**L;.OBJECTIVE**:

A detail-oriented Validation Engineer with 7 years of experience in Computer System Validation and Equipment Validation techniques in the medical device and pharmaceutical industry. Strong interpersonal skills with proficiency in handling communications with cross functional teams about project details. Looking forward to leveraging my skills and ultimately contribute to the growth of the company.

**PROFESSIONAL SUMMARY:**

* Validation engineering professional with 7 years of hands-on experience in Computer systems, Equipment and Process Validation in thePharmaceutical Industry.
* Expertise of validation practices in FDA regulated environment with good understanding of cGxP (cGMP, cGCP, cGLP) standards.
* Experienced in validating and testing computer systems that comply with FDA regulations 21 CFR Part 11, Part 210, Part 211, Part 820 and ISO regulations.
* Experienced in authoring quality system (user requirements, functional requirements, validation plan, Test plan etc.) documentation to ensure that they comply with FDA regulations and company policies.
* Experienced in generating the validation deliverables like User Requirements Specification (URS), Functional Requirements Specification (FRS), Installation qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), Requirement Traceability Matrix (RTM), and Validation summary report (VSR).
* Proficient in Validation environments, V-Model, Software Development Lifecycle and QA Methodologies.
* Proficient in dealing with Quality Management System (QMS), Laboratory Information Management System (LIMS), Enterprise Document Management System (EDMS)
* Experience in performing Risk Assessment and Gap Analysis for various software applications and systems that are used in Pharmaceutical and Medical Device Industry.
* Experience with validating laboratory equipment like HPLC, HVAC System, Depyrogenation tunnels, Autoclaves, cooling towers, compressors, vacuum system, air circulation system, Freezers, Coolers, etc.
* Experience in conducting Corrective and Preventive Action (CAPA), Root Cause Analysis and Risk Analysis.
* Worked independently and collaborated in teams with effective, multi-tasking, critical-thinking, goodcommunication, and documentation capabilities.

**SKILLS:**

|  |  |
| --- | --- |
| Computer System Validation | 21 CFR Part 11, 210, 820, EMEA Annex 11, GMP, GLP, GCP, GDP, SOP’s, GAMP, Summary Reports, Audit trails, Validation protocols (IQ, OQ, PQ), CAPA, FMEA, Change Control management |
| Methodologies | Agile, Waterfall, V model |
| Applications | TrackWise QMS, LIMS Labware, Sample Manager, Kneat, EDMS |
| Technical Writing | Validation Master Plan (VMP), Functional Specification (FS), Design Specification (DS), Test Plans, Requirement Traceability Matrix (RTM), Test Cases, Test Summaries, GxP Compliance Reports, Validation Summary Reports. |
| Tools | MS Office (Word, Excel, PowerPoint), MS Visio, MS Access, MS Project, SharePoint, HP ALM, Minitab, Autocad, Solidworks. |

**PROFESSIONAL EXPERIENCE: -**

**Abbvie Pharmaceutical**  North Chicago

***Validation Tester/Analyst*** Nov 2021 – Present

* Worked as a validation analyst on multiple applications:
* **One Track: Multiple Releases (Medical Device, Bodysculpting}**
* **Sample Manager**
* **Antares Global Tracking System**
* **TrackEM**
* **Complaint Trend Monitoring System**
* **IPAS**
* **DSA**
* **Secure Sync**
* Authored and reviewed the Validation Master Plan and Validation Protocol, User Requirement Specification (URS) and Functional Requirement Specification (FRS).
* Maintained the requirements traceability matrix (RTM) and mapped test cases with the User Requirements and Functional Requirements.
* Authored, reviewed and approved Test Protocols, Test Case Summaries and Validation Summary Report.
* Conducted manual testing like functional, regressiontesting and requirements management through HPALM
* Responsible for analyzing and identifying errors that occurred during the execution of Test protocols such as the Operational Qualification (OQ), Performance Qualification (PQ) Test case.
* Raised Incident Reports (IR) on HP ALM to track defects
* Worked with multiple teams to support day-to-day operations in areas such as performing testing, defect management, streamlining the communication between project teams.
* Conducted OQ/System and User Acceptance/PQ Testing and documented the test summary reports.
* Coordinated with project core team, Quality and Business Representatives to ensure SDLC deliverables are consistent and meet the requirements and business needs.
* Played an active role in developing and reviewing Computer System Validation deliverables: Validation Plan, Overall risk assessment, reviewed User and Functional requirements specification documents, 21 CFR Part 11 Assessment, Detailed Risk Assessment, OQ and PQ test cases.

