**Srikanth Yadav**

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**Summary**:

* Over 7 years of extensive experience in pharmaceutical industry with emphasis in Computer System Validation (CSV), Process Validation, Laboratory Instrument Control System, Technical Writing, and Testing.
* Extensive knowledge in Food and Drug Administration (FDA) regulations, 21 CFR, Part 11 (Electronic Records and Electronic Signatures), Part 210 (cGMP in manufacturing, processing, packaging and holding of goods), Part 211 (cGMP for Finished Pharmaceuticals), Part 810 (Medical Device Revise Authority), and Part 820 (Quality System Regulation).
* Experience authoring and developing Validation deliverables including Validation Master Plan (VMP), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), Validation Summary Report (VSR), Requirements Traceability Matrix (RTM).
* Performed Equipment Qualification, Packaging Qualification, Process Validation and Vendor & Material Qualification.
* Good knowledge of Software Development Life Cycle (SDLC) and Software Testing Life Cycle (STLC).
* Striking documentation skills in compliance with Good Documentation Practice (GDP).
* Experience in performing integration testing, back end and front end testing, Black Box testing, sanity testing, smoke testing, volume testing and User Acceptance Testing.
* Experience in reviewing Corrective and Preventive Actions (CAPA) and highlighting and suggesting the remediation plans to mitigate the non-compliance.
* Knowledge of Change Control Software like TrackWise and report generation software like Crystal Reports, Oracle Reports.
* Experience in Validating Spreadsheets.
* Experience in Validation of Laboratory Information Management System (LIMS).
* Experience on performing CSV for analytical equipment such as HPLCs, TOC Analyzers, GCs, UV-Vis spectrophotometers in QC environments.
* Experience in writing Test Cases, executing and writing Test Summary Reports.
* Coordinate validation activities by constant communication with affected departments and personnel; oversee and review validation area processes and procedures.
* Provide hands-on guidance to testing teams pertaining to the creation, execution, and defect reporting while utilizing good testing practices.
* Knowledge of Data base software, Design software, Spreadsheet software and word Processing software.
* Dealt with writing, reviewing and revising Standard Operating Procedures (SOPs) particularly 21CFR Part 11 and User manuals.
* Experience in designing Gap Analysis, Remediation plans and Required Traceability Matrix (RTM).
* Directed the plants to quarantine labeling items which required in depth knowledge of FDA guidelines and how to apply them.
* Excellent interpersonal, organizational, verbal and written communication skills and strong ability to perform as a part of a team.
* Advanced experience in conducting GAP Analysis and developing Remediation Plans.
* Member of International Society for Pharmaceutical Engineering (ISPE).

**Technical Skills:**

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| --- | --- | --- | --- |
| Validation | FDA Quality system regulations, 21 CFR Part 11 (210, 211, 50, 820), protocols (IQ,OQ,PQ) cGXP (GLP, GMP), Standard Operation Procedures (SOP), LIMS, AERS, Gap Analysis, RTM, Audit Trials, Remediation | |  |
| Laboratory Equipment | | HPLC, Spectrophotometer, Autoclaves, pH meters, humidity controllers, freeze dryers and incubators, Tablet Presses, Filter Skids, Delta V, CIP, and SIP | |
| Operating System | | Windows2000/2003/XP/Vista/7/NT, MS-DOS | |
| Language | | C, C++, Java | |
| Database | | MS Access, Oracle 8i/9i/10g, SQL Server 2005/8, PL/SQL | |
| Tools | | MS Office (Word, Excel, PowerPoint, Access), IBM Cognos, Documentum, Quick Test Pro, JDA i2 Technologies, Quality  Center | |

