**Nageshwar Rao**

**Sr. Validation Engineer/Analyst**

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**Objective**: A Versatile and accomplished Computer System Validation (CSV)professional with 7 years of experience in pharmaceutical and medical device industries. Adept in navigating organizational ladder and influencing team members in accomplishing goals. To be given an opportunity where I can use my experience to company’s interest

**Professional Summary**

* Excellent Knowledge in **GAMP 5** and **21 CFR Part 11 regulation** pertaining to data integrityof Electronic records, Electronic signatures, Audit trials and Documentation.
* Expertise of validation practices in FDA regulated environment with good understanding of **GxP (cGMP, cGCP, cGLP)** standards.
* Good experience in Software Life Cycle (**SLC**), comfortable with Waterfall, V-Model and Agile methodologies
* Strong Expertise in preparing, reviewing and approving User Requirement Specification (**URS**), Functional Requirement Specification **(FRS)**, Validation protocols Installation Qualification **(IQ)**, Operational Qualification **(OQ)**, Performance Qualification **(PQ)** and Validation Plan (**VP**)
* Strong knowledge and working experience in executing **Gap Analysis**, establishing Remediation Plans, preparing Corrective Action Prevention Action (**CAPA**) and Change Control Process
* Risk-based assessment on the Computer Systems to determine the required test cases
* Involved in preparing test artifacts like Test Scripts, Test Cases, Test Plans, Test Strategy, Test requirements and Testing standards based on URS
* Good experience in Functional Testing, Integration testing and User Acceptance Testing **(UAT)**
* Expertise in test management and defect management using **HP** **ALM**
* Involved in preparation of Requirement Traceability Matrix (**RTM**), Validation Summary Report (**VSR**), Defect Report, and Weekly Status Reports
* Good knowledge of FDA Medical Device Reporting and International medical device regulations including **21 CFR parts 210, 211, 806, 820**
* Strong expertise in developing successful data migration plans while working with development teams
* Working knowledge with **Veeva Vault RIM**, Documentum (EDMS), JIRA
* Worked with Laboratory Information Management System (**LIMS**), Change Control Management System (**CCMS**)

**Technical Skills**

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| --- | --- |
| Computer System Validation | 21 CFR Part 11, 210, 211, 820, GAMP, cGxP, GDP, GLP, IQ, OQ, PQ, RTM, SOPs, CAPA, VMP, Risk Assessment, Summary Reports, Audit Trails |
| SDLC Methodologies: | Waterfall, V-Model, Agile |
| Tools: | MS Office (Word, Excel, Power Point, Access Visio), Documentum, JIRA, HP ALM, MS SharePoint |

**Work Experience**

**Client: Sanofi**

**Location: Bridgewater, NJ** June 2019 – Present

**GRA Validation Lead**

**Project Title:** Bioverativ Sanofi Regulatory Integration (Veeva Vault RIM)

**Overview:** Global Regulatory Affairs (GRA) Data Migration between Bioverativ Vault RIM to Sanofi Vault RIM. It involved migration of 3 modules – Document Management (DM), All Dossier Management and Storage (ADMS), Registration Tracking (RT).

Responsibilities:

* Followed Sanofi’s **PUMA** (Project Unified Methodology Approach) to validate the Veeva Vault RIM data migration project activities.
* Conducted **GAP** analysis with business team to identify the requirements that are to be present for the Sanofi business process.
* Authored Validation Plan (**VP**) to capture all the validation deliverables, migration methodology, test strategy and acceptance criteria for the validated system (**GxP**).
* Data mapping workshops with business team and SME to identify the missing source and target fields.
* Data Enrichment to supplement and incorporate the new fields after analyses together with the Data Governance team.
* Drafted Data and Content Migration Plan (**DMP**) to outline the migration approach for data and documents in the BIVV Veeva Vault RIM Suite to the Sanofi Veeva Vault RIM Suite.
* Authored test cases as part of System Integration Test (**PQ**) and User Acceptance Test (**UAT**) Designs from Migration Specifications in **HP ALM**.
* Conducted Business review sessions post dry-runs to address the issues pertaining to mapping and Vault security profiles in test environment.
* Lead the team in User Acceptance Testing (**UAT**) to validate the migration in Test Environment.
* Defects from testing resolved using the Testing Anomaly Management based on the criticality.
* Data Migration Report (**DMR**) to document acceptance, and the acceptance under conditions of the migrated data.
* Authored and reviewed Authorization for Use (**AFU**) and Validation Report (**VR**)

**Client: Gilead Sciences Inc.**

**Location: Foster City, CA** May 2017 – May 2019

**Sr. Validation Analyst**

**Project Title**: Labware LIMS Stability Module Implementation

**Overview**: Implementation of Stability Module for Labware LIMS and other Quality Systems at Gilead Sciences Inc. I was responsible for the theory and content of validation documents for systems, software and on-going review and to ensure that validation documentation is cGxP compliance.