**Merck & Co.** Kenilworth, New Jersey

***ValidationEngineer*** Feb 2021 – Nov. 2021

* The project involved change control implementation of documents in Trackwise QMS, Labware 7 LIMS for organizing documents and storing them.
* Assisted and documented all phases of system life cycle complying with the Federal regulations under 21CFR Part 11(Electronic Records and Electronic Signatures).
* Responsible for creating flowcharts to understand the flow of applications functional requirements and overview of the software system.
* Coordinated with Business Analyst, clients, End users to documented User Requirements Specification (URS), analyzed and authored Functional Requirements Specification (FRS).
* Performed Risk Assessment for each functional requirement to determine the risk level associated with each requirement and documented them according to SOP.
* Developed and documented Requirements Traceability Matrix (RTM) to link and trace the requirements throughout the system life cycle.
* Developed and reviewed the IQ, OQ, PQ Protocols according to SOP/Work Instructions.
* Prepared Test Plan, Test Cases and Test Summary Report for functional, integration, System Integration and Regression Testing in HP ALM.
* Documented all aspects of the Computer System Validation (CSV) Life Cycle in accordance with Good Documentation Practices (GDP)
* Responsible for performing the GAP Analysis of the current system and developed Deviation Report.
* Authored and Documented the Validation Summary Report and Change Control Summary Report.
* Performed the Change Impact Assessment to analyze the system compliance on the proposed changes to the current system
* Developed and document Change Control Documentation such as Change Request Form, Change Control Implementation Plan, Change Control Summary Report

**Ajanta Pharma Ltd.** Mumbai, India

***ValidationEngineer*** Oct2016 – June 2018

* Collaborated with manufacturing facility, Quality, Packaging, and Corporate Engineering to ensure that R&D tasks are being completed appropriately
* Developed, executed, and reviewed FAT, SAT and validation protocols (IQ, OQ, PQ), specification requirement documents (URS, FRS), test plans, project plans and procedures. Responsibilities include computer validation for manufacturing and related automation systems, formulation and solution validations, and validation of packaging and manufacturing processes and equipment
* Performed installation and operational and performance qualification (IQ/OQ/PQ) of critical manufacturing equipment, facilities, and utility systems for Oral Solid Dose (OSD) and Sterile Injectable facility.
* Written, reviewed, performed and executed Qualification and Requalification protocols for various manufacturing equipment for pharma& biotech products.
* Provided technical leadership in process-related investigations, deviations, CAPAs, and change controls
* Validated bioreactors, autoclaves, lyophilizer, filtration units, incubator, clean steam generators, vial washers, depyrogenation units and other utilities in compliance with FDA regulations.
* Implemented process improvements for spray drying, resulting in greater efficiency, safer practices, and increased revenue
* Conducted root cause analysis of production deviations, resulting in corrective and preventive actions
* Reviewed and developed validation master plan and summary reports.
* Prepared and executed commissioning and qualification documents for utilities and equipment.
* Involved in documentation practice of different stages of validation life cycle in compliance with 21 CFR Part 11.
* Developed various types of user documentation, including how-to guides, references and comprehensive technical documentation.
* Assisted technical support team for troubleshooting any problems in the manufacturing operations.
* Creating Requirements Traceability Matrix (RTM) to map the user requirements to the functional requirements, design specification and test script references
* Managed documentation on internal portal using Change Control Request (CCR) in TrackWise.
* Reviewed processes and workflows, communicated probing questions with the business unit, provided gap analysis for process improvements, and verified information to produce high-quality policies and procedures.
* Responsible for inspecting equipment in the regulated pharmaceutical sector in accordance with GxP systems.

**Kopran Pharmaceuticals**Mumbai, India

***ValidationEngineer*** August 2013 – September 2016

* Facilitated collection of User Requirements with collaboration from Business Analyst, clients, End users and preparation of Business requirement documents (BRD) that provided appropriate scope of work for technical team to develop prototype and overall system.
* Responsible for all Validation deliverables as part of Validation lifecycle process according with Company policies.
* Assisted in validation of HPLC Instruments, Mass Spectrometer, GC and Plate Reader including preparation of protocols (IQ, OQ, PQ).
* Conducted Gap Analysis and Recalibrations of Lab instruments for Part 820 compliance.
* Authored and documented 21 CFR Part 820 Checklist and Assessment to ensure that the system complies with the requirements according to FDA Regulations.
* Reviewed existing test scripts to familiarize with the current Business system and its operation/process.
* Assisted in initiating and conducting Gap Analysis and Remediation Plan for lab equipment and software interfaced with LIMS for 21 CFR Part 11 compliance and prepared Deviation Reports.
* Developed/Maintained the Requirements Traceability Matrix (RTM).
* Involved in the writing of IQ/OQ/PQ Test scripts.
* Maintained CAPA procedure, supporting investigation of non-conformances through root cause analysis, evaluation of the effectiveness of CAPA process.
* Reviewed Vendor's audit report to assure adequate Quality Management System.
* Ensured complete 21CFR part 11 compliance assessments for manufacturing systems
* Prepared list of documents required for the cleaning validation system based on GAMP5
* Responsible for inspecting equipment in the regulated pharmaceutical sector in accordance with GXP systems.
* Send out equipment for calibration as per ISO calibration.
* Responsible for Change control process and Prepared Change Notification Forms (CNFs).
* Authored Validation and verification Summary Report of involved systems software’s and Lab instruments.

**EDUCATION**: -

* Lawrence Technological University - Michigan

Master of Science in Industrial Engineering

* University of Mumbai – India Bachelor of Engineering in Mechanical Engineering