***CONFIDENTIAL CLIENT,* GLOBAL**

CASE STUDY

Biotechnology Manufacturing Program Management

Program & Project Management

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Biotechnology Manufacturing Program Management

Project Overview

A global biotechnology manufacturing company was executing several interrelated projects of strategic importance to its global supply chain at one of its manufacturing facilities. The projects included qualification of two manufacturing trains as well as the associated regulatory submission preparations required to commercialize the products manufactured on both trains. Site resources were shared across the multiple project activities as each project had aggressive and compressed timelines. The project activities targeted corporate financial commitments as well as product development/commercialization commitments with partner companies. The client encountered schedule challenges due to technical issues and resource constraints.

Objective

CAI was asked to analyze all the interrelated activities and clearly define the interdependencies and resource requirements. This involved examining projects on both manufacturing trains, activities required in preparation to submit for regulatory inspection, projects required to accelerate the production rate, and projects related to small capital improvements at the site. As an outcome of the analysis, CAI provided recommendations that would help the site achieve all the critical project outcomes and honor schedule and financial commitments.

Services Provided

- Program and project management consulting services to analyze the project plans and implement solutions to achieve the site's goals
- Human performance services to analyze the batch record generation and review process and lead improvements to reduce the processing time and the backlog
- CQV services to plan, coordinate, and execute cleaning validation on one manufacturing train
- CQV services to plan, coordinate, and execute qualification on one manufacturing train
- Quality compliance services to drive inspection readiness activities

CLIENT:
CONFIDENTIAL CLIENT

LOCATION:
GLOBAL

TIME FRAME:
1 YEAR

CONTRACT SIZE:
$5 MM

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Value Delivered

CAI conducted a thorough review of all the cross-functional activities ongoing at the site. This involved discussions with engineering, validation, quality assurance, quality control, technical operations, manufacturing, supply chain, and site leadership. CAI's expertise in understanding operations, engineering, quality, and other site functions at a biotechnology manufacturing site enabled a robust analysis of the situation. This expertise allowed CAI to ask intelligent questions and understand the context of the answers. CAI's proficiency and experience with planning sessions, workshops, visual scheduling tools, and organization of resources and tasks were utilized in understanding the situation and developing appropriate recommendations.

- CAI developed and presented recommendations to site leadership and senior leadership, which laid out the actions necessary to achieve the site's critical goals. CAI's experience in pharmaceutical manufacturing allowed a discussion between CAI and the client's senior leaders to be conducted as a partnership conversation instead of a traditional consulting presentation. CAI managed these conversations as an owner, invested in project success, not a third party without any skin in the game. Because of this, CAI helped to transform and increase the site's confidence that the critical deadlines could be met. Previous consultants and experts from other companies had not been able to achieve this result. CAI's recommendations were adopted and implemented.
- CAI approaches all its consulting work with this same spirit of partnership and collaboration. It is our mission to help you achieve your critical goals.