ARE YOU READY?

LIFE SCIENCES COMPANY, US, UK, SINGAPORE

VACCINE FILL LINE OPERATIONS

CASE STUDY: OPERATIONAL READINESS

Vaccine Fill Line Operations

CLIENT HISTORY

CAI has a longstanding and positive relationship with this life sciences company, a global leader in life sciences, clinical research, and biotechnology. The client is recognized worldwide for its comprehensive portfolio, which includes analytical instruments, laboratory equipment, clinical development solutions, specialty diagnostics, and pharmaceutical services.

Over the years, CAI has successfully partnered with the client on multiple projects, consistently delivering high-quality outcomes that align with their operational and compliance goals. These engagements have helped strengthen CAI's credibility and trust within the organization, resulting in strong relationships with key decision-makers and stakeholders across various business units. Our proven track record positions CAI as a trusted partner capable of supporting our client in achieving its mission of enabling customers to make the world healthier, cleaner, and safer.

WHY CAI?

Our client secured manufacturing rights with major COVID-19 vaccine suppliers during the height of the global pandemic. With unprecedented demand for vaccine production, the primary challenge was accelerating commercialization and achieving operational readiness within extremely compressed timelines.

CAI was selected based on our reputation as a trusted industry leader with a proven track record in delivering complex projects under critical conditions. CAI's global presence, deep expertise in aseptic manufacturing, and highly experienced SMEs in Commissioning, Qualification, and Validation (CQV) set us apart from competitors. Our ability to provide scalable resources and execute operational readiness programs efficiently made us the ideal partner to support the rapid delivery of life-saving COVID-19 vaccines to the market.

PROJECT OVERVIEW

The contract was to support the global fill-finish operations for COVID-19 vaccines, ensuring timely delivery to a worldwide population during a critical public health crisis. To achieve this, three manufacturing sites were selected globally, each equipped with at least one high-speed vial filling line sourced from leading vendors such as Optima and IMA.

The filling lines were fully integrated systems, including:

- Internal Vial Washer
- Depyrogenation Tunnel
- Filling Machine
- Capper
- External Vial Washer
- Tray Loader
- Semi-Automatic Visual Inspection Machines
- Manual Inspection Booths

The scope also included the qualification of clean utilities and Grade C classified facilities housing the filling lines. These utilities included nitrogen and compressed clean air, in addition to qualification of ancillary equipment such as autoclaves and parts washers.

PROJECT KICKOFF:

Q2 2020

INSTALLATION & INITIAL QUALIFICATION ACTIVITIES:

Within 3–4 months of equipment arrival

OPERATIONAL READINESS ACHIEVED:

Under 6 months, significantly faster than industry norms for projects of this scale

COMMERCIAL PRODUCTION START:

In time to support global vaccine distribution during peak demand in 2021

INITIAL ENGAGEMENT AND EXPANSION

The project began with a single U.S. site, with the potential for international expansion contingent upon CAI's performance. CAI's ability to deliver under aggressive timelines and complex technical requirements led to additional work at two more global sites.

PROJECT SCALE AND INVESTMENT

Projects of this magnitude, encompassing facility design, high-tech aseptic equipment integration, and cleanroom construction, typically represent investments in the hundreds of millions of dollars, with the CQV scope alone valued at approximately $5 million.

OBJECTIVE & APPROACH

The primary objective was to enable commercial production of COVID-19 vaccine batches as quickly as possible. This was accomplished through a lean, risk-based validation strategy, close collaboration with equipment vendors and client teams, and deployment of CAI's SMEs in CQV and aseptic operations.

IMPACT

- Delivered operational readiness in record time, reducing typical CQV timelines by over 40%
- Enabled production of millions of vaccine doses, supporting a critical global health initiative
- Established a scalable CQV framework that allowed rapid replication across multiple sites worldwide

CLIENT CHALLENGES

The project presented both explicit and implicit challenges due to the urgency of the COVID-19 pandemic and the global scale of operations. One of the most significant explicit challenges was global coordination—aligning CQV strategies across three geographically dispersed facilities, each subject to different regulatory authorities, including the FDA, MHRA, and HSA. Maintaining consistency in approach while adhering to local regulatory expectations required exceptional planning and communication.

Another major challenge was scalability and efficiency. With vaccine demand at an all-time high, Thermo Fisher needed to rapidly qualify and bring into operation fill-finish processes that could handle unprecedented production volumes without compromising quality or compliance. Simultaneously, the project demanded strict regulatory compliance, ensuring adherence to Good Manufacturing Practices (GMP) and data integrity standards to facilitate expedited regulatory approvals within an accelerated timeline.

