**Surendran R**

**Validation** **Lead/Engineer**

**732-769-8272**

Diversely experienced individual, expertise in Planning, Implementing and Monitoring the Validation Strategies in Pharmaceutical and Medical Device Manufacturing sectors. Adaptive and Detail-oriented in validating computer system and medical equipment by running system specification, implementing regulatory guidelines and coordinating onshore and offshore team.

**Professional Summary**

* 7+ years of hands on experience in validating the computer system in Pharmaceutical and Medical Device Manufacturing industries as Sr. Validation Engineer.
* Extensive knowledge in **Validation Lifecycle** and **Software Development Lifecycle**.
* Worked on the following systems: **LMS, LIMS, CTMS** and **EDMS**
* Proficient in GAMP regulation and FDA regulations **21 CFR Part 11, Part 210, Part 211 and Part 820**.
* Proficient in ISO standards **ISO 13485, ISO 14971 and ISO 10993-1**.
* Extensive knowledge on **cGxP (cGMP, cGCP, cGLP, cGDP)** guidelines and regulations.
* Participated in High Level Risk Assessment **(HLRA)** to determine regulatory and system scope.
* Developed and Documented the Business Work Flow Chart.
* Authored **User Requirement Specification** **(URS)**, **Functional Requirement Specification (FRS)** and **Design Requirement Specification (DRS).**
* Actively Involved in Vendor Selection and Assessments.
* Experience in preparing and documenting **Validation Master Plan, Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Requirement Traceability Matrix** **(RTM).**
* Experience in developing and documenting **Test Cases, Test Plan, Standard Operating Procedures (SOP) and FDA audits.**
* Actively involved in **Deviation Management, Remediation Planning, Change Control Management, Document Control Management, Audit Management, Risk Management, Supplier Management and Training Management.**
* Experience in performing **CAPA, GAP Analysis** and **Audit trail** for computer systems used in Pharmaceutical and Medical Device Manufacturing industry.
* Performed **User Acceptance Testing (UAT) and System Testing**.
* Prepared and Documented **Validation Summary Report (VSR)**.
* Experience in using **ServiceNow,** **HP ALM, TrackWise and JIRA** for issue tracking and managing the testing activities.
* Proficiency in computer skills including **Microsoft Office, Minitab and SolidWorks**.
* Experience in coordinating **onsite and offshore team** to maintain smooth testing activities.
* **Trained and mentored** junior team members.
* Strong **organizational skills, time management skills, excellent writing and communication skills**.
* Ability to work **independently** and in a **team environment**, interacting with individuals at all levels in an organization and departmental areas.

**Technical Skills**

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| --- | --- |
| Computer System Validation | HLRA, RACI, RTM, IQ, OQ, PQ, Deviation Management, Risk Assessment, CAPA, FMEA, Change Control Management, GAMP, cGxP, and RTM |
| Applications | ComplianceWire, Labware, Veeva, Master Control and Documentum. |
| Tools | ServiceNow, HP ALM, JIRA, Trackwise, Snagit, Minitab and SolidWorks |
| SDLC | Waterfall, Agile and V-model |
| FDA Regulations | 21 CFR Part (11, 58, 210, 211, 820) |
| ISO Standards | ISO 13485, ISO 14971, ISO 10993-1 |
| Documentation | Microsoft Office |

***Professional Experience***

**Abbvie- North Chicago, ILJul 2019 – Current**

**Validation Lead**

Project Summary:

The scope of the project was to upgrade various GxP and Non-GxP application’s database Oracle/SQL Server Operating System (OS) and the database version**.** As a Validation Engineer, I was responsible for validating various computer systems, capturing and documenting the testing strategy, database/server version and project summary etc. in ServiceNow and also involved in the decommission of old database and servers.

