

Optimizing GxP Compliance: Streamlined Application Validation for a Leading Pharma Hub Services Provider in the U.S.

CASE STUDY

Success Story

Neutrino successfully helped a leading Pharma Hub Services provider in the U.S. streamline its application validation process, aligning it with stringent GxP regulations while maintaining the validated state throughout the application lifecycle.

Challenges

Lack of Streamlined Workflows: The client's application & its workflows were disorganized and lacked a structured validation process.

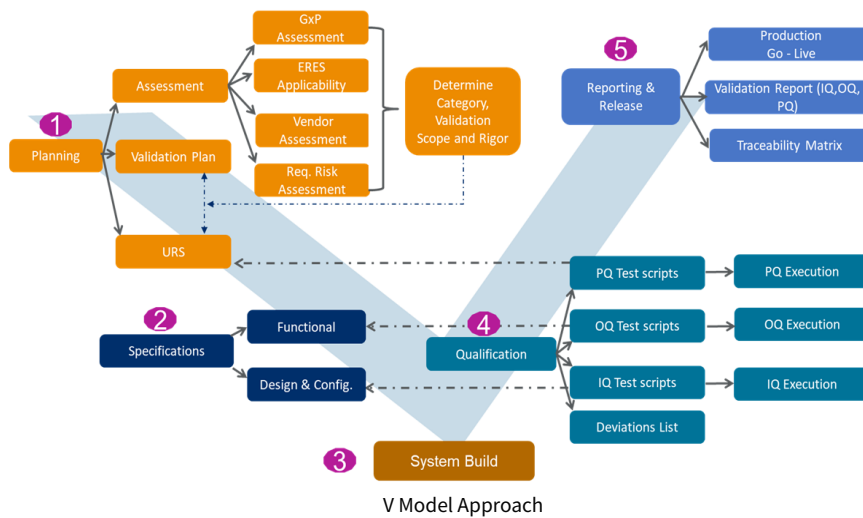
Absence of Defined Processes: The absence of established processes hindered efficient validation efforts.

Testing Coverage Issues: Testing was not comprehensive, which raised concerns about application reliability.

Production Defects: Defects in the production environment posed potential challenges for end-users.

Regulatory Compliance: Adherence to FDA regulations and other GxP standards was essential but difficult to achieve.

Solutions



- ✓ Implemented best practices via OQ Test, PQ Test, Test strategy & planning, test cases, test execution, traceability, defect tracking, and overall validation report.
- ✓ Requirement Management & Identification
- ✓ Test Strategy & Test Planning
- ✓ Execution
- ✓ Defect Management
- ✓ Streamlined Deployment
- ✓ Staging server process implementation

Process Implementation

OQ and PQ Implementation: Operational Qualification (OQ) and Performance Qualification (PQ) were carried out to ensure the application's reliability. We managed end-to-end documentation to meet necessary good practices; built a validation plan, did risk assessments, did FRS document, Validation summary report, tollgate review report, traceability matrix, test summary report, and validation summary report.

End-to-End Documentation: Neutrino meticulously managed documentation to align with GxP best practices.

Validation Plan: A comprehensive validation plan was created, outlining the entire validation process.

Risk Assessment, Data Integrity, Authentication & Authorization: Streamlined end-to-end validation process including roles, responsibilities, and communication channels to define compliance activities plus conducted risk assessments (production go-no-go decision making).

Deliverables



Functional Requirements Specification (FRS) Document:

An FRS document was developed to clearly define the application's requirements.



Validation Summary Report:

Neutrino prepared a validation summary report to capture all validation activities.



Traceability Matrix:

A traceability matrix was established to link requirements, test cases, and validation activities.



Test Summary Report:

Comprehensive test summary reports were generated to track the testing process.

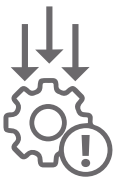
600+
OQ Scripts

200+
PQ Scripts

3
Executions & Iterations

20+
Defects

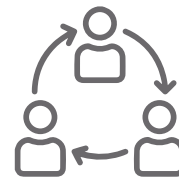
Neutrino's expertise and implementation of best practices resulted in the successful streamlining of the application validation process. Our holistic approach to application validation, incorporating risk assessment, documentation, testing, and compliance, has significantly benefited the client, ensuring that their critical systems adhere to the rigorous standards of the life sciences and pharmaceutical industry.



Error Reduction



Time-to-Market



Collaboration



Security