**Namratha.R |** [**namrathar432@gmail.com|**](mailto:namrathar432@gmail.com|) **+1 949-210-9861**

**SUMMARY**

Diverse experience as Validation Specialist with strong emphasis on cGMP manufacturing testing regulations, Quality systems management, FDA 21 CFR (Part11, 210, 211, 820) Validation protocols, regulatory compliance, risk management, gap analysis, Technical documentation including product development life cycles in pharmaceutical industry.

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| **EDUCATION**  Bachelor of Pharmaceutical Sciences JNTU Hyderabad  **TECHNICAL SKILLS**  Validation: 21 CFR Parts (11, 58, 210, 211, 820), Annex 11, cGxP Validation Protocols, (IQ, OQ, PQ) URS, FRS, Audit Trails, SDLC, GAP analysis, Risk Assessments, Change  Control, Validation Summary Report,  Corrective Preventive Actions.  Software: SharePoint, eDoc, LIMS,  ELN, Trackwise, Nextdoc.  Software Development Lifecycle:  Waterfall Model, Agile Model, Spiral and GAMP V Model.  Quality Improvement Tools: CAPA, FMEA, CCM, Gap and Root Cause Analysis, Defect & Configuration Management.  Tools: Microsoft Office (Word, Excel,  Access, Project, PowerPoint, Visio), Adobe Photoshop | **PROFESSIONAL EXPERTISE**   * Good expertise in developing and reviewing Computer system validation deliverables– Risk Assessments, 21 CFR Part 11 Regulatory Assessments, Validation Plans, IQ/OQ/PQ protocols, Deviations/Incident handling, Gap Analysis, Validation summary reports, and Change Controls. * Experience in reviewing and writing User Requirement Specifications (URS), Functional Requirement Specifications (FRS), Design Specifications (DS), Standard Operating Procedures (SOP’s), Work Instructions (WI’s), Requirement Traceability Matrix (RTM), Validation Summary Report (VSR), Audit Trails, Periodic Review of Computer Systems to ensure compliance with FDA regulations. * Good knowledge and detailed understanding of Software Development Life Cycles (SDLC), and various life cycle methodologies such as Waterfall model, Spiral, GAMP V-model and Agile model in relation to development and testing. * Detailed knowledge of 21 CFR Part 11: Electronic records, Electronic signatures & Audit Trails to ensure Data Integrity and Security of the application. * Proficient in developing as well documenting all aspects of Validation lifecycle: Validation Plan (VP), Installation Qualification (IQ), Operation Qualification (OQ), Performance Qualification (PQ), and Validation Summary Report. * Strong working experience in FDA regulated environment and good understanding of cGxP (GMP, GDP, GLP, GCP) standards, CGMP, ISPE, GAMP guidelines and regulations to ensure compliance and adherence with corporate guidelines. * Comprehensive knowledge and expertise in writing, reviewing and executing Validation Protocols (IQ/OQ/PQ), test scripts, test plans, Test Summary Reports, Requirement Traceability Matrix (RTM) for all phases of testing i.e. unit testing, system Integration testing IQ, OQ, PQ and UAT Testing. * Performed Risk Analysis activities to support Product Impact Assessments, Product Risk Evaluations, and CAPA investigations. * Provided cross-functional support for QMS to identify non-conformances through Root Cause Analysis (RCA) and implement Remediation Plans to drive out deviations and compliance issues. * Expertise in validating Laboratory Information Management System (LIMS), Enterprise Document Management System (EDMS). * Participated in Failure Mode and Effect Analysis (FMEA) and Operational Quality Risk Assessment processes to help reduce process deviations. * Hands on experience in Risk Analysis, Gap Analysis, also identifying gaps, handling deviations and implementing Corrective Action and Preventive Action (CAPA), also preparing Remediation plans to mitigate with the non-compliance. * Expertise in writing audit plans, assessments on documents and systems for QA. * Ability to work in an action-oriented, fast-paced, rapidly changing environment and possess strong interpersonal, organizational and communication skills with strong abilities in requirement capture, analysis, design and development. |

**WORK EXPERIENCE**

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| **QPharma, (Morristown, NJ)**  **CSV Specialist** | **Oct 2019 – Present.** |

QPharma is a premier provider of IT technological solutions, Healthcare compliance, Computer Validation services focusing on the brand solutions and regulatory compliance consulting to the life sciences industries. There are several clients with requirements from time to time which involves Qualification, Validation and compliance activities also responsible for change controls and deviation handling.