**Professional Experience:**

**Medtronic, Mounds View MN March 2016 - Present**

**Validation Engineer**

**Responsibilities:**

* Developed excel spreadsheet validation packages in an FDA Regulated environment.
* Involved in preparing, executing and defending Remediation Plans, Change Controls, Requirements, Design Specs, Traceability Matrices, IQ, OQ and PQ protocols and summary reports for spreadsheets.
* Developed and implemented software development lifecycle (SDLC) policies, procedures, and test methods.
* Provided validation/QA consulting services preparing /executing OQ/PQ/UAT test cases.
* Collected inventory from different sites of the company.
* Provided guidance, mentoring, training in creating validation packages for spreadsheets. Including, providing assistance with resolution of testing incidents and deviations.
* Prepared, maintained, or review validation and compliance documentation, such as schematics, or protocols
* Draw conclusions from data, observations, deviation/exception and investigation as to whether process is considered valid.
* Involved in preparation and documentation for all aspects of the computer system validation to ensure compliance in accordance with cGxp (cGMP, cGLP and cGCP) and FDA rules and regulations
* Performed validation of High risk spreadsheets.
* Written summary reports for validation/qualification protocols following criteria as outlined within the validation/qualification procedures and policies.
* Maintained protocols and system documentation in an orderly library so that information can be provided to regulatory bodies in a timely manner.
* Involved in all phases of SDLC according to Company procedures, FDA Guidelines, GMP and (21CFR Part 11)
* Ensured protocols, verifications, validation plans and summary reports generated during validation/ qualification activities are stored according to procedure.
* Maintained current knowledge in the areas of compliance and validation and other regulatory issues that may impact the Company.  Worked proactively to maintain the highest level of compliance in all areas.
* Gathered current knowledge from QA/QC, regulatory, periodicals and/or appropriate training programs.
* Adhered to all cGMPs, compliance/regulatory mandates and quality requirements.
* Involved in reviewing Corrective Action and Preventive Action (CAPA) and drafting remediation plans for the project management approval after GAP analysis.
* Reviewed deliverables as required by Medtronic’s QMS.
* Created and maintained the Requirement Traceability Matrix (RTM) for the application.
* Responsible for keeping and maintaining the documents to comply with 21 CFR Part 11 requirements.
* Performed other related duties as assigned to meet departmental and Company objectives.
* Completed work consistent with company's quality standards, policies and procedures.
* Regular and effective communication of project status to Project Management.

**Biosense Webster, Irwin dale CA Dec 2013 – Feb 2016**

**Validation Analyst**

**Responsibilities:**

* Involved in analyzing business and functional requirements of Track Wise to track.
* Conducted audit of TrackWise and co-led configuration of workflows affecting all departments at the facility.
* Used TrackWise for reviewing, organizing and managing all complaint data and patient information from different BSC sites for easy access and quality assurance.
* Managed company's production process for FDA regulations.
* Authored Test scripts and Test cases for Automated and regression testing.
* Created SOPs and trained on oversight of course production.
* Actively participated in developing the Design of Experiments (DOE) and manufacturing process flow with help of MS Visio.
* Reviewed the Validation Master Plan, SDS, Traceability Matrix, Validation Summary Reports.
* Documented reports for installation qualification, operating qualification and performance qualification validation protocols (IQ, OQ, PQ).
* Created templates, procedures, SOPs and manuals for validation including infrastructure qualification, analytical instruments, lab equipment, spreadsheet and SAP based applications.
* Maintained excel spreadsheet and access data base applications for data collection, customer service RMA information and QA reports and performed administrative tasks consisting of fulfillment of department supplies and facility copier maintenance.
* Verification/validation of new test tools/test protocols/processes in a medical/FDA regulated environment within an agile SDLC.
* Validated computerized laboratory equipment based on GAMP 5 requirements.
* Supported the validation of Standardized Packaging System (base off of SAP Enterprise Central Component (ECC), Environment, Health, and Safety) Category 4, which is configurable SAP software module, which supports all packaging activities including approved and marketed presentations along with new product package development.
* Created traceability matrices between the various requirement types - Business & Functional requirements and Functional Requirements.
* Created and maintained Regression testing and automated test suites by using QTP (Quick Test Professional) and QC.
* Created CSV Risk Assessments, Validation Plans, Test Summary Reports, and Validation Summary Reports.

