**Harshil Patel**

**Phone: 412-541-2229**

**Email: harshiljpatel2794@gmail.com**

**SUMMARY**

* Diverse experience as Validation and Quality Specialist of GMP Computerized systems, laboratory instrument, process equipment, facility and utility systems Validation.
* Experience as QA Specialist in GMP environment and performing 21 CFR Part 11 and Annex 11 Assessment, Data Integrity, Process Improvement, GAMP Assessment and Quality Risk Management.

**EXPERTISE**

* Deep knowledge and understanding of all the phases in Software Development Life Cycle (SDLC), Validation Life cycle (VLC), Quality Assurance and Quality control.
* Experience working with FDA regulations including 21 CFR Part 11: Electronic Records, Electronic Signatures and Audit Trails.
* Experience working on GMP Computerized systems such as Maximo, ComplianceWire, LabWatch, LIMS, Denodo and TraceLink.
* Experience working on GMP Equipment and instruments such as Autoclaves, Incubators, and Bioreactors, Analytical balances, pH Meters, TOC Analyzer, Particle Size Analyzer and Particle Counters.
* Writing documents according to Good Documenting Practices (GDP).
* Good understanding of GAMP, cGxP (cGMP, cGLP, cGDP, and cGCP) standards and Corrective and Preventive Actions (CAPA) investigation.
* Working knowledge in Data Migration, Periodic Review, GAP Analysis, Risk analysis, Data Integrity, CAPAs and documenting Remediation Process.
* Handling Change-Controls and document tracking in pharmaceutical manufacturing environment.
* Expertise in writing and documenting all validation deliverables such as compliance/validation plans, validation reports and summaries.
* Planning, testing, and implementation of system enhancements and conversions, which included developing detailed documentation for training and testing.
* Developing Requirement and Functional Specifications, IQ and OQ Test Cases and Requirement Traceability Matrix (RTM).
* Extensive experience in preparing Validation plan and summary report.
* Good understanding and experience in FMEA, Root cause analysis and CAPA investigations and reviews in compliance with FDA.
* Expertise in Data Migration and preparation of Data Migration Summary documents.
* Good understanding and knowledge of GAMP5 and GAMP4 rules and regulations.
* Generating, reviewing, sharing and maintaining system documents using EDMS
* Knowledge in reviewing current operating procedures and developing Standard Operating Procedures (SOPs).
* Excellent problem solving and troubleshooting skills, communication and organizational skills, ability to work in cross-functional teams, quick learner and capability to perform well under pressure.

**EDUCATION**

* MS – Engineering Management, Point Park University, Pittsburgh, PA, USA
* Bachelors in Mechanic Engineering – KJ Institute of Engineering, Gujarat, India

**PROFESSIONAL EXPERIENCE**

**Baxter HealthCare, Deerfield, IL**

**QA Validation specialist (Jan 2020 – Present)**

**Responsibility:**

* QA review of Computer System Validation (CSV) deliverables in compliance with 21 CFR Part 11, GxP and FDA Compliance Regulations.
* Worked on validation of GMP Computerized systems: Maximo – Asset Management System and ComplianceWire.
* Ensured performance standards are established and follow all cGMP and safety requirements, SOP’s and Company policies and procedures.
* Developed all validation deliverables (Validation Plan, IQ, OQ, PQ Traceability matrix, Summary Report, Configuration Specification, System Requirement Spec and facilitated in System and Integration testing.
* Created business process flow and data flow diagrams using MS-Visio.
* Communicating and managing expectations with the final users regarding the Developed standard documents for validation deliverables like User Requirement Specifications (URS), Functional Requirement Specification (FRS) and System Design Specification (SDS).
* Reviewed System Testing Protocols, ensuring GDP and proposed approval system.
* Drafted the Validation Strategy Document and documented the Vendor Assessment Report.
* Documented and executed Installation Protocol (IQ), Operational Protocol (OQ), Performance protocol (PQ) and reviewed them.
* Created and managed project templates, Use Case project templates, requirement types and traceability matrix.
* Coordinated with business team to prioritize projects according to business need.
* Worked in a cross-functional team to support lifecycle qualifications, commissioning, and decommissioning of instruments and equipment in the laboratory.
* Provided authoring support for investigations as needed.

