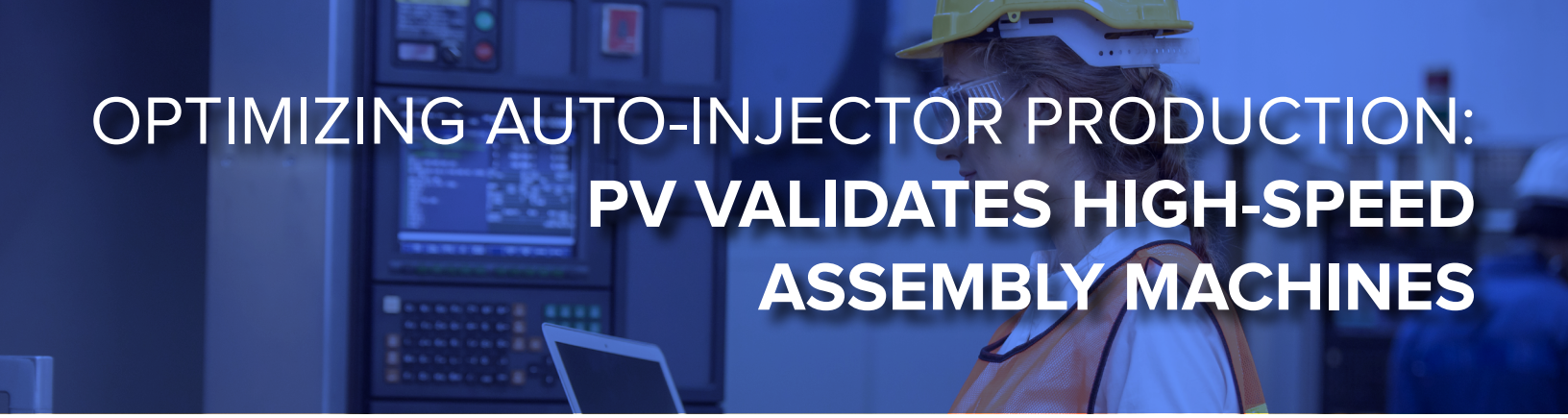

OPTIMIZING AUTO-INJECTOR PRODUCTION: PV VALIDATES HIGH-SPEED ASSEMBLY MACHINES

AT A GLANCE

An equipment manufacturer of high-speed automated assembly machines in Illinois partnered with Performance Validation (PV) to validate its drive/reject assembly machine.

The equipment manufacturer was a vendor for one of the largest pharmaceutical manufacturers in the Midwest. The pharmaceutical manufacturer needed to produce more auto-injector pens for its drug products, so it contracted the equipment manufacturer to build a drive/reject assembly machine to construct the components used in the auto-injector pens. The machine had two core functions: drive assembly and reject assembly. Ultimately, the machine could run independently to create assembled components for the pharmaceutical manufacturer's auto-injector pens.

PV had prior experience working with both the equipment manufacturer and the pharmaceutical manufacturer. This familiarity with the equipment and technical aspects proved helpful as the PV team developed solutions to project challenges.

Expert Quality Control and Validation Processes

Throughout the engagement, the PV team had two primary roles:

- Develop factory acceptance testing procedures.
- Prepare for official factory testing execution.

Develop Factory Acceptance Testing Procedures

Factory acceptance testing (FAT) ensures that equipment functions as intended before it is delivered to the customer. The manufacturer tests the equipment at its facility to verify the system meets design specifications and performs according to the required standards.

One of PV's main roles was handling FAT for the equipment manufacturer's drive/reject assembly machines. PV was responsible for supplying all the necessary documentation related to the system and developing test cases that would be used during the factory testing process. By documenting the system's functionality and performance, PV helped ensure that the equipment was ready for installation at the pharmaceutical manufacturer's site.

Prepare for Official Factory Testing Execution

The pharmaceutical manufacturer managed the official factory testing and worked alongside the equipment manufacturer to verify the equipment's performance. Before official testing took place, PV assisted with shakedown testing to ensure that everything would go smoothly during the final inspection.

PV developed all the test cases that would be used for the official testing. Once these test cases were created, PV worked with the equipment manufacturer's team to execute a preliminary test. This shakedown allowed them to walk through the entire testing process, checking that each test case was effective, accurate, and adequately documented. By doing so, PV could identify potential issues or adjustments before the official factory testing.

This preparation was crucial because it allowed PV to fine-tune the testing process and ensure the equipment would perform as expected. PV's attention to detail and proactive approach meant the process would be smooth, clean, and free of surprises when the pharmaceutical manufacturer conducted the final factory testing. Their work behind the scenes minimized the risk of last-minute changes or delays, contributing to a successful and efficient factory testing experience.

Services Provided

- Equipment Validation
- Factory Acceptance Testing
- Shakedown Testing
- Project Development and Execution Support
- Project Design and Documentation

Developing Effective Solutions for Project Challenges

PV faced two major obstacles during the project, but the team's expertise and dedication helped them identify paths forward for each.

Solution #1: PV Manually Formatted Test Cases

To save time, PV sought to reuse test cases from a previous project, as the drive and retract assembly machines were very similar to machines previously built for this same pharmaceutical customer. However, that wasn't possible. While the test cases were similar, they couldn't be directly copied and pasted into the electronic document system used by the customer due to system limitations.

Therefore, PV exported the old project's test cases into Word documents. Then, the PV team manually copied and pasted the content into the new project's electronic document system. This process introduced an additional layer of complexity because the formatting from the old project did not transfer perfectly, requiring PV to make manual updates and adjustments to clean up the formatting inconsistencies.

Although this process took more time and effort than expected, PV ensured that the testing documentation met the system's requirements and allowed for a smooth continuation of the project.

Solution #2: PV Improved Electronic Testing

The pharmaceutical manufacturer intended to use electronic testing for its equipment. However, the existing testing formats didn't fully meet its needs.

To address this issue, PV collaborated closely with the pharmaceutical manufacturer's engineers to reformat and refine the testing procedures. This involved a series of project meetings where PV and the pharmaceutical manufacturer reviewed the testing formats and discussed potential improvements. The goal was to make the testing process more intuitive and better suited to the pharmaceutical manufacturer's requirements.

The solution involved a collaborative, iterative approach. PV updated the testing documentation based on feedback from the pharmaceutical manufacturer, who provided suggestions for further refinement. This back-and-forth process allowed both teams to reach a consensus on how the testing should be structured and executed.

PV's planning, modifying, and reviewing process led to a more streamlined and effective testing method.

PV's ability to adapt quickly and plan for the unexpected allowed the team to keep the project on track while delivering high-quality results.

Project Summary

PV effectively validated the drive/reject assembly machines for the equipment manufacturer, who then delivered the machines to the pharmaceutical company. As a result, the pharmaceutical company was able to produce auto-injector pens to meet increased demand.

PV's timely and budget-conscious execution of the project fostered a lasting partnership with the equipment manufacturer. The pharmaceutical company continues to rely on this manufacturer for its auto-injector pen production, and in turn, the equipment manufacturer continues to rely on PV to help with validation support for its equipment.

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.