**Amneal Pharmaceuticals, Piscataway, NJ. Feb 2011 – Dec 2013**

**Validation Analyst**

**Responsibilities:**

* Responsible for developing and implementing Master Validation Plans, Test Cases and associated validation documentation for Chromatography Data System (CDS), Laboratory Information Management System (LIMS), and Distributed Control Systems (DCS) Reviewed Business Requirements and involved in preparing Validation Master Plan (VMP).
* Prepared Validation Master Plan (VMP) and formulated Installation Qualification (IQ), Operation Qualification (OQ), and Performance Qualification (PQ) protocols for validating the system in accordance with the compliance regulations.
* Prepared Standard Operating Procedures (SOPs) according to required specifications.
* Developed validation and quality assurance programs including templates for validation related documentation such as Validation Protocols, Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ).
* Involved in good documentation practice with 21 CFR Part 11.
* Foster communication and cooperation between QA team, software quality, software.   
  Development, information technology, software support teams and the user community.
* Hands on experience in all the functional areas of CAPA (Investigation, Implementation, Effectiveness Verification).
* Performed Global adverse effect case data management and regulatory reporting to the industry using Argus safety.
* Developed and reviewed GxP computerized system documents including those related to system performance, compliance evaluation and validation.
* Provide computer systems validation support for electronic quality management systems, spreadsheets, databases and other systems subject to 21CFR Part 11 requirements.
* Involved in technical writing of User Requirement, Design Specification, and Traceability Matrix.
* Provided status updates for the project as per the management required.

**Client: Media Forge Business Solutions Inc -Hyderabad, INDIA Jun 2009-Dec 2010**

**Role: QA Tester**

LoCoCatalogMapper  **Description:** It is a backend catalogue application for EasyPrice mobile application. It will pull item and its details from e commerce applications such as FlipKart, Amazon and SnapDeal and based on our own matching algorithm it will display the top 3 corresponding items to match. Then catalogue will match new item with corresponding match or will manually map it. Even un map the items and map it to new item manually. It's a backend applications to match the items from different e commerce portals.

**Responsibilities:**

* Worked as a Manual Tester with developer and support teams to test web based applications for the client.
* Perform functional testing such as Smoke Testing, User Interface testing, Integration testing, Regression testing, Security testing and Performance testing.
* Explanation of the security requirements to the design team in initial stages of SDLC to minimize the efforts to rework on issues identified during penetration tests.
* To address and integrate Security in SDLC by following techniques like Threat Modeling, Risk  Management, Logging, Penetration Testing, etc.
* Providing fixes & filtering false findings for the vulnerabilities reported in the scan reports.
* Responsible for identifying and escalating vulnerability assessment and Penetration testing results.
* Conduct external, internal, wireless, and segmentation penetration testing for clients in their Payment Card Industry (PCI) environments.
* Performed GUI Testing, Functional, Testing manually
* Worked with SQL to do the backend testing, reading logs and server commands
* Design/review test scenarios, test data and test cases for different financial user groups based on system requirements, solution diagrams, help files, and screen mockups.
* Wrotetest cases using Quality center and logged defects
* Involved in testing all backend processes using SQL
* Designed and developed test plans, test scripts, for manual testing of all the modules.
* Performed GUI testing using Win Runner automation tool.
* Tested process flow to handle the e-training application process efficiently.
* Performed extensive Data Integrity testing by executing SQL Statements.
* Supported with testing team when there are production issues by doing Emergency Bug fix testing. Maintained defects in Quality Centre based on Defect Tracking Life Cycle.
* Performed Regression testing, Integration testing, User Acceptance testing (UAT), Functional testing, End-to-End testing.
* Performed database integrity testing by executing SQL statements.
* Performed end-to-end testing on the released version of the software application and detected lot of GUI bugs.
* Talked to the end users to create the process requirements and to proper explain to the design and development team the flow of future data modules.
* Created, executed Manual Test Cases and scenarios
* Planned and managed testing strategies through all phases of the software development, test and revision cycles.

**Education:** Bachelor of Technology, Jawaharlal Nehru Technological University, India.