**Manish Maharjan**

**Phone: 469-237-9715**

**Email:** [**mmaharjan879@gmail.com**](mailto:mmaharjan879@gmail.com)

**SUMMARY:**

* Over 6 years of diverse experience in **Quality Assurance, Validation Analyst, Manual Testing of Stand Alone, Client/Server** and **Web Applications**.
* In depth experience in implementing various **QA** methodologies involving preparing **Test Plans**, writing **Test Cases**, **Test Scripts**, **Test procedures** and executing them; performed defect reporting and tracking through the entire life cycle.
* An in-depth understanding of all the phases of **Software Development Life Cycle (SDLC) models such as Waterfall, Agile/Scrum**.
* Experience managing validation and testing of **FDA compliant systems for Pharmaceutical Corporations**.
* Adept in defining software testing and **software validation processes** tailored to client's requirements.
* Extensive experience in developing and reviewing **Validation deliverables -Validation Master Plan (VMP), Test Plans, Test Scripts, Standard Operating Procedures (SOPs), IQ/OQ/PQ, Traceability Matrices, Risk Assessments, and Validation Summary Reports**.
* Good understanding of **FDA’s 21 CFR p11** & experienced in working on Regulatory submission products.
* Prepare **User Acceptance Test Scripts**, coordinate testing activity and review test results.
* Strong knowledge of **good documentation** and **good testing practices**.
* Experience in developing **business process maps** for business processes.
* Significant experience **creating, editing, and managing approval of validation documentation** for **major customizations** to **COTS document management systems**.
* Hands-on experience coordinating the **acceptance, review and approval of validation documentation** by following the necessary policies and requirements.
* Strong interpersonal skills and pride in developing a team atmosphere and managing in a fashion where teamwork is the norm not the exception.
* Proficient in Manual and Automated testing.
* Proficient in different phases of testing like **System Integration Testing (SIT), User Acceptance Testing (UAT), Smoke Testing, Functional Testing, GUI Testing, Load Testing, Stress Testing, Unit Testing, Regression Testing .**
* Carried out **Back End Testing using SQL queries**.
* Experience in bug reporting tools like **Quality Center and ALM(Application Life Cycle Management**.
* Involved in developing and maintaining **Test Matrix and Requirements Traceability Matrix and performing Gap Analysis**.
* Analyzed **Enhancement Requests** and **Modification Requests**.
* Excellent Organizational, Communication and Interpersonal skills.

**TECHNICAL SKILLS**

|  |  |
| --- | --- |
| **Bug Reporting Tools** | Mercury Quality Center, Clear Quest, JIRA |
| **Operating Systems** | Windows, UNIX, Linux |
| **Web Technologies** | XML, HTML, |
| **Databases** | MS Access, MS SQL Server, Oracle |
| **Programming Languages** | SQL |
| **MS Tools** | MS Excel, PowerPoint, Word, Visio, MS Project. |
| **DesignTools** | UML, MS Visio, MS Project, |

**Professional Experience:**

**Parexel International, Billerica, MA**

**Nov 2015 – Present**

**Quality Analyst/ Validation Analyst**

It is an early phase clinical trial project where new Web Application is developed in compliance to the FDA 21 CFR part 11 to replace the existing old system with more updated features. This new system accommodates modern Early Phase Requirements as well as regulatory and standard industry requirements. It deals with study Management, Subject enrollment, Procedures and Profile Management, Laboratory Management, Lab Results and Data Management.

**Responsibilities:**

* Involved in daily Scrum calls, biweekly Planning and grooming team meetings.
* Designed and developed Test Plans, Test Scripts and Test Cases for integrated and non-integrated system in ALM and executed them.
* Worked on various source systems analysis and prepared gap analysis documents, impact analysis documents, Source-to-Target Mapping documents and Data Definitions documents
* Performed integration testing of Client-server and Web Application.
* Responsible for performing dry run testing for User Stories and logging in any issue found during testing to JIRA.
* **Managed 21 CFR Part 11 validation** activities for clinical trial and development laboratory information systems.
* Tested lab profile, order management, label printing/ validation and clinical lab results
* Responsible for preparing Traceability Matrix to track requirement with test cases and bugs.
* Use SQL developer to run and execute SQL queries to validate the data in the database.
* Tested the database to check field size validation, check constraints, stored procedures and cross verifying the field size defined within the application with metadata
* Verified correctness of data after the transformation rules were applied on source data
* Written SQL queries to access, modify and create test data in the database for Back-end testing
* Co-ordinate with offshore QA team members in a daily handshake calls and other Knowledge Transfer sessions.
* Made sure that the systems complied with the rules of HIPAA and **21** **CFR Part 11.**
* Work closely with Business Analyst and developers in understanding the business requirement.
* Perform Adhoc testing and Regression testing to assure quality validation.
* Actively participate in bug triage meeting at the end of the release.

**Sun Pharmaceuticals Industries, Cranbury, NJ**

**Jan 2014 - Sep 2015**

**Quality Analyst/ Validation Analyst**

Sun Pharma is an international specialty Pharma Company, building a continually replenished pipeline of specialty generics where Research and Development Projects are geared to enable development of formulations of the latest molecules and bring them to market, at a reasonable cost and ahead of competition.