**Syndax Pharmaceutical, Waltham, MA**

**QA Validation Specialist (Jan 2019 – Dec 2019)**

**Responsibilities:**

* Supported Validation activities for the various GMP equipment, lab instruments and computer systems.
* QA reviewer and approver for the manufacturing equipment, such as Autoclaves, Incubators, and Bioreactors and Instruments such as Analytical balances, pH Meters, TOC Analyzer, Particle Size Analyzer and Particle Counters.
* Compliance review of Automated Manufacturing Equipment to comply with FDA regulations.
* Periodic Review of various laboratory instrument, process equipment and computerized systems.
* Review SOPs / Computer Work Instructions (CWI) / Laboratory Equipment Procedures (LEP) against business use, local policies / procedures, and regulations.
* Responsible for performing GAP Analysis of executed validation reports for solid forms to ensure compliance with FDA requirements, regulations and company policies and procedures
* Supported manufacturing related studies and processes.
* Gathered and recorded semi-complex production information.
* Participated in complex repairing and retesting for product and/or manufacturing facilities. Helped develop estimates of requirements arising from process changes.
* Performed technical and compliance review of validation documents – System Impact Assessment, GXP Applicability and Criticality Assessment, 21 CFR Part 11 Assessment, Vendor IOQ and PQ Protocols, Execution of IOQ and PQ protocols, Traceability Matrix and Validation Summary reports.
* Co-ordinated with the development team for fixing issues in the software.
* Responsible for review of Software Test Protocol, Test Report and Test Results.
* Reviewed and approved the Change Management and Deviation Handling Procedure.

**Aavis Pharmaceuticals, Hoschton, GA**

**Validation Engineer (Jul 2017 – Dec 2018)**

**Responsibilities**:

* Performed validation of GMP Systems – LabWatch, Denodo – Data Virtualization Platform and TraceLink.
* Responsible for writing validation deliverables – change control, risk assessment, impact assessment, validation protocols (IQ/OQ/PQ), execution of validation protocols, discrepancy reports, validation summary reports, traceability matrix.
* Attended meetings to provide status updates as required and to coordinate construction, execution schedules to ensure CRs are meeting their timelines for different projects.
* Worked with SMEs of the sales department to document As-Is processes understanding the industry jargon, business peculiarities and work culture.
* Authored OQ, PQ and assisted in reviewing all the validation deliverables and end user requirements.
* Executed validation plans, OQ, PQ scripts for end-user functionality testing against system and user requirements.
* Worked with various project teams on Change Records (CR) strategy based on Plant production schedules.
* Initiated CRs and maintaining the life cycle of CRs for CAPAs (Corrective Action and Preventive Action), continuous improvement to the automation software and the process equipment.
* Enabled the release of process equipment from Validation to Production Environment for GMP use to meet the specific timeline.
* Worked with Environmental Quality Control (EQC) to ensure changes are executed in a safe environment
* Travelled along with engineers, construction and assessors to understand the opportunity of the change and the impact.

**Nirlife Healthcare, Gujarat, India**

**QA Analyst (Aug 2015 – May 2017)**

**Responsibilities:**

* Reviewed and approved validation documents for computer systems validation lifecycle in accordance with FDA regulations, particularly 21 CFR part 11, including: Validation Plan and Protocols for Installation Qualification (IQ), Operation Qualification (OQ), and Performance Qualification (PQ) and Validation Summary report (VSR).
* QA Support for various GMP Computerized systems: Process Control System, LIMS, Building Management System.
* Cooperated with the R&D team in gathering and documenting User Requirements Specifications (URS).
* Reviewed and approved Functional Requirements Specifications (FRS) for LIMS sample module.
* Reviewed versions of Data Migration document and prepared a Data Migration Summary document.
* Reviewed and Approved Validation deliverables to guarantee compliance with 21 CFR Part 11 (Electronic Signatures & Records) and FDA Regulations in Software Development Life Cycle (SDLC).
* Performed Gap Analysis and Remediation procedures for LIMS modules that helped in preventing bugs.
* Created and maintained Requirements Traceability Matrix (RTM) to track user and functional requirements.
* Created Test Plans and uploaded in Quality Center, executed and validated Test cases, validated the Test Reports generated by the LIMS application for compliance with 21 CFR Part 11 requirements.
* Inscribed Working directions for different users of the application and assisted in drafting the Standard Operating Procedures (SOP).