



CONFIDENTIAL CLIENT, GEORGIA, USA

CASE STUDY

Full-Scale Operation Services for Blood Fractionation

Program & Project Management



Full-Scale Operation Services for Blood Fractionation



Project Overview

CAI partnered with a leading blood fractionation manufacturer and utilized an FSO approach during the design, construction, and commissioning phases of their new \$2B greenfield blood fractionation plant in Georgia, USA.

Project

CAI led an integrated project delivery system through accelerated milestones, delivering on time and within the approved budget. Additionally, CAI helped develop a safety-first culture, reaching almost one million safe man-hours during the start up and commissioning phases of the project.

People

CAI helped to establish a culture of sustainable operations by supporting human performance roles, such as training operators in the proven principles of monitoring operating equipment for trends which can indicate problems. The team established a robust human performance system, focusing on areas such as plant operator skills enhancement, SOPs, training, and other tasks to reduce operational risks.

Process

CAI helped author and implement the Site Validation Master Plan, establishing an efficient process for verifying that manufacturing systems were fit for intended use and that risks to product quality and patient safety were effectively managed. An ASTM E2500 approach to qualification was employed, ensuring the satisfaction of critical parameters and attributes.

Facility

In order to achieve the initial operational readiness of the facility, CAI focused on physical equipment, providing support in areas such as alarm management, equipment and operational trouble-shooting, redesign, spare parts identification and analysis, supply chain readiness, maintenance job plan development, and other tasks. CAI worked to develop methods for the optimization of maintenance planning and execution to extend timeliness between shutdowns or eliminate them altogether.

Quality

Quality management was employed throughout the project at the organizational level to meet project goals. BioVoke eVLM, CAI's GMP Information Management System, was used to manage and track information, and was a significant factor contributing to the success of the project. Discrepancies and punch list items that were uncovered during startup were managed and tracked in BioVoke.



CLIENT:
CONFIDENTIAL

LOCATION:
GEORGIA, USA

TIME FRAME:
4 YEARS

CONTRACT SIZE:
\$40 MM