Resource availability was also a critical factor, as the project required deploying highly experienced fill-finish and aseptic SMEs across three global regions. These experts had to apply a lean, risk-based CQV approach to meet compressed timelines while maintaining the highest standards of quality and safety. Additionally, knowledge transfer was essential for success; lessons learned at the first site had to be quickly and effectively applied to subsequent sites to streamline processes, eliminate redundancies, and accelerate project execution.

Beyond these explicit challenges, the team faced implicit issues such as managing stakeholder expectations under intense public and political pressure to deliver vaccines quickly. There was also the delicate balance of mitigating risk while reducing project duration, ensuring that speed did not come at the expense of quality. Furthermore, supply chain constraints for specialized equipment created additional complexity, as global shortages and logistical disruptions threatened delivery schedules.

Unexpected issues also arose during execution, including variability in equipment lead times and shipping delays due to pandemic-related restrictions. Additionally, differing interpretations of regulatory requirements across regions introduced complexity, requiring adaptive CQV strategies and continuous engagement with local authorities to maintain compliance and alignment.

CAI SOLUTIONS

This project fell under Operational Readiness (OR) with a strong emphasis on CQV activities to ensure rapid commercialization under pandemic-driven timelines. To achieve the aggressive objectives, CAI deployed a structured, standardized approach anchored in risk-based validation principles and aligned with regulatory requirements across multiple jurisdictions.

One of the first steps was the development and implementation of a harmonized Commissioning, Qualification, and Validation (CQV) corporate master plan. This standardized strategy ensured compliance with international regulatory authorities while maintaining flexibility for site-specific requirements. The CQV scope included executing Performance Qualification (PQ) and Process Validation (PV) activities such as aseptic media fills, critical for demonstrating consistency and sterility in the fill-finish process across all three global facilities.

To address production demand and efficiency challenges, CAI led capacity expansion and process optimization initiatives in collaboration with client and vendor teams. These efforts streamlined cycle times and improved Overall Equipment Effectiveness (OEE) by 25% across all lines. In parallel, CAI introduced automation and digital integration, including the adoption of paperless validation systems and standardized CQV templates. This innovation accelerated qualification timelines by 30%, reduced deviations, and minimized document development bottlenecks.

Stakeholder and regulatory alignment was another critical success factor. CAI worked closely with site leadership, Quality Assurance (QA) teams, and manufacturing groups to maintain consistent communication and ensure regulatory expectations were met without delays. Additionally, proactive engagement with health authorities helped secure rapid approvals, enabling an expedited path to commercial manufacturing.

To ensure sustainability and knowledge retention, CAI developed comprehensive SOPs and training programs for site teams. These programs standardized operational practices across all locations and facilitated a smooth transition from project mode to routine commercial operations.

Unexpected challenges, such as equipment delivery delays and regional regulatory discrepancies, were mitigated through agile project management and real-time problem-solving. CAI leveraged lessons learned from each site to accelerate deployment at subsequent locations, ensuring a consistent and scalable solution across the global network.

> “CAI’s expertise and responsiveness were instrumental in helping us meet an unprecedented challenge. Their ability to deliver operational readiness under such compressed timelines was critical to ensuring global vaccine availability.”

PROJECT SUCCESS

The project was an unequivocal success, delivering operational readiness at all three sites within timelines that exceeded client expectations and industry benchmarks. CAI's lean, risk-based CQV strategy and deployment of global SMEs enabled commercial production readiness in less than six months, compared to the typical 10–12 months for projects of similar scale. This accelerated timeline allowed production to begin on the COVID-19 vaccine batches significantly earlier, ensuring millions of doses were distributed during peak global demand.

Financially, the streamlined approach and use of paperless validation systems resulted in substantial savings for the client. By reducing qualification timelines by approximately 40%, the client achieved an estimated $1–2 million in cost avoidance associated with delayed production. For CAI, the successful delivery of this program strengthened its reputation as a trusted global partner for operational readiness in highly regulated, time-critical environments. The performance on the first site led directly to additional work across two more global facilities, reinforcing CAI's strategic value to the client.

Lessons learned from this engagement were significant. The project validated the effectiveness of harmonized CQV master planning for multi-site deployments and underscored the value of digital integration in validation activities. Additionally, the importance of early stakeholder alignment, proactive regulatory engagement, and adaptive problem-solving under crisis conditions were key takeaways that will inform CAI's future large-scale programs.

TIME SAVINGS	Operational readiness achieved in under 6 months, reducing typical timelines by 40%
FINANCIAL IMPACT	Estimated $1–2 million in cost avoidance through early production and optimized CQV execution.
EFFICIENCY GAINS	Improved Overall Equipment Effectiveness (OEE) by 25% across all lines; reduced CQV document development time by 30% via paperless validation systems.
GLOBAL SCALE	Successfully delivered CQV and operational readiness across three international sites under varying regulatory authorities (FDA, MHRA, HSA).
INNOVATION	Standardized CQV approach and digital template integration for rapid scalability.

ARE YOU READY?

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