***Responsibilities*:**

* Involved in Developing Validation Plan, Validation Protocols, Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ) Specifications.
* Reviewed Risk Assessments, Test Summary Documents and Validation Summary Report (VSR) to summarize overall validation activities and establish documented evidence that the system was validated in compliance with 21 CFR Part 11.
* Performed ETL testing from Veeva to Titanium and Database Testing using SQL scripts in order to verify the Data Mapping and Data Integrity between the source and target systems.
* Performed periodic review of validated applications and end to end validation documentation to ensure compliance with company policies and procedures.
* Responsible for Integration/ ETL testing and documentation for various client requirements and involved in data migration projects to ensure data integrity and data validation.
* Asserted validation documentation, maintained and all logs through Docusign to comply with cGMP compliance.
* Expertise in Test Management, Functional and Regression testing, test summary reports, defect report documentations and onsite-offshore coordination.
* Maintained and controlled Electronic Records, Digital Signatures, Electronic Signatures and capturing Audit Trails with respect to 21CFR Part 11 requirements.
* Managed the Change control system and proactively drive closures for on-time completion.
* Responsible for CAPA process regarding the escalation, investigation, and addressing of manufacturing and quality system process issues.
* Involved in Quarterly Internal Audits and perform Monthly Self-Inspection Audits across the site to ensure company standards are maintained.
* Supervised the Data Integrity (DI) program to implement data integrity controls and improvements for GxP systems and trained on-site personnel to identify and prevent Data integrity issues.
* Initiated, edited and/or updated policies, procedures, work instructions or other supporting documentation and originated appropriate change notification documentation.
* Conduct Periodic reviews as a critical aspect on GxP systems/processes that have already been validated to review system or process for changes – both physical and procedural in order to verify that a system or process is operating as expected.
* Perform periodic review for systems, including complete listing of critical subsystems/components (e.g. equipment, hardware, software) to identify any system against regulatory, GMP requirements and/or company policy changes established since the last periodic review or qualification.
* Monitored and reviewed all Deviations/Incidents including frequency and reasons, relating to the computerized systems and responsible to analyze and report trends also, perform Root Cause Analysis (RCA) for non-compliances to identify whether there is a trend away from the qualified state and ensure corrective actions to improve operation of the system and maintain compliance.

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| **Perrigo, (Allegan, MI)**  **Validation Analyst** | **Nov 2017–Aug 2019** |

Perrigo is a pharmaceutical company engaged in the development, manufacture and marketing of multi-source and branded pharmaceutical products in the United States. I worked as a Validation Analyst for validating LIMS used in R&D applications. I was responsible for validation of individual workstations and its linkage to laboratory equipments in compliance with regulations.

***Responsibilities****:*

* Performed validation of Lab station module for LIMS interfacing with lab instruments.
* Validated Login screens, crystal reports and access profiles in LIMS based on the URS for User Interface (UI) testing.
* Responsible for gathering User Requirement Specification (URS), Functional Requirement Specification (FRS)

based on Business Process Requirements Specifications (BPRS) also storing and maintaining the documents to comply with 21 CFR Part 11.

* Involved in reviewing Validation Plan, URS, FRS, Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ) Specifications.
* Involved in writing the Risk Assessment documents, Test Summary report, Validation Summary Report (VSR) summarize overall validation activities and to establish documented evidence that the system was validated in compliance with 21 CFR Part 11.
* Analyzed and reviewed the business requirements, design specifications for LabWare LIMS.
* Created and Reviewed Operation Qualifications (OQ) and User Acceptance Testing (UAT) test cases for different modules of LIMS based on the User and Functional Requirement specifications (UFRS).
* Maintained batch records to keep the track of Lot History, Working List, and Rejected Samples.
* Maintained all the logs and documents through a document management system NextDoc.
* Created Design specification documents for Lab station module of LIMS and executed test scripts for positive, negative testing.
* Analyzed Requirement Traceability Matrix (RTM) to track requirements and to correlate with the executed test cases and using Defect tracking to report deviations in HP Quality center (ALM).
* Participated in Data Integrity assessments of lab equipment/systems to analyze input and output points of data from LIMS and ensure Integrity with the other systems.
* Ensured compliance with FDA (21 CFR Part 11) for documents pertaining to the validation life cycle.
* Involved in periodic auditing of the change management systems to ensure that these systems are compliant with the SOP’s.
* Maintained and controlled Electronic Records, Electronic Signatures and capturing Audit Trails to ensure Data Integrity, and security of the application with respect to 21CFR Part 11 requirements.
* Involved in Change control procedures for LIMS to implement changes in validation and production environment and perform Gap analysis considering the user and system requirements to identify any non-conformances and responsible for creating the Corrective and Preventive Action Plan (CAPA’s) and remediation plans for various compliance issues.
* Documented test execution report and prepared Requirement Traceability Matrix (RTM).

