**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 Regulatory systems like **Veeva Vault RIM**
* Worked with Laboratory Information Management System (**LIMS**), Change Control Management System (**CCMS**) and JIRA

**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 – December 2020

**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: Pfizer**

**Location: Peapack, NJ** 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** February 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

**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*

**EDUCATION**

Master of Science | University of Bridgeport, Connecticut

Mechanical Engineering

Bachelor of engineering | Osmania University, India

Mechanical Engineering