



ARE YOU READY?

# BIOTECH PLANT SCALE-UP SUPPORT SUMMARY

CASE STUDY: WORKFORCE DEVELOPMENT



# Biotech Plant Scale-up Support Summary

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The CAI team utilized our operational readiness (OR) approach to provide a wide range of support for a client who was on a challenging timeline sufficient but tightly managed budget to scale up their plant from lab-centric production to commercial site production.

CAI's Manufacturing Process experts developed a tech transfer plan for the scale-up, while our CQV-experienced team led the equipment and utility qualification, including project planning, development of dozens of URSSs, and the development and execution of over 50 qualification documents.

CAI's OR consultants guided the client through an OR workshop – setting the project objectives, milestones, timelines and primary activities integrating this readiness roadmap across multiple functions.

In addition, CAI's operations and quality specialists drafted over 80 procedures for manufacturing, quality, labs, supply chain, and EH&S. In parallel, this CAI team worked closely with the client SMEs to prepare the site for scaled-up manufacturing by mapping the new processes, then using these scaled process maps to develop a role-based staffing plan and production schedule.

The CAI team's expertise and experience with operational readiness for new biotech manufacturing sites helped the client achieve a successful startup and subsequent larger scale production. The site's director of manufacturing and project manager both praised CAI for our diligence, stating that they would not have met their goals in such a timely manner without the CAI team.



# CAI's Operational Readiness Support for New Production Site

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Facing an aggressive timeline and a tightly managed budget, the client needed to scale their operations from lab-scale production to full commercial manufacturing. CAI leveraged our proven Operational Readiness (OR) approach to provide comprehensive, integrated support across multiple disciplines:

## **MANUFACTURING PROCESS EXPERTISE**

Developed a comprehensive tech transfer plan to guide the production scale-up.

## **CQV LEADERSHIP**

Led equipment and utility qualification efforts, including project planning, authoring the URSs, then developing and executing over 50 qualification documents.

## **OPERATIONAL READINESS ROADMAP**

Conducted an OR workshop to define project objectives, milestones, timelines, and key activities, creating an integrated readiness plan across all site functions in support of the client's internal PMO.

## **PROCEDURE DEVELOPMENT**

Authored over 80 SOPs covering manufacturing, quality, laboratories, supply chain, and EH&S.

## **STAFFING & PRODUCTION PLANNING**

Collaborated with client SMEs to map scaled-up processes and used these to build a role-based staffing plan and initial production schedule.

CAI's depth of operational readiness and startup expertise was an essential factor in the successful site launch and timely scale-up to commercial production. Leadership from the client's manufacturing and project management teams praised CAI's diligence and support, emphasizing that meeting their aggressive goals would not have been possible without the CAI team.



**ARE YOU READY?**

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