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| **Amgen Inc, (Thousand Oaks, CA)**  **Validation Consultant** | **July 2016 – Aug 2017** |

Amgen is a Biotechnology company with expertise in developing innovative oncology, cardiovascular and neuroscience medicines. Responsibilities included the validation of Trackwise (Quality Management System).

***Responsibilities:***

* Involved in the creating of Validation Deliverables for TrackWise and standalone systems involved.
* Involved in developing and executing Installation Qualification (IQ), Operation Qualification (OQ), and Performance Qualification (PQ) and documented using standard templates.
* Created risk matrices for system impact and functional risk assessment
* Managed project records in TrackWise QMS (Incident reports, change controls).
* Documented test cases for positive, negative, unit, integration, system, & user acceptance testing.
* Responsible to develop Test cases, Test Scenarios and Test plans according to development specifications, run the tests and track defects using HP Quality Center (ALM).
* Prepared UAT test cases and mentored execution of UAT test cases to business users.
* Interacted with the users, Trackwise developer team to qualify configured modules in TrackWise web team access and TrackWise administrator.
* Composed work instructions, monitored deviations, reported management team of Change Control.
* Developed SOP’s that were in accordance with cGMP regulations and trained the required users.
* Developed System Investigation Request to initiate the change process.
* Created, reviewed, updated, and routed documents using eDoc.
* Reviewed and executed test scripts based on test plan and in accordance with (GDP).
* Created Requirement Traceability Matrix (RTM) for both automated and manual system testing to cross-reference the functionality to co-relate with the executed test cases using HP Quality center.
* Conducted Gap Analysis and provided cross-functional support for Quality Management Systems to identify discrepancies and ensure compliance with 21 CFR Part 11 regulations and global standards.
* Facilitated and performed Root Cause Analysis (RCA) to identify non-conformances.
* Documented Change control coordinating with regulatory operations to open a new Validated System Change Request in TrackWise.
* Participated in operations to resolve technical issues and implemented Corrective and Preventive Action (CAPA’s) to identify the non-conformances in the project.
* Developed and drafted Work Instructions for Business and System Administrators, Standard operating procedures (SOP) and training guides.

**Amneal Pharamaceuticals Mar 2015 – July 2016**

**Junior Validation Analyst**

Scope of this Project was qualification of various legacy and newly automated equipments and Laboratory instruments. It involved developing, executing and maintaining validation activities in compliance with applicable regulatory requirements

and industry best practices.

***Responsibilities:***

* Involved in development of Validation protocols- IQ/OQ/PQ activities, change controls and validation summary reports for the manufacturing equipment, such as Autoclaves, Incubators, Refrigerators, Ovens, portable vessels, heat sealers, Freeze dryers.
* Executed and documented the Qualification and Validation of manufacturing equipment, processes, and other manufactured components to meet the specification requirements.
* Involved in Qualification of Kaye Validator 2000 System using Temperature mapping of equipments like autoclaves, incubators, Lyophilizers and thermocouple calibration.
* Performed PQ tests for Autoclaves on a regular basis such as: Bowie-Dick test, Air leak test, B.I, Empty chamber and Heat penetration tests and documented the results as per compliance.
* Responsible to document Temperature mapping reports and utilizing data loggers to gather data for analysis and troubleshooting issues.
* Involved in the validation Purified water system and performed water sampling for Conductivity, TOC, bioburden and endotoxin content in compliance with the specified requirements.
* Reviewed and verified test results, and identified, reported issues to provided summary test reports.
* Participated in Failure Mode and Effect Analysis (FMEA) program and Operational Quality Risk Assessment processes to help reduce process deviations.
* Regularly supported production in Class 7 clean room to identify, support and fix equipment issues.
* Assisted in Deviations activities to identify non-conformances, Product Impact Assessments, Product Risk Evaluations, and CAPA investigations.
* Conducted validation activities according to the GAMP V-model and was part of drafting Remediation Plans and implementing those corrective action plans.