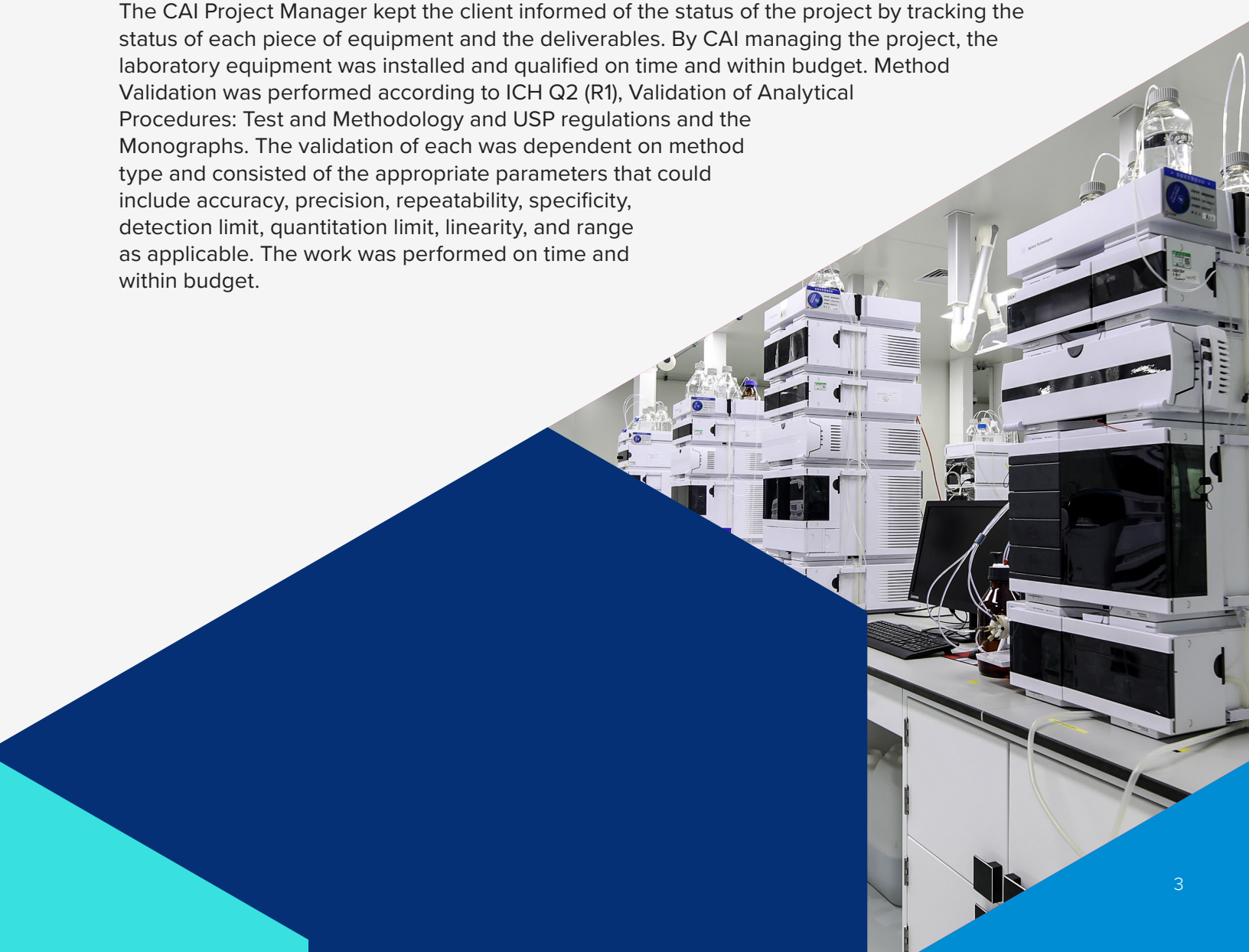
SOLUTION

A holistic approach to this project was vital, so CAI experts with project management and laboratory equipment knowledge and regulations were utilized to manage the project. This included generating equipment user requirement specifications, qualification protocols and reports, operational and maintenance SOPs, as required by USP 1058; Analytical Instrument Qualification and FDA regulations. At the completion of the work, which met all regulatory requirements, the client extended the CAI scope of work to include methods validation.

CAI SME experts evaluated the project through three lenses: quality, deliverables, and timing of equipment availability. We did not promise to simply help qualify the equipment; we managed the project, tracked the delivery of the equipment, obtained manuals for the generation of SOPs prior to the receipt of the equipment, and liaised with the equipment vendors/manufacturers to install and qualify the equipment. CAI provided full support to allow the client to focus on other urgent matters.

After reviewing the list of the laboratory equipment and delivery dates, the team was able to prioritize document deliverables. By obtaining the equipment manuals prior to receipt of the equipment, we were able to generate the operational and maintenance SOPs as well as the DQ, IQ/OQ and PQ protocols prior to the arrival of the equipment, which allowed the aggressive timeline to be met.

The CAI Project Manager kept the client informed of the status of the project by tracking the status of each piece of equipment and the deliverables. By CAI managing the project, the laboratory equipment was installed and qualified on time and within budget. Method Validation was performed according to ICH Q2 (R1), Validation of Analytical Procedures: Test and Methodology and USP regulations and the Monographs. The validation of each was dependent on method type and consisted of the appropriate parameters that could include accuracy, precision, repeatability, specificity, detection limit, quantitation limit, linearity, and range as applicable. The work was performed on time and within budget.



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