ARE YOU READY?

LIFE SCIENCES COMPANY, AUSTRALIA

VACCINE FACILITY COMMISSIONING & VALIDATION

CASE STUDY: ASSET MANAGEMENT & DELIVERY

Vaccine Facility Commissioning & Validation

OVERVIEW

CAI partnered with a leading biopharmaceutical company to help bring a new mRNA vaccine manufacturing facility online. The facility was developed in response to global health needs, ensuring national vaccine security and building long-term biomanufacturing capability.

SCOPE OF WORK

CAI's scope encompassed the full technical lifecycle of the new facility — integrating engineering, CQV, asset management, and operational excellence. By operating across all major manufacturing areas and utilities, CAI ensured the systems were brought online safely, compliantly, and in alignment with global standards.

FACILITIES & ASSET MANAGEMENT

CAI established a fully integrated asset and maintenance ecosystem for the new facility, including:

- Deployment and configuration of Maximo to align with the client's global standards
- Development of asset hierarchies, criticality assessments, and preventive maintenance strategies
- Creation of fixed asset registers and compliance frameworks
- Establishment of a complete spare parts store — from cataloguing and stocking through to supplier onboarding, procurement workflows, and inventory governance

This solid operational foundation allowed the client to commence manufacturing with a compliant, reliable, and fully digitalized asset management platform.

124
Air flow test cases completed (up from 63)

188
Validated videos generated from AVS program

$100K
Value recovered through WFI vendor remediation

100%
GMP critical equipment validated before launch

PACKAGING & FILLING OPERATIONS

CAI led the full commissioning, qualification, and validation of the Packaging Line, coordinating with multiple international vendors across Europe, the United States, and Asia. Key responsibilities included:

- Coordination of FAT and SAT activities across global vendor sites
- Managing logistics, installation sequencing, and integration with site utilities
- Developing and executing IQ, OQ, and PQ protocols
- Aligning extensive vendor documentation into digital validation systems
- Creating SOPs, troubleshooting guides, and alarm response protocols
- Supporting operator readiness to ensure seamless transition to routine production

CAI's structured vendor management approach minimized delays, reduced documentation rework, and ensured a fully qualified packaging line aligned with global standards.

CAI also supported installation, qualification, and readiness activities for an additional filling line, including engineering fills and integration with downstream packaging flows.

VALIDATION & CRITICAL EQUIPMENT COMMISSIONING

CAI delivered comprehensive validation and commissioning services across critical GMP equipment and utilities, providing the technical expertise required for a greenfield biomanufacturing facility. Activities included:

- Full lifecycle qualification of autoclaves and parts washers (FAT, SAT, IQ, OQ, PQ)
- Development of detailed validation master documents, including matrices, risk assessments, testing plans, and traceability tools
- Execution of commissioning and qualification for controlled temperature units, environmental monitoring systems, CIP/SIP systems, and facility utilities
- Authoring and executing deviation investigations, impact assessments, and corrective actions to maintain validation continuity
- Leading cross-functional review cycles to ensure alignment between engineering, QA, CQV, digital systems, and operations
- Managing vendor performance, resolving documentation gaps, and coordinating technical clarifications to minimise rework
- Establishing spare parts lists and maintenance requirements to ensure validated state is maintained post-handover

CAI's deep validation expertise ensured that all equipment and systems met regulatory expectations and were ready for inspection and commercial operation.

WFI SYSTEM OVERHAUL & VALUE RECOVERY

CAI project-managed a full overhaul of the site's Water-for-Injection (WFI) system, addressing design deficiencies, reliability risks, and compliance concerns. The work included:

- Root-cause analysis and documentation of long-standing performance issues
- Managing mechanical repairs, component replacements, reconfiguration works, and requalification
- Challenging the original equipment supplier based on technical findings
- Recovering $100,000 in value for the client through vendor remediation

AIR FLOW VISUALISATION STUDY (AVS)

Conducted one of the largest AVS programs in Australia, expanding from 67 to 124 test cases, generating 188 validated videos. Coordinated cross-functional reviews and achieved regulatory approval.

CHALLENGES & ACHIEVEMENTS

CAI navigated evolving scopes, vendor delays, and tight documentation timelines — all while maintaining delivery speed and quality. The team's flexibility and technical depth cemented CAI's role as a trusted partner and established a benchmark for future biomanufacturing projects in the region.

OUTCOME

CAI's work was instrumental in achieving operational readiness for the facility — strengthening pandemic preparedness and positioning the client as a leader in biomanufacturing.

ARE YOU READY?

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