**Vamsi**

973-554-4004

Computer System Validation

**SUMMARY:**

* Over 7 years of experience as a Validation engineer with strong expertise on Computer System Validation (**CSV**) skilled with FDA regulatory compliance in Pharmaceutical and Medical Device Industry.
* Extensive knowledge and understanding on the **SDLC** (Software development life cycle), Agile and Waterfall methodologies.
* Expertise on **21 CFR Part 11, 210, 211, 820,** and associated FDA Regulations.
* Planned, tracked, and managed Multiple agile and software development projects in **Jira**
* Track execution status, defects and report status using standard dashboards in **JIRA**.
* Good understanding and experience in validating the computer systems as per FDA regulations and **cGXP (GLP/GCP/GMP)** guidelines.
* Experienced with Computer System Validation (**CSV**) of Enterprise Level applications like Laboratory Information Management System (**LIMS**), Learning Management System (**LMS**), and Adverse Reaction Information System (**Argus**)
* Authored and reviewed Validation Master Plan (**VMP**) and Standard Operating Procedures (**SOPs**).
* Extensive hands-on experience in developing protocols, executing tests and Constructing Summary Reports for Installation Qualification(**IQ**), Operational Qualification (**OQ**), Performance Qualification (**PQ**) Validation Summary Report (**VSR**) and Requirements Traceability Matrix (**RTM**) in validation deliverables for validations in various pharmaceutical companies
* Knowledge in various types of testing such as Load testing, Stress testing, Performance testing, Positive testing, Negative testing, and User Acceptance Testing (**UAT**) and Unit/Smoke testing using manual and automated tools
* In depth experience working with Electronic Document Management system (**DMS**) like Documentum, SharePoint to archive and retrieve documents
* Strong experience in implementation of Change Management/Control (**CM**) and Corrective Action and Preventive Action (**CAPA**) procedures
* Efficient in testing and defect handling using **HP-QC/ALM**
* Strong communication skills for clearly delegating tasks to team numbers and for effectively communicating results to management

**CERTIFICATIONS:**

**Lean Six Sigma - Green Belt Certification**

**FMEA- Certified FMEA Lead**

**Skills:**

**Skills:** Process Validation, HP QC/ALM, JIRA, Process Audits, Quality assurance, Quality Engineer, ISO Train, Maintenance Authoring & Executing Validation Protocols (IQ, OQ, PQ), CAPA Administration, Root Cause Analysis (RCA), Closing Nonconformance Reports (NCR) & Nonconformance Material Reports (NCMR), Control Plans, ISO 13485, ISO 14971, QSR 21 CFR Part 820 (198, 200), Test Method Validation (TMV), Gage Reproducibility & Repeatability Studies (Gage R&R), Fault Tree Analysis, 5-Why Analysis, Control Process Parameters (CPP), Statistical Process Controls(SPC), Minitab, Geometric Dimensioning & Tolerance (GD&T), Design History Files (DHF), PFMEA, Continuous Improvement, Product design and development, Product Validation, Six sigma, Root cause analysis, , Process Audits, Quality assurance, DOE, FMEA, 6S, QC tools, ERP tools, Microsoft Office and Minitab.

**Expertise in process improvement tools:** HPQC/HP ALM, Jira,Six Sigma, Lean, Value Stream Mapping, Quality Assurance and Control, Supply Chain management and Operations Management, SAP, Trackwise

**Strong management, analytical and problem-solving skills:** Engineering Management, Team work, Leadership skills and Multitasking.

