***CELL & GENE COMPANY,* CALIFORNIA, USA**

CASE STUDY

Assessment and Execution

Operational Readiness

WHEN YOU NEED TO MEET A HIGHER STANDARD®

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Assessment and Execution

Why CAI?

A Cell Therapy Company is building a manufacturing facility in Newark, CA to produce novel CAR-T therapeutic products and sought an Operational Readiness partner with expertise in Cell & Gene Therapy facilities and CAI was selected.

Project Overview

Allogenic C&GT company built a manufacturing facility in Newark, CA to produce novel allogeneic CAR-T therapeutic products for the treatment of blood cancers and solid tumors. The facility consists of 105,000 sq. ft. of office, quality control labs, warehouse, and cGMP bio-pharmaceutical manufacturing space. The project goal was to achieve clinical manufacturing operations by September 2021.

Client Challenges

The client was a startup company, this brought many challenges around availability of key resources, limited budget, and aggressive schedules. Most significantly, COVID restrictions impacted the schedule and availability of resources.

CAI Solutions

- Executed CQV activities for utilities, facilities, process equipment (e.g., Robotic Filler and Isolator), QC washer and autoclave.
- Developed an engineering change management solution.
- Procedures were developed for Process & Utilities Equipment in the CAR-T Suites.
- Integrated Operational Readiness Master Plan was implemented for all workstreams.
- Implemented Operational Readiness Dashboards for all workstreams.
- Implemented project controls to maintain project budget & schedule.

CLIENT:
CONFIDENTIAL

LOCATION:
NEWARK, CA, USA

TIME FRAME:
2 YEARS

CONTRACT SIZE:
$3.2 MM

Assessment and Execution

Project Success

CAI developed and managed the integrated schedule: General Contractor for Facility fabrication, Manufacturing, Supply Chain, Validation, Quality Assurance & Quality Control for Operational Readiness. This schedule was the master plan to meet client's need of having the facility ready for Clinical Manufacturing operations in September 2021. We utilized risk based (ISPE Baseline Guide 5, 2nd Edition) CQV approach to accelerate the Operational Readiness schedule by 2 months.

CAI facilitated multiple OR workshops leading to an integrated schedule and reporting dashboards which kept the project team up to date at a glance. The team was able to quickly respond to challenges and keep the project moving forward with the timely information provided.

The project goal was met to achieve clinical manufacturing operations by September 2021.