

SEIDENADER (KÖRBER) INSPECTION SYSTEM UPGRADE WITH LARGE PHARMACEUTICAL MANUFACTURER

At a glance

A client's current automated inspection system was old and beyond its serviceable life. A new automated filing system and semi-automated system were purchased to increase production detection capabilities for parenteral presentations.

Services Provided

- Shakedown Testing
- PoD testing to meet United States Pharmacopeia (USP) requirements
- Global System Integration
- Equipment Qualification & Validation
- Computer System Validation (CSV)
- Project Management Support



SYSTEM VALIDATED
and proper documentation
provided



TIMELINE MET



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Two Park Fletcher
5420 W. Southern Avenue, Suite 100
Indianapolis, IN 46241

NEW CONTROL SYSTEM REQUIRED INTEGRATION WITH GLOBAL SYSTEM



- Our client purchased an inspection system that included a relatively new control platform that would provide them with greater detection capabilities. The control platform also had to function with the other global systems, which was a major objective.
- Our client made a commitment to the FDA to update its aging inspection system to meet new Probability of Detection (PoD) regulatory requirements with an aggressive timeline.

SHAKEDOWN PROVIDED A FASTER PATH TO SUCCESSFUL VALIDATION



This was a new platform for the client and knowledge was limited, especially on the new control platform, therefore PV immersed itself in understanding its capabilities and limitations. The knowledge gained allowed the team to quickly shakedown all customer requirements through high-level testing, and work through and resolve discrepancies with the equipment vendor.

The shakedown approach allowed subsequent validation to be completed faster and at lower cost, with much smaller discrepancies and produced a more robust final solution.



Shakedown: high-level testing that is performed to an application after it has been migrated or deployed to a given environment to assure that it is up and running without major glitches.

Additionally, in order to verify the new platform was communicating properly with the global system, PV assisted in testing the integration to ensure everything was properly captured within the client's data historian system.

Because of PV's extensive shakedown and software expertise, our team was able to save time, money and assist our client in releasing a higher-quality product.

Phase 1

User Requirements

Phase 2

Shakedown

Phase 3

Qualification & Validation
Process

Phase 4

Summary Report



Validation
Services



Global System
Integration



Project
Management

SMEs SUPPORTS CLIENT WITH NEW CONTROL SYSTEM



During this project, our team was faced with learning a new control platform and had to train the client in how the system works, under tight deadlines. PV's SMEs provided the resources to support all the shakedown activities and learned the limitations and capabilities of the control system to provide our client with a successful validation.

PROJECT SUMMARY



Our client purchased a new automated and semi-automated system to provide better inspection capabilities to help detect defects as well as future capabilities for high-voltage leak detection. The control platform was new to the client and had to be able to integrate with global systems and align globally in terms of approach. PV was able to learn the new platform and move products from the old semi-automatic machine to the new one while meeting updated FDA requirements. Our SMEs facilitated a heavy shakedown to ensure there were no issues with the system prior to starting the qualification process. Our teams worked hand in hand to ensure quality and patient safety were met.

OTHER SERVICE AREAS



- > Commissioning, Qualification & Validation
- > Computer System Validation
- > Critical Airflow Studies

- > Temp Mapping
- > Medical Device Validation
- > Building Commissioning

WE TURN CRITICAL INTO COMPLIANT



Since 1988, Performance Validation has been providing clients with expertise in the commissioning, qualification and validation service areas in the life science industries. Our team thrives on the importance of quality, integrity and teamwork, giving our clients peace of mind during every step of the project.



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