Responsibilities:

* Responsible for handling/documenting all the Change Request created in ServiceNow for application’s in scope under Database Modernization project.
* Used ServiceNow for creation of Change Request and managing the documentation and RRB approvals from Assessment stage to Implementation stage.
* Conducted **Joint Application Development (JAD)** sessions with the Business System Owners and IT System Owners in drafting the **Functional Requirement Specification (FRS).**
* Drafted **Validation Test Protocols (VTPs)** for each requirement associated with the computer system.
* Engaged in executing the testing protocols in HP ALM for various Validated and Non-Validated systems.
* Drafted **Requirement Traceability Matrix (RTM)** ensuring all the **Validation Test Protocols (VTPs)** are linked with the **Functional Requirement Specification (FRS).**
* Authored **Validation Plan (VP), Project Plan (PP) and Project Summary (PS).**
* Prepared **Incident Reports (IR)** for documenting the deviation in the computer system.
* Drafted **Validation Summary Report (VSR)** summarizing end to end validation activities.
* Ensured all the deliverables follow **FDA 21 CFR Part 11**, **GxP** and **GAMP** regulations.
* Involved in database/server decommission activities, created decommission request form and worked on the closure of this activity.
* Involved in system characterization of the computer system.
* Collorbarated with various team of different timezone in managing and proceeding with the testing activities.

**Celgene- Summit, NJJan 2018 – Jun 2019**

**Senior Validation Engineer**

Project Summary:

The scope of the project was to enhance the functionalities and capabilities of **Learning Management System (LMS).** As a Validation Engineer, I was involved in validating the upgraded **ComplianceWire Learning Management System (LMS),** authored Validation Master Plan, Validation Protocols and coordinated the offshore and onsite team.

Responsibilities:

* Reviewed and updated the **User Requirement Specification (URS)** and **Functional Requirement** **Specification (FRS)** and mapped it with business workflow.
* Developed **Requirement Traceability Matrix (RTM)** to map Test Cases with the User Requirements and Functional Requirements and ensuring there is no gap in the system.
* Participated in determining **RACI** matrix to define project roles and responsibilities.
* Performed **Functional Risk Assessment** **(FRA)** to determine the **Risk Class** and **Mitigation Action** for **Functional Requirement Specification (FRS).**
* Authored and reviewed the **Validation Master Plan (VMP)** and **Validation Protocols** **(IQ, OQ, PQ)** for computer systems.
* Drafted and Documented **Test Plan, Test Cases, Test Strategies** and **Test Protocol.**
* Engaged in the execution of **IQ, OQ and PQ** protocol for the computer system.
* Performed Informal Testing (**Dry Run**) in the development environment and later **Formal Testing** was carried out in the Testing Environment.
* Documented the **Deviations, Remediation Plan and performed Corrective Action and Preventive Action (CAPA).**
* Prepared **Validation Summary Report (VSR)** containing end to end validation activities.
* Reviewed and Documented all the validation deliverables in compliance with **21 CFR Part 11** and **cGxP** regulations.
* Collaborated with the **offshore team** in coordinating the testing activities and to maintain the business continuity.

**Gilead Sciences- *Foster City, CA* Oct 2016 – Dec 2017Senior Validation Engineer**

Project Summary:

The scope of the project was to manage thechange control process in the **Labware Laboratory Information Management System (LIMS).** As a Validation engineer, I was responsible for managing and guiding the validation activities for the computer system and documenting the change control artifacts.

Responsibilities:

* Assisted the Business Team in drafting the **User Requirement Specification (URS)** and **Functional Requirement Specification (FRS).**
* Reviewed **User Requirement Specification (URS)** and **Functional Requirement Specification (FRS)** and mapped it with Business workflow.
* Reviewed and analyzed the **Validation Master Plan (VMP)** and defined the **Validation Strategy**.
* Interacted with the stakeholders to document the changes in the **Change Request Form (CRF)** and initiate the change control process.
* Reviewed the changes and performed **Change Impact Assessment and Risk Assessment**.
* Reviewed the **Change Control plan and Change Control Implementation plan.**
* Developed **Requirement Trace Matrix (RTM)** to map Test Cases with **User Requirement Specification (URS)** and **Functional Requirement Specification (FRS).**
* Drafted and reviewed the **Validation Protocols** **(IQ, OQ, PQ)** for the computer system.
* Authored **Test Plan, Test Cases, Test Strategies** and **Test Protocol.**
* Reviewed all the change control documents to ensure it follows **FDA 21 CFR Part 11** and **GAMP** regulations.
* Reviewed and modified the **Standard Operating Procedure (SOPs).**
* Drafted and Documented the **Validation Summary Report** **(VSR)** and **Change Control Summary Report.**
* Used **TrackWise** tool to organize and manage initial change request to implementation process, securing regulatory approvals and integrating quality process.

