MEETING CGMP COMPLIANCE: PV VALIDATES A LOGISTICS COMPANY'S EQMS

AT A GLANCE

An Indianapolis-based logistics company looking to cold-store vaccines partnered with Performance Validation (PV) to validate its electronic quality management system (eQMS).

The logistics company, which had GMP storage facilities with walk-in freezers, wanted to use their extra space to stockpile COVID-19 vaccines. Before this could happen, however, the company would need to validate its eQMS to ensure it met 21 CFR Part 11 and FDA CGMP compliance. Requiring an experienced, efficient partner, the company turned to PV.

Validating QT9™ QMS

PV's team took the lead in developing and executing comprehensive validation protocols for the QT9 QMS, a cloud-based software designed to track and manage GxP records. This was crucial for ensuring the client maintained regulatory compliance and safeguarded data integrity across its operations.

Collaborating closely with the company's QT9 QMS subject matter expert, PV developed a robust validation plan that outlined the system's testing requirements. Through rigorous validation documentation, the PV team ensured that the QT9 QMS met all necessary regulatory standards, enabling the client to maintain product traceability, monitor storage conditions, and address nonconformances effectively. This was vital for ensuring that the vaccines remained safe, compliant, and effective throughout the entire supply chain.

Services Provided

- **Validation Planning with Risk and Part 11 Assessment**
- **User Requirements Specifications**
- **Script Testing**
- **SOP Development/Updates**
- **Validation Summary Reporting with Traceability Matrix**
- **Validation Project Management**

Overcoming Challenges with Flexible Solutions

The PV team's expertise and resourcefulness allowed them to stay ahead of a number of challenges along the way, any one of which could have prolonged the length of the project.

Building a Validation Program from the Ground Up with Proven Expertise

PV's clean slate approach optimized the process, resulting in improved efficiency and quicker document turnaround. With extensive experience in QMS validation, the PV team utilized proven methodologies to build a strong validation framework. By applying lessons from previous successful projects, they ensured the solution met the highest regulatory standards and exceeded strict compliance requirements.

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Creating a Comprehensive Framework for Future System Updates and Compliance

PV played a pivotal role in developing a set of SOPs specifically tailored to the logistics company's eQMS. These SOPs were designed to guide the company through system updates and ensure ongoing compliance with regulatory requirements.

PV's SOPs outlined clear processes for managing system modifications, ensuring that updates—whether new features like the maintenance module or routine adjustments—would follow a formal change control process. This approach ensured that all changes were properly documented, reviewed, and validated to meet compliance standards, equipping the company with the tools to handle future audits with ease.

Beyond the eQMS-specific SOPs, PV also developed validation SOPs for key areas like change control, system maintenance, and validation oversight. These procedures provided a structured framework for future functionality enhancements or updates to the eQMS, minimizing risks and ensuring continuous compliance. Although the company had some administrative SOPs in place, PV's contribution filled a critical gap in validation, giving them a complete and compliant roadmap for managing system changes.

Collaboration Ensured On-Time Project Completion

The PV team adapted quickly to the constraints imposed by the pandemic, conducting the entire project remotely while maintaining efficiency and productivity. Despite the absence of in-person meetings, PV successfully collaborated with the logistics company to complete the project on schedule.

Remote work allowed for greater flexibility, enabling PV to align with the client's availability and avoid the logistical challenges of travel or scheduling in-person sessions. This approach streamlined communication, allowing PV to adjust quickly to the client's needs. For example, if the client had a brief window before lunch, PV could immediately shift focus to document writing or review sessions. This agile collaboration minimized delays and kept both teams focused on their respective tasks, ensuring the project proceeded without interruptions.

Ahead of Schedule and Under Budget: Completing eQMS Validation 4 Months Early with 24.5% Cost Savings

PV successfully validated the logistics company's eQMS to ensure full compliance with 21 CFR Part 11 and FDA CGMP standards. This validation enabled the company to securely store COVID-19 vaccines and other critical products, ensuring that key data related to storage conditions, product integrity, and regulatory requirements were meticulously tracked and maintained.

Through PV's expertise and efficient project management, the validation was completed four months ahead of schedule, delivering cost savings of nearly 24.5% of the total budget. The streamlined process and exceptional results exceeded the client's expectations, leading them to entrust PV with additional projects, including qualification and temperature mapping for their GMP warehouse facilities.

Your Validation Partner for What's Next

Performance Validation (PV) is a global Commissioning, Qualification and Validation partner for pharmaceutical and medical device manufacturers, extending its expertise to include Building Commissioning for Building Owners in a broader scope of industries. Headquartered in Indianapolis, IN, we specialize in turning compressed timelines into compliant ones across a diverse array of environments, using innovative, adaptive approaches that balance production realities with strict regulatory requirements. With Building Commissioning, we leverage our deep understanding of regulatory standards to ensure facilities operate at peak performance, enhancing efficiency, safety, and environmental sustainability. Our dedicated team, consisting of more than 95% engineers, works closely with regulators, equipment suppliers, and construction teams to keep validation and commissioning services ahead of production curves, ensuring quality and operational excellence across all projects.