Responsibilities:

* Responsible for documentation of all aspects of the Computer System Validation (**CSV**) Life Cycle in accordance with **21 CFR Part11**, **xGLP** and **xGDP**.
* Involved in Gap Remediation for user requirements verification and devised remediation plans
* Prepared work flowcharts In MS Visio to illustrate the User Requirements
* Developed Master Validation Plan for the implementation of the new application
* Involved in drafting the User Requirement Specifications (**URS**) and Functional Requirement Specification (**FRS**) by conducting meetings with the users.
* Drafted Functional Risk Assessment (FRA) with input from Business and Technical Team.
* Authored and documented Validation Protocol documents like Operational Qualification **(OQ)** and Performance Qualification **(PQ)**
* Developed and maintained Requirement Traceability Matrix (**RTM**) to track the requirements
* Performed dry runs to check if the test cases have covered the functionalities.
* Lead the team in the formal test execution of test scripts and documented the deviations
* Performed deviation investigations, root cause analysis, and implemented **CAPA**s to business units which improved efficiency
* Authored End-User Training Manuals and SOP’s
* Prepared and documented Validation Summary Report (**VSR**) including Deviation investigation, Resolution and Quality System Development

**Client: Catalent Pharma Solutions**

**Location: Somerset, NJ** January 2016 – April 2017

**Sr. Validation Analyst**

**Project Title:** Windchill Product Lifecycle Management (PLM) Change Management system Project

**Overview**: Involved in Change Management of Windchill Product Lifecycle Management (PLM) system and validation activities. Involved in managing and maintaining project deliverables and related documents

Responsibilities:

* Followed Validation Master Plan to prepare, review and approve CSV deliverables like User Requirement Specifications (**URS**) and Functional Requirement Specification (**FRS**) as per **GxP** guidelines
* Involved in sessions with Subject Matter Experts and system owner to draft the Change Requests
* Performed risk assessment and prioritized Change Requests and ensured the Change Requests are moved accordingly
* Reviewed and approved change requests after verification of completeness of documentation like Change Request Form, Change Control Implementation Plan and Change Control Summary Report.
* Developed Validation Protocols (**IQ, OQ, PQ**) as per the specifications and requirements
* Authored, reviewed and maintained Traceability Matrix (**RTM**) document
* Prepared procedural Test script and test cases for the new requirements.
* Performed Document Reviews to be compliant according to FDA guidelines and GAMP5
* Drafted templates, SOPs and manuals for validation
* Prepared Test Summary Reports and Validation Summary Report (**VSR**)

**Client: KVS Technologies**

**Location: Gujarat, India** July 2013 **–** November 2015

**Validation Analyst**

**Project Title:** Laboratory Information Management System (LIMS) Upgrade Project

**Overview**: The project was on Laboratory Information Management System (LIMS) Upgrade Project with Electronic Laboratory Notebook (ELN) integration. Involved in upgrading and properly maintaining the solution streamlines laboratory management.

Responsibilities:

* Worked in compliance with **21 CFR Part 11** and **cGLP** regulations for this project.
* Developed and reviewed User Requirements Specification (**URS**) and Functional Requirements Specification (**FRS**) artifacts
* Participated in writing the Test Plans, Test Scripts, Retractability Trace Matrix (**RTM**) and Test Summary Reports for executing test scripts according to SOPs
* Involved in the execution of **IQ/OQ/PQ** protocol for the application
* Performed Integration testing, System testing and User Acceptance Testing (UAT) for the test cases
* Lead the team in the dry run of **OQ** and **UAT** test scripts in Development environment and formal testing/execution of **UAT** test scripts in Validation test environment
* Developed End User Training Manuals
* Prepared the Validation Summary Report (**VSR**) summarizing the validation activities that were performed for the LIMS application

**Client: Slisco Lab Instruments**

**Location: Ambala, India** August 2012 – June 2013

**Equipment Validation Engineer**

**Project Title:** Equipment Validation of Pharmaceutical Instruments

**Overview**: Involved in design and implement improvements to manufacturing processes on the production floor of Pharmaceutical Instruments and Pharmaceutical Testing Machines. Performed shopfloor validation activities as per the GMP policies and procedures

Responsibilities:

* Drafted User Requirement Specifications (**URS**) and Functional Requirement Specification (**FRS**) as per the regulatory guidelines
* Designed jigs and fixtures in SolidWorks as a part of tool setup in the new manufacturing facility
* Prepared and documented Operational Qualifications (**OQ**), Performance Qualifications (**PQ**).
* Assisted in procedure development and maintenance, capability studies, Gauge R&R
* Developed the Risk Assessment for current procedure manufacturing equipment
* Drafted all Change Request (**CR**) assessments to evaluate any change to the manufacturing process in relation to validation
* Prepared Retractability Trace Matrix (**RTM**) and Validation Summary Report (**VSR**)

**PUBLICATIONS**

Nageshwar K Rao, Vijayasree K, Srikanth D V (2015). *“***Optimization of Process Parameters of Abrasive Jet Machining on Epoxy Glass Fiber Composite***”*, ‘*International Journal of Scientific Research and Education’, Vol 3, Issue 9*