ARE YOU READY?

PHARMACEUTICAL COMPANY, MONTANA, US

VACCINE FACILITY OPERATIONAL READINESS & DELIVERY

CASE STUDY: FACILITY & EQUIPMENT READINESS

Vaccine Facility Operational Readiness & Delivery

PROJECT OVERVIEW

The client's project involved constructing a new 40,000 sq. ft. brownfeld facility dedicated to manufacturing a critical vaccine adjuvant. This facility featured complex processes involving high volumes of combustible solvents, resulting in areas classified as C1D1 and C1D2. The highly automated production facility incorporated advanced technologies such as inline solvent dilution and was optimized to be operated efficiently by just five operators per shift, managing a nine-unit-operation process.

THE CHALLENGE

Initially, the QS21 project timeline was set for four years from Basis of Design (BOD). It demanded seamless technology transfer, comprehensive commissioning, qualification, and validation (CQV), and rigorous compliance given the operational risks associated with handling combustible solvents.

CAI'S APPROACH

Leveraging our Operational Readiness philosophy, CAI employed an integrated and strategic approach focusing on: Strategy Leadership, Execution Excellence, Workforce Capability, Equipment & Facility Readiness, Digital & Data Enablement, and Quality Advancement. Key initiatives included:

- **Tech Transfer Centrality:** At the project's core, CAI implemented a rigorous technology transfer methodology characterized by clear process characterization and a continuously maintained Process Control Strategy.
- **Operational Readiness-Centric Commissioning & Qualification (C&Q) Plan:** A pivotal element was a comprehensive three-day stakeholder workshop resulting in a jointly signed OR-centric C&Q plan by CAI, the client, and the design-build firm. This living document was consistently championed and meticulously maintained throughout the project's lifecycle.
- **Structured Project Governance:** Monthly project steering committee meetings and proactive risk management through an active risk register provided robust governance.
- **Detailed Prospective Planning:** Emphasizing a forward-looking strategy, CAI facilitated detailed planning for testing and operational readiness activities. Daily operational briefs and weekly engineering change management reviews ensured agile and proactive issue resolution.
- **Frontloaded Design and Rapid Change Management:** A significant project investment was made to fully establish critical design details and associated test plans down to the component level early in the project. Coupled with a robust and rapid change management process, this approach enabled the omission of traditional phase gates, facilitating early functional testing, often completed well ahead of mechanical completion. This strategy allowed for early identification and rapid correction of issues.
- **Technology-Driven Execution:** Advanced digital tools, including Kneat and Exitus, streamlined documentation, testing, and qualification processes, significantly enhancing efficiency and compliance.

OUTCOMES ACHIEVED

CAI's strategic intervention resulted in substantial project efficiencies:

- **Accelerated Delivery:** The project was delivered in 3.5 years, surpassing the original four-year schedule.
- **Robust Compliance:** The QS21 facility successfully integrated comprehensive Quality Risk Management (QRM) and maintained full compliance with FDA and GMP standards from Day One.
- **Optimized Workforce Capability:** Intensive workforce training programs and well-defined role clarity ensured that operators were fully capable and qualified at operational startup, achieving production targets immediately.
- **Enhanced Digital Integration:** Implementation of digital platforms allowed real-time visibility, improved decision-making, and reduced administrative friction, ensuring streamlined operational workflows.
- **Sustainable Operational Readiness:** The rigorous OR approach facilitated a seamless transition from project execution to sustainable operations, ensuring long-term operational excellence and reliability.

LESSONS LEARNED

- Early integration of OR-centric CQV planning significantly reduces downstream compliance and operational risks.
- Real-time and transparent project governance effectively mitigates risks and aligns stakeholders.
- Frontloading detailed design planning and rapid change management enhances early issue detection, significantly improving project timelines and reducing overall risk.
- Leveraging digital technologies is critical for maintaining documentation integrity, compliance, and operational efficiency.

COMMISSIONING MANAGER/SYSTEM OWNER

As the commissioning manager, our role in handover, turnover, and custody transfer focuses on managing a structured and controlled transition of systems from construction and verification into operational ownership. We develop and enforce standardized turnover packages containing all required design, verification, and maintenance documentation, confirming that each system is validated, documented, and technically sound prior to transfer.

Working in alignment with the project's handover roadmap, we coordinate the stepwise progression from mechanical completion to substantial and final completion, collaborating with vendors, design builders, and the client's responsible system owners. We facilitate the readiness of maintenance and operational teams by providing complete training, procedures, and safety authorizations before custody is accepted. Throughout this process, we maintain clear status visibility through integrated communication and documentation systems, minimizing delays, clarifying accountability, and making each transfer of responsibility fully traceable and compliant with regulatory and operational requirements.

CONCLUSION

The client's project is a testament to CAI's ability to deliver complex, compliance-driven pharmaceutical projects efficiently. Utilizing their Operational Readiness framework, frontloaded design detailing, and integrated commissioning and qualification strategies, CAI demonstrated unparalleled capability in enhancing project delivery outcomes, significantly benefiting future brownfield pharmaceutical projects.

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