



ARE YOU READY?

LIFE SCIENCES COMPANY, AUSTRALIA

OPERATIONAL READINESS & GMP ENABLEMENT

CASE STUDY: OPERATIONAL READINESS



Operational Readiness & GMP Enablement

OVERVIEW

CAI supported the operational readiness of a clinical and commercial-scale cell and gene therapy CDMO transitioning from a non-GMP environment to a fully GMP-ready facility. The engagement focused on Validation, Process Engineering, MSAT, Quality Assurance, and the development of a comprehensive Contamination Control Strategy to accelerate GMP compliance and enable advanced therapy manufacturing.

SCOPE OF WORK

CAI rapidly deployed a multidisciplinary team of 12 who embedded directly with the client's own staff, delivering an integrated Operational Readiness program spanning Validation, Process Engineering, MSAT, Quality Assurance, Computer System Validation, documentation development, and contamination control. This enabled the accelerated implementation of robust systems, processes, and risk-based frameworks across QC laboratories, production operations, and supporting functions, advancing their path toward full GMP compliance.



VALIDATION & CQV

CAI authored and executed full lifecycle validation documentation for QC and production equipment, ensuring all systems met regulatory and operational requirements. The team qualified critical laboratory and manufacturing assets to establish a compliant foundation for GMP operations.

PROCESS ENGINEERING & MSAT:

CAI supported the development of the client's process control strategy by facilitating upstream and downstream FMEAs and conducting sterile filtration and aseptic handling risk assessments. The team drafted PPQ templates and provided process insights during engineering runs to support optimisation and readiness for GMP operation.

COMPUTER SYSTEM VALIDATION & DATA INTEGRITY

CAI executed CSV activities for Bioreactor software and aligned system controls with Annex 11 and GAMP5 expectations. The team also developed their Data Integrity Plan, implementing ALCOA+ principles and audit-ready digital governance processes.

QUALITY ASSURANCE & DOCUMENTATION

CAI reviewed validation documents, released raw materials for GMP use, and authored or revised SOPs supporting validation and operational workflows. More than 220 documents were updated or transformed into commercial-ready formats to strengthen their documentation framework.

CONTAMINATION CONTROL STRATEGY (CCS)

CAI developed core CCS elements, including HACCP analyses, CCS FMEAs, and CCS SOPs. This work established a risk-based contamination control framework that integrates facility design, operational practices, and environmental monitoring.

CHALLENGES & ACHIEVEMENTS

The client required multiple validation, documentation, and risk-management workstreams to be delivered in parallel while the facility transitioned rapidly toward GMP compliance. CAI addressed these challenges by providing flexible, technically experienced resources who integrated seamlessly with their teams to resolve documentation gaps, accelerate equipment qualification, and strengthen quality and operational governance.

CAI successfully completed full lifecycle qualification for a wide range of QC and manufacturing equipment, established foundational CCS and FMEA frameworks, and standardised validation and method-validation documentation. The team improved audit readiness by addressing deviations, NCRs, and CAPAs, and delivered a robust Data Integrity and CSV foundation. These achievements positioned the client for timely progress toward GMP operation and future regulatory inspection.

OUTCOME

CAI's ongoing Operational Readiness support is enabling them to establish the systems, processes, and compliance foundation required for GMP viral vector manufacturing. Through deep validation expertise, risk-based process engineering, robust documentation, and comprehensive quality oversight, CAI is helping them prepare for regulatory inspection, clinical supply, and future commercial-scale viral vector production.



ARE YOU READY?

+1 317-271-6082
CAIREADY.COM

©2026 CAI. ALL RIGHTS RESERVED.