**Johnson and Johnson- *Bridgewater, NJ* Nov 2014 – Aug 2016
Validation Engineer**

Project Summary:

The scope of the project was to implement **Veeva Vault Electronic Data Management System (EDMS).** As a Validation Engineer, I was assisting in capturing the **User Requirement Specification (URS) & Functional Requirement Specification (FRS)**, validated the implemented module and documented the validation deliverables.

Responsibilities:

* Drafted the **Business Workflow Chart** using **MS Visio**.
* Assisted in drafting **High Level Risk Assessment (HLRA)** to define regulatory scope and functional scope.
* Assisted the business team in capturing the **User Requirement Specification (URS)** and **Functional Requirement Specification (FRS)** in compliance with **21 CFR Part 11**
* Participated in the **Vendor Selection and Assessment**.
* Participated in defining the **RACI charts** to determine the roles and responsibilities in the project.
* Developed **Requirement Trace Matrix** **(RTM)** to keep track of test cases with **User Requirement Specification (URS) and Functional Requirement Specification (FRS).**
* Conducted **Functional Risk Assessment** **(FRA)** on **Functional Requirement Specification (FRS)** to determine the risk scenarios and the impact on the system.
* Authored **Validation Master Plan (VMP)** and **Validation Protocols** **(IQ, OQ, PQ).**
* Drafted **Test Strategy, Test Plan, Test Cases and Test Case Summary Report**.
* Tested the requirements in the Development Environment by performing **Dry Run** and a **Formal Testing** was performed in the Validation/Testing Environment.
* Performed **Integration Testing, System Testing** and **User Acceptance Testing (UAT)**
* Documented the **Deviations, Remediation Plan** and performed **Corrective Action and Preventive Action (CAPA).**
* Authored **Validation Summary Report (VSR), SOPs and User Manuals.**
* Used **HP ALM** tool to monitor and manage all the activities in the validation process.

**Data Migration Experience:**

* Drafted **Data Migration Plan and Data Migration Strategy**.
* Performed **Data Assessment and Data Cleansing**.
* Developed **Data Mapping** to ensure target data is not lost/mis-represented.
* Performed **ETL** (Extract, Transform, Load) processes.
* Participated in **Qualitative and Quantitative validation** during Pre-migration testing and Post-migration testing.
* Performed Data Validation to ensure migrated data are following the **GxP guidelines**.

**Allengers Medical Systems Limited- Chennai, India July 2013 – Oct 2014
Validation Engineer**

Project Summary:

The scope of the project is to design and manufacture class 2 medical device. As a validation engineer, I performed the validation activities and analyzed the input design values in Minitab as well as involved in designing basic medical fixtures. Also responsible for documenting and delivering the validation deliverables.

Responsibilities

* Reviewed work flow processes, manufacturing plan and work instruction
* Prepared **Validation Approach, Validation Strategy and Test Method**.
* Participated in **Design and Verification** of Class 2 device.
* Coordinated Labeling and Packaging by implementing **Unique Device Identification (UDI).**
* Prepared and Documented **Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), CAPA and GR&R.**
* Developed and Maintained **Master document** constitutes the validation package.
* Extensive knowledge on FDA Regulations: **21 CFR Part (11, 58, 210, 211, 820)** and ISO Standards: **ISO 13485, ISO 14971, ISO 10993-1.**
* Performed **Gap analysis** and created a **Remediation plan**.
* Analyzed statistical data using **Design of Experiment (DOE)** technique in Minitab.
* Enhanced product manufacturing process by following **DFM** and **DFA** guidelines.
* Modelled and Analyzed small medical fixtures using **SolidWorks and Ansys Workbench**.
* Reviewed and Documented **Design History File** **(DHF)** summarizing the design and development process.
* Prepared all **Validation Plan, Studies and Validation Summary Report (VSR)** in compliance with **21 CFR Part 11.**

**Education:**

Anna University, Chennai, India
*Bachelor of Engineering*