**Responsibilities:**

* Involved in **validation of lab systems and medical products**.
* Utilized a **Risk-Based approach to Validation**.
* Specialized in bug tracking, bug-reporting, analyzing results, and defect tracking procedures.
* Involved in preparation of **Validation Plan to Validation Summary Report**of systems software.
* Coordinated and **developed periodic project schedule** reports giving up-to-date status.
* Worked as a QA Tester and responsible for analyzing and understanding the requirements.
* Involved in writing various test cases and test scripts.
* Brought a critical facility into GMP compliance with the FDA through sound business process definition and ensured **21 CFR Part 11 compliance.**
* Extensive use of SQL to query the Oracle database.
* Involved in database testing by writing SQL queries.
* Defect tracking and reporting using Quality Center.
* Developed **Traceability Matrix**to track requirements for the software application module.
* Reviewed and **developed Procedural and Technical Remediation plans**.
* Developed Test Plans and executed Test scripts, prepared Test Summary Report.
* Developed a test database in Microsoft Excel to conduct Data driven test.
* Developed and implemented **test case mapping to requirements, project status reports, issue/defect matrices, UAT test plans and user training documents**.

**Par Pharmaceuticals, Spring Valley, NY**

**April 2012 - Jan 2014**

**Quality Analyst**

Par Pharmaceuticals ranked 5th in US as generic company developing, manufacturing, marketing and distributing high quality pharmaceuticals. Par is pioneer in bringing new, high-quality authorized generics to market quickly and cost-effectively as the patents expires on brand-name pharmaceuticals. The project aimed to testing and validating systems as per cGxP guidelines. The project aimed to **testing and validating systems as per cGCP guidelines**.

**Responsibilities:**

* Prepared validation deliverables such as **Validation Plan, Validation Checklists, Traceability Matrix and Validation Summary Report**.
* Effectively managed laboratory resources and **evaluated test results** for product quality against multiple specifications.
* Organized and managed the **daily operations of the validation group** and assured that master plans, protocols and reports are generated and approved within predetermined timelines.
* Executed and reported validation projects in addition to writing **SOPs and conducting compliance audits**.
* Interacted with users for the collection of User Requirements and involved in writing **Functional Requirements** for the Systems.
* Conducted weekly project meetings, team meetings, and follow-up meetings and allocate various issues and deliverables.
* Involved in entire Software Development Life Cycle (SDLC).
* Tracked and logged defects in Quality Center and coordinated meetings with developers and business analysts to prioritize the defects, defect fixes and problem resolution
* Generated Defect Reports and Test case coverage reports for status meeting and also involved in resource planning for test cases coverage
* Coordination of test plan, test results and reports in central repository
* Worked with the business users on User Acceptance Testing by mentoring them on various aspects of testing.
* **Facilitated collection of functional requirements** from system users and preparation of business requirement documents that provided appropriate scope of work for technical team to develop prototype and overall system.
* Developed summary and final reports to document the total compliance with federal regulations.

**Affinity Health Care, Bronx, NY**

**Oct 2010 – March 2012**

**Systems Analyst/QA**

I have worked on the project for Health Claims Scanning and Data Extraction (OCR) for HCFA 1500 and UB92 claims. I developed and managed needs analysis, requirements gathering, gap analysis, creation of vendor disaster recovery plan, design, layout, business rule development and associated software interface development and test documents, development, and EDI implementation insuring HIPAA compliance. The project had a budget of $800K and the system was anticipated to have an annual volume 1.5M claims

**Responsibilities:**

* Coordinated User Acceptance testing with the UAT group to ensure the correct business logic.
* Performed Backend Testing on MS Sequel Server as part of UAT.
* Participated in qualifying various applications that are based on Microsoft technologies (SQL Server).
* Analyzed, revised and created test plans according to business requirements.
* Maintained test cases, Use Cases and UML Diagrams in Excel Spread Sheets.
* Created documentation for testing and business side during and after project execution using Microsoft Word.
* Designed system architecture diagrams in collaboration with developers to ensure smooth data flow.
* Writing Use cases and Activity Diagrams.
* Provided status reports and created deliverables.
* Mentored and acted as a first line supervisor to lower level staff
* Tracked and developed metrics for testing
* Involved in both Manual and Automated Testing.
* Analyzed consumer surveys and gave technical inputs in Business meetings.
* Involved in the meeting with Business process owners, SME (subject matter experts) and Marketing Team for Requirements gathering in definition stage.
* Facilitated the customer in defining the high-level functional requirements and needs.
* Extensively involved in Data Mapping and Cross Walks.
* Worked with business analysts for UAT testing
* Performed UAT by formally documenting the results of each test and provided error reports and correction requests to the developers
* Responsible for designing and performing User Acceptance Test evaluations that ensure adherence to the company’s quality assurance standards. Assured compliance with company and/or external requirements and specifications for user acceptance testing.
* Performed day to day back-end testing procedures using SQL statements for various online customer interactions.
* Worked for UAT Entrance and Exit criteria
* Wrote test plans for UAT and created a time line for execution.