



CONFIDENTIAL, CA, USA

CASE STUDY

QC Lab

Program & Project Management





Project Overview

A confidential client has an 88,000 square foot greenfield building designed to support multiple biotech manufacturing buildings and processes at the site. The QC Lab is a three story facility with lab and office spaces on each floor. Some labs are qualified Grade D, while others are Grade F. The labs are designed to Biosafety Level 2 requirements, where applicable. The building receives electrical power, plant steam, instrument air, chilled water, and potable water from the site and generates clean steam and purified water for use within the building. The building has been designed to meet LEED standards in achieving LEED Gold Certification.

Objective

Project objectives include consolidating the quality control laboratory operations on the site into one facility and operate as one organization. The project requires start up, transferring and qualifying all laboratory analysis, and performing analytical analysis, all while maintaining the currently facilities operations. Once all methods are fully qualified in the new building, the existing facilities will be decommissioned under another project.

Services Provided

- Coordinated the efforts of Customer Stakeholders, Design Team, and Construction Team
- Defined project scope and associate project budget
- Developed Request for Proposals (RFP's), led the interview process, and received customer approval for subcontractors for the following C&Q tasks:
 - **Facility and Utilities:** 43 building and utility systems including HVAC, purified water, clean steam, autoclave, two glassware washers, depyrogenation oven, two isolators, and laboratory gases.
 - **Analytical Instruments:** 88 instruments supporting chemistry, raw materials, environmental monitoring, and other analyses and methods supporting biotech operations.
 - **Laboratory Equipment:** 169 supporting lab equipment items, including biosafety cabinets, fume hoods, microscopes, centrifuges, etc.



CLIENT:

CONFIDENTIAL

LOCATION:

CALIFORNIA, USA

TIME FRAME:

UNKNOWN

CONTRACT SIZE:

UNKNOWN



Services Provided (Continued)

- **Controlled Temperature Environments:** 154 refrigerators, freezers, incubators, and ovens.
- **Integrated Technology Systems:** building automation system, supervisory control and data acquisition system, REES system (monitoring system for CTE's), and 120+ LIMS system computers, printers, and scanners.
- Supervised the Project Scheduler and provided direction in establishing and maintaining the projects schedule
- Established project tools for tracking budgets, progress, and earned value
- Established project procedures for managing documents, quality, etc.
- Supervised and coordinated the day-to-day operations of subcontractors
- Established and implemented the project's safety program
- Managed budgets and scope changes

Project Success

The CAI team has had to overcome several major challenges, including a four month delay in construction, six month delay in automation system delivery, redesigns of several facility systems, major revisions to the Client's SOPs, implementation of a data integrity initiative requiring significant changes to lab procedures, equipment failures during testing, and analytical instruments that are not like-for-like replacements for existing methods. Despite these challenges, the project team met the target date for achieving the qualification/method verification of the 1st analytical method, and are on track to deliver the project as scheduled.