**Professional Experience:**

**Baxter, Round Lake,IL Feb 2019 to Present**

**System Validation Engineer**

**Responsibilities:**

* Integrated TrackWise systems into AWS-DEVOPS for different Environments (INT/QA/SBX)
* Gathered Requirements for TrackWise from different Business Teams globally and rolled out them to Configuration, Developers and QA teams.
* Developed test and administer new standard Crystal Reports for newly developed workflows in TrackWise for CAPA. Maintain, update and configure existing single and multi-record Crystal Reports.
* Based on the Requirements assigned the **JIRA User Stories** and have experience in handling more than 400 tickets in one Sprint (AGILE Methodology).
* Worked on Complaints and CMS changes in Trackwise for different medical regulations (EUMDR DT-MIR/ LATAM DT/ COLOMBIA DT/ ECUADOR DT/ VIGILANCE REPORT/US DT-eMDR/Japan DT-JMDR)
* Conducted vendor audits and was responsible for computer systems software validation part of Labware (vendor for Trackwise).
* Completed 21 CFR Part 11, GxP and Functional Risk Assessment for the system.
* Developed Validation Plan to outline activities, deliverables and roles and responsibilities.
* Responsible for review and approval of validation documents including but not limited to Validation Plan, Installation Qualification Protocol (IQP), Operational Qualification Protocol (OQP), Performance Qualification Protocol (PQP), Test Plans, Traceability Matrix, Validation Registry Checklist and Validation Summary Report.
* Develop and verify Periodic Review plan, Back-up and Disaster Recovery plan and Change Control plan for post-deployment support.
* Attended requirements gathering sessions, reviewed System Design Specifications and System Baseline Configuration.
* Created Testing Documentation including Test Plan, Test Cases, Test Scripts, Requirements Traceability Matrix (RTM), Defect Report and Test Summary Report.
* Used Quality Management tools such as HPQC to manage requirements, test plan, test scripts and defects.
* Managed defects by ensuring that proper documentation and corrective actions have been implemented.
* Reviewed Requirements Traceability Matrix to ensure that all the requirements are appropriately tested in designated test phases.
* Closely worked with business representatives to provide guidance on creation of User Acceptance Test (UAT) scripts during implementation.
* Review and approvals of execution of IQ, OQ and PQ Scripts.
* Summarized Validation activities, test results, and open issues in the Validation Summary Report.
* Authored and worked closely with the QAs to write Test Cases
* Performed UAT testing when necessary.
* Reviewed and Approved all the Test cases and test results for different QMS TrackWise Implementations in HPALM
* Elicit and clearly document business and systems requirements.
* Documented user design requirements for user interface in SharePoint
* Based on the Requirements assigned the JIRA User Stories and have experience in handling more than 400 tickets in one Sprint (AGILE Methodology).
* Managed Large Data sets with different Product codes from different parts of the world using SQL queries and drew insights and consolidated them for the Developers based on Business Req.
* Defined and articulated business rules required for data accuracy and consistency.

**Abbott Laboratories, Maple Groove, MN Jan 2016 – Jan 2019**

**Validation Engineer**

* Participated in the SAP improvement design, documentation and testing of the interfaces between SAP and other application modules like CRM, ECC, GRC, PI, SCM, BW...etc.
* Followed Computer Systems Validation CSV Master Plan to author, review and approve CSV deliverables for systems as per GxP GLP, GCP, GMP, GDP, cGMP FDA Assessment.
* Worked on change control documentation such as Change Request Tickets (CRQ's), Change Control Implementation Plan, Change Control Summary Report.
* Ensure day to day operation of the support and ongoing operation of the SAP module across multiple SAP sites. Conduct issue resolution to resolve issues identified by the business users (to include functionality, process, data and training issues.
* Used Quality Management tools such as HPQC/HP ALM to manage requirements, test plan, test scripts and defects.
* Managed defects by ensuring that proper documentation and corrective actions have been implemented.
* Ensure the use of best demonstrated practices for application and Business Process Integration into SAP, SAP Solution design, configuration, integration, programming, data, testing, and change control
* Responsible for developing validation documents as part of computer system validation.
* Authored and developed IQ, OQ and PQ protocols for Validation purposes.
* Involved in documentation/Review of Lifecycle development for CSV (OQ, PQ) and SDLC processes
* Prepare computerized systems documentation such as Validation Plan, CSV Risk Assessment, Test Plans, Test Summary Reports, Test Scripts, Traceability Matrix, Validation Summary Reports
* Created and maintained company quality documentation, such as quality manuals, quality procedures, standard operating procedures (SOPs), Risk Management files.
* Analyzed and reviewed Validation deliverables like Validation Plan, User Requirement specification, Functional requirement Specification, System Design Specification document.
* Extensively involved in testing phase, which includes various testing activities like Unit Level Testing, Verification and Validation.
* Analyzed and reviewed validation deliverables like Validation Plan, User Requirement specification, Functional requirement Specification, System Design Specification document.
* Reviewed Test Method Validation (TMV) for all functional and interface test methods for Disposable products
* Developed risk management plans: FMEA, PFMEA, Compliance testing requirements
* Supported and performed Quality Audits - Internal, External, FDA, BSI Regulatory Bodies.
* Developed and maintained Requirement Traceability Matrix (RTM) to cross-reference the functionality to the required verification and validation documents.
* Involved in designing procedures and test methods which comply with business, FDA and industry best practice guidelines: FDA - 21 CFR 11 & 820; ISO 14971 and 13485, CGXP guidelines(GLC/GCP/GMP)

**Zimmer Biomet, Warsaw, IN Aug 2014 – Dec 2015**

**Validation Engineer**

* Part of the validation and compliance group at Zimmer Biomet.
* Reviewing new projects from regulatory standpoint. Ensuring part 11 assessment gets completed in the tool kit and review of all evidences and evaluations done before going live of projects.
* The company uses Labware LIMS. Involved preparing documentation for validation of LIMS as per 21 CFR Part 11 and FDA regulations.
* Involved in validating Laboratory Information Management System (LIMS).
* Involved in gathering and documenting User Requirements and developing Validation Master Plan.
* Conducted vendor audits and was responsible for computer systems software validation part of Labware (vendor for LIMS).
* Completed 21 CFR Part 11, GxP and Functional Risk Assessment for the system.
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**EDUCATION:**

Master’s in industrial engineering, Wayne State University, MI

Bachelor’s in mechanical engineering, VIT University, India