**Rohit Bataju**

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# Qualification Summary

* Six years of experience in Software Testing, Quality Assurance, Defect reporting, product verification and validation, and data warehouse experience in pharmaceutical, medical devices and Healthcare domain.
* Comprehensive knowledge of software development life cycle (SDLC), product development life cycle, risk assessment, and validation protocols.
* Experienced in manual testing of applications on Windows and UNIX environment. Expertise in HP ALM/QC.
* Extensive knowledge of methods and process of medical device design control
* In-depth knowledge of the concepts of engineering change control, statistical techniques, and IQ validation protocols
* Expertise in technical writing of validation protocols like Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). Familiar with FDA Quality System Requirements/ISO 13485, quality auditing, and engineering drafting.
* Proficient knowledge in various types of Software Testing such as Black box testing, System Testing, Positive Testing, Negative testing, Performance Testing, Smoke Testing, Regression Testing, Stress Testing, System Integration Technique, and Back End Testing.
* Good understanding of Health Insurance portability and accountability act (HIPPA) 5010 version. Worked with ASC X12 5010 transactions changes and migration strategy.
* Strong knowledge of programming languages such as Java, VBScript, Python
* Strong knowledge of HIPAA 5010 EDI transaction such as 270/271, 276/277, 834, 835/837. Profound understanding of insurance policies like HMO and PPO and proven experience with
* Experienced in executing SQL scripts to perform backend testing for data validation.
* Excellent understanding of feed Gap Analysis.
* Extensive experience in preparing and maintaining Test Matrix and Requirement Traceability Matrix (RTR).
* Advance level written, verbal and presentation skill; Adept with Microsoft Office suite, MS Visio, MS Project, Programming tools, multimedia tools.
* Ability to multi-task, prioritize and work with time constraints while paying attention to details
* Good problem-solving, judgment, and decision-making skill.
* Advance level written, verbal and presentation skill; Adept with Microsoft Office suite, MS Visio, MS Project, Programming tools, multimedia tools.

# Technical Skills

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| **Testing Tools** | HP ALM/QC, JIRA |
| **Test Documents** | Test Scenarios, Test Plan, Test Cases, Test Scripts, Use Cases & Requirement Traceability Matrix |
| **Programming Language** | UNIX script, Java, VBScripts, Python, Ruby |
| **Operating System** | Windows, Linux, Mac OS |
| **Database** | Oracle, MS Access, SQL Server |
| **Methodology** | Agile SCRUM, Waterfall, Hybrid |
| **Productive Tools** | MS Office Suite, MS Visio, MS Project, SSMS, SSRS, Crystal Reports |

# Professional Experience

**Aptalis, Bridgewater, NJSept 2015- Sept 2016**

**QA Tester**

Montreal-based Axcan Pharma formed Aptalis in 2011 after the acquisition of Eurand Pharmaceuticals. Axcan's area of specialty was the treatment of gastrointestinal disorders.I worked as QA Tester in validating the user requirement specification for Point-of-Care manufactures diagnostic products for blood pressure analysis to provide health care professionals diagnostics information at the point of patient care. I also validated Functional Requirement Specification and System Requirement Specification in accordance with 21 CFR Part 11.

**Responsibilities:**

* Worked with Business Analyst and QA Lead in reviewing and analyzing the business requirements Documents and functional requirements.
* Followed the Agile Methodology Process throughout the project and all artifacts are generated for each discipline.
* Imported preexisting Microsoft Word and Excel-based requirements and tests for analysis in HP ALM
* Developed and wrote test cases for the testing efforts in compliance with Pharmaceuticals Policy, which were written to comply with the rules and regulations of FDA 21 CFR Part 11.
* Read and understood all the policies and procedures involved in the manufacturing operations
* Responsible for updating the QA manager on weekly updates regarding the progress of testing efforts and open issues to be resolved. Used SharePoint to store and share documents.
* Validated the test results and reported the status of assigned test tasks and issues to project QA Lead.
* Involved in Product verification and validation process.
* Extensively used SQL statements to query the Oracle Database for Data Validation and Data Integrity.
* Executed test cases, found errors, reported defects, determined repair priorities, did regression testing
* Monitored the Defect Tracking Process and generated customized graphs and reports for the client using Jira
* Actively participated in walkthroughs and enhancement meetings including offshore calls.
* Extensively used SQL statements to query the Oracle Database for Data Validation and Data Integrity.
* Actively participated in walkthroughs and enhancement meetings including offshore calls.
* Followed the Agile Methodology Process throughout the project and all artifacts are generated for each discipline.

**Environment:** Windows, UML, MS Office Suite, SharePoint, MS Visio, 21 CFR Part 11, MS Project, Oracle, Agile, SIT, UAT, HP ALM, Jira.

**McGuff Company, Inc., Santa Ana, CA Jan 2014 - August 2015**

**QA Analyst**

The McGuff Company, Inc. is a medical products wholesale distributor of pharmaceutical and medical products, and oral nutritional supplements. Established in 1979, the company initially provided a full range of disposable medical office products and specialized in parenteral ranging from vaccines to vitamin B12.

