STREAMLINING A CRITICAL VIAL PRODUCT LINE FOR A LARGE **PHARMACEUTICAL MANUFACTURER**

AT A GLANCE

One of the largest pharmaceutical manufacturers in the Midwest partnered with Performance Validation (PV) to inspect its vial production process. The pharmaceutical manufacturer had two main objectives:

1. Upgrade its vial product line to enhance and expand its capabilities.
2. Improve its process as a commitment to the FDA.

The PV team had nearly a decade of experience supporting the inspection process for the pharmaceutical manufacturer, which allowed them to build expertise with the client's processes. That experience proved helpful as the project evolved and challenges arose.

Expert Qualification, Equipment Testing & Technical Guidance

Throughout the engagement, the PV team's role involved:

- The qualification of inspection equipment.
- Performing an engineering shakedown.
- Providing technical guidance.

The Qualification of Inspection Equipment

The PV team qualified the inspection equipment by thoroughly assessing the requirements and determining the necessary tests. They developed a comprehensive plan to test the system, considering various issues and potential failure modes. This included identifying how different products might impact the machine's performance and ensuring the equipment could handle a diverse range of products.

A key part of PV's strategy involved recognizing operational differences and segmenting them accordingly. Once the planning was complete, PV conducted tests simulating both failure scenarios and normal operations to verify that the equipment functioned as intended.

Performing an Engineering Shakedown

In addition to qualification, the PV team supported the engineering shakedown when the inspection equipment arrived on-site. They rigorously tested the machinery to ensure that qualification testing would proceed smoothly, identifying and resolving any issues or bugs early to prevent potential failures during formal testing.

The PV team inspected the products using Korber's automated inspection and semi-automated machines. Korber automated inspection machines allow for much faster inspections than manual processes, while the semi-automated machines provide a more consistent inspection capability than human operators.

Providing Technical Guidance

The PV team also offered technical guidance, particularly in aligning with the pharmaceutical manufacturer's "release by exception" model. This model focused on identifying outliers or deviations from established standards, allowing for targeted human intervention. PV was crucial in identifying sources of potential product quality impact early on, ensuring that only products meeting the highest standards were released.

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Services Provided

- Equipment Commissioning and Qualification
- Integrated Computer System Validation
- Temperature Mapping
- Engineering Shakedown
- Vision Support

Delivering Accelerated Timeline & SME Solutions

The large pharmaceutical manufacturer had two significant needs that required attention. PV used the team's expertise and commitment to excellence to steer the project to the finish line.

Solution #1: PV Supported Accelerated Schedule

Initially, the pharmaceutical manufacturer primarily focused on the automated process because of its faster inspection capability. However, halfway through the project, the FDA performed an audit that found issues with the existing process. The pharmaceutical company wanted to show initiative by moving to a new process while meeting the FDA's response time. Therefore, the semi-automated process became a priority that required rapid acceleration in its implementation.

PV collaborated closely with the client during the engineering shakedown to develop a robust testing process for the semi-automated system. This process was crucial for identifying and addressing bugs the vendor was unaware of. PV not only identified these bugs but also pinpointed their root causes and implemented stopgap measures to prevent recurring issues, especially if immediate fixes weren't available. Through diligent testing and troubleshooting, PV ensured the system was thoroughly qualified once the bugs were resolved and saved a significant amount of time on the back end.

The accelerated schedule demanded intense effort to fit a large amount of work into a short timeframe. By identifying potential issues early, PV gave the team sufficient time to implement fixes without repeating testing, which ensured that the project stayed on track and met its deadlines.

Solution #2: PV SMEs' Readiness Filled a Gap

Since the project involved replacing an existing process, much of the pharmaceutical manufacturer's engineering focus was on keeping the old line operational until the new process was in place. That meant the client's subject matter experts (SMEs) were occupied with maintaining the old process.

PV's solution was two-fold. First, the PV team worked closely with the client to understand their needs so they could seamlessly integrate the new process without disrupting ongoing operations. Second, PV's local SMEs provided additional expertise and technical support to bridge the gap. This approach allowed for a smooth transition and minimized downtime, ultimately ensuring the project's success.

Project Summary

PV successfully brought the new comprehensive vial product process online with minimal issues. The team's deep understanding of the equipment allowed them to assist the client in diagnosing and resolving issues with parallel processes, ultimately helping the client optimize its own operations.

The project significantly increased speed and detection capabilities, enabling the client to requalify the system for a broader range of product inspections. For example, the existing system was limited to two vial types, while the enhanced system supported seven vial sizes.

Despite an accelerated timeline to meet FDA commitments, PV completed the project a couple of months ahead of schedule and within budget.

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.

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