

21 CFR Part 11 Validation



The Client: Client is a leading biopharmaceutical company which manufactures generic active pharmaceutical ingredients.



Business Requirement



Validate the cloud based Learning Management System for 21 CFR Part 11 regulatory compliance



Design and execute test cases for Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)



End to end validation for different user roles and document all validation activities including test protocols, test scripts, test evidences and test reports



Our Solutions



Leveraged our jumpstart kit that includes Template, Guidelines, Checklists and Reports for 21 CFR Part 11 assessments



Developed and executed 1500+ test cases for IQ, OQ & PQ and 73 critical defects were reported



Performed exploratory testing as value addition and proposed a list of recommendations from user perspective



Created Traceability Matrix that includes test cases linking requirements of 21 CFR Part 11



94 test cases were developed and reported to assess the System for 21 CFR Part 11 compliance



Business Impact



Successfully passed the external compliance audit



Documentation for all the validation activities with evidences for the purpose of audit trail

Technologies : Software : Microsoft Azure Cloud service | Defect Tracking : Customized tool specialized for project