



LIMS Software Validation (IQ/OQ/PQ)

Client Overview

The client an “Analytical Services Provider” is revolutionizing the Drug metabolism and pharmacokinetics (DMPK) with complete focus on rapid turn-around and high quality data for GLP and non-GLP bioanalysis, drug metabolism, and LC-MS analytical services.

Challenges

Bioanalysis is a vital part of clinical and pre-clinical drug development. Well-organized assay validation, bioanalysis of samples, instrument interfacing, sample tracking, and reporting of results are key steps in progressing pharmacokinetic and toxicokinetic evaluation of research compounds through R&D activities right into regulatory submissions. The client has implemented ThermoFisher’s Watson LIMS solution, a highly specialized protocol driven system which has been specifically developed to support DMPK and bioanalytical studies in drug development. Client had a need to perform validation of the Watson LIMS system for capturing bio analysis data in their analytical lab.

The client needed Optra’s Validation & verification services for operational (OQ) and performance qualifications (PQ) to be performed in accordance with the validation protocol. Client was looking to create the subset of the OQ scripts covering only those the functionalities of LIMS system those were frequently used by the client for their lab workflow, in addition to creation of PQ and configuration test scripts . One of the key requirements was that the client wanted all the execution to be done remotely from offshore location to save costs.

Solution (Watson LIMS software validation-IQ/OQ/PQ)

Optra proposed and delivered the solution after analyzing the client documentation. The recommended versions of servers were suggested for purchase to resolve compatibility issues. Optra team reviewed the servers and completed the IQ, OQ and PQ validation successfully. As per client's specific requirement, Optra team prepared the configuration test scripts, PQ test scripts and also identified the necessary subset of OQ scripts with all desired functionalities. The client had faced issues related to access rights for specific users and document management system, which was also resolved by Optra team.

Technology Environment

- Remote server with Watson LIMS installed
- Client machine with Watson LIMS client installed
- Remote desktops for remote connectivity
- Analyst (AB-Sciex MS instrument control & analysis application)

Benefits

- Optra teams's existing exposure to Watson LIMS helped in quickly aligning with the client's bespoke requirements.
- Optra team's existing experience in software validation for IQ, OQ & PQ allowed client to get the activities done successfully without increasing any headcount in a cost effective manner.
- Time difference between US and India was used for quick turn around & increased output.

About Optra Health

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Contact Optra Health Today

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