



CONFIDENTIAL, GA, USA

CASE STUDY

PCR Lab

Program & Project Management



PCR Lab



Project Overview

The PCR lab at the client's facility had previously been used for research purposes only. The decision was made to move the lab to a newly re-modeled space at the facility; therefore, making the lab GMP compliant. There were delays early on due to Project definition and management issues. CAI was requested to assist in Program & Project Management (PPM) of the project to complete instrument qualification and meet timelines for submittal to the FDA.

Objective

The objective was to lead the team through qualification of the PCR lab, while tracking and maintaining scope, schedule, and budget in order to submit to FDA on-time.

Services Provided

- Created integrated schedule for PCR lab installation, method validation, and regulatory submission
- Organized and ran daily war room/communication meetings for CAI and client staff to facilitate timely accomplishment of project deliverables
- Organized and ran weekly communication meetings to steering committee and client's upper management
- Coordinated with client's regulatory team for drafting of CB-30 submission
- Tracked the budget for the overall PCR project
- Identified and appropriated escalation of PCR project issues for resolution
- Prepared and presented "Lessons Learned" presentation for client's corporate management team

Value Delivered

The project was successfully completed within the original budget. The schedule was extended approximately two months due to early management issues. The project was successfully completed and the submission was drafted for regulatory department. Due to the success of this project, CAI was requested to submit a proposal for project management of a method transfer from Dublin to Argentina.



CLIENT:

CONFIDENTIAL

LOCATION:

GEORGIA, USA

TIME FRAME:

4 MONTHS

CONTRACT SIZE:

\$85.6K