As a QA Analyst**,** I was involved in validating an Adverse Event Reporting System (AERS) and also worked on Product Development, Process Improvement, Procedures and Systems, assisting the project manager.

**Responsibilities:**

* Gathered all the business requirements for AERS validation.
* Involved in the validation of AERS in compliance with 21 CFR part 11
* Involved in preparing documentation for all aspects of the computer system validation life cycle, in accordance with FDA design control and regulations, particularly 21 CFR Part 11
* Assisted the project manager in documenting SOPs in the drug production phase.
* Involved in Design of Experiments (DOE) for process improvement
* Interfaced with the team lead in order to implement the new raw materials for optimizing the costs incurred and process efficiency
* Conducted UAT (User Acceptance Testing) to make sure that all the user requirements are catered by the application
* Prepared test cases, test scripts, test summary reports for overall product, part wise assessment and improvement, report concerns if any to the suppliers
* Extensively used Enterprise Data Management platform Documentum for maintaining validation life cycle documents
* Performed production data analysis and suggested process parameters for process optimization, process control and product development

**Environment:**Windows, MS Office Suite, Oracle, HP ALM, MS Visio, MS Project, UML, Agile, SIT, UAT.

**Quark Pharmaceuticals, Fremont, CA Mar 2013 – Dec 2014**

**QA Analyst**

**Quark Pharmaceuticals** is a pharmaceutical company that develops RNA interference-based treatments for chronic and acute diseases.

The project was creating an application where customers can enroll in new healthcare plan, check eligibilities manage their portfolio, claim processing and claim status. As a QA, I was involved in testing Claims Processing (EDI 837), Utilization Management and Facets Workflow module of the application.

**Responsibilities:**

* Imported preexisting Microsoft Word and Excel-based requirements and tests for analysis in HP ALM.
* Worked with Business Analyst and QA Lead in reviewing and analyzing the business requirements Documents and functional requirements. Assisted in developing Use Cases using MS Visio.
* Worked in agile environment. Created Test Plans, Test scenario and developed Test cases.
* Involved in weekly status updates showing progress of testing. Used SharePoint to collaborate documents.
* Maintained Test Matrix and Requirement Traceability Matrix between requirements and test cases.
* Tested various operations in the claims processing (Adjustments, Claims, and Overpayments, underpayments, External Claim editing).
* Responsible for GUI Testing, System Testing, Integration Testing, Regression Testing and Acceptance Testing.
* Tested the claims processing with EDI transactions (270, 271, 835, and 837) in HIPPA.
* Involved in FACETS Implementation, involved end to end testing of FACETS workflow, Claim Processing and Subscriber/Member module.
* Validate the date from EDI transaction. Tested various interfaces to Facets in HTTPS Environment.
* Worked on Unix Platform and used SQL Queries to extract the data from the database.
* Bug reporting using Defect Track Management in Quality Center and participated in bug reviews.
* Maintained test logs and test summary reports. Assisted in preparing Test Status Report.
* Support project planning efforts by providing inputs to and estimates for project schedules, scope and resource requirements.
* Support the Sr. Quality Control Test Manager during internal and external audits of the software development life cycle and contributes to improvements to the overall life cycle.
* Coordinated with concerned developer/developer teams for design reviews per the business requirements for both UAT and Production testing
* Monitored the Defect Tracking Process and generated customized graphs and reports for the client using QC.

**Environment:**Windows, UNIX, SQL, Quality Center, Facets, MS Visio, MS Word, MS Excel, SIT, UAT, Manual Testing.

**Spotlight Innovation, West Des Moines, IA Mar 2011 – Feb 2013**

**Junior QA**

**Spotlight Innovation Inc.** is a pharmaceutical holding company that identifies and acquires early stage pharmaceutical companies that are developing unique intellectual property often in academic settings.The company currently maintains two subsidiaries: Memcine Pharmaceuticals, Inc.and Celtic Biotech Iowa, Inc.

I worked as Junior QA Analyst in testing of an application where user can find the status of the member at any instance. This would help health insurance with its Membership and Claims Management Information Tracking System and Finance System modules.

**Responsibilities:**

* Formulating detailed Test Plan using Quality Center (QC), after analyzing functional and software requirement artifacts.
* Interacted with the users to ensure meaningful development of the scripts and simulated real time business scenarios.
* Created and executed numerous Test case based on the functional requirement of the project. Maintained the Requirement Traceability Matrix (RTR).
* Assisted developers for performing and executing Unit and Integration testing.
* Performed numerous manual testing of the application.
* Used QC for GUI tests and tested GUI Standards of this application. Conducted Usability Testing and Black Box Testing according to specifications.
* Participated in numerous Joint Application Discussion (JAD) sessions, brainstorming to understand the in-scope of the project.
* Assisted in Back-End integration testing to ensure data consistency on front-end by executing SQL statements on the Database
* Reviewed manual testing methods and developed and executed automated scripts using QC to perform regression testing.
* Investigated Software bugs and interacted with developers to resolve technical issues using JIRA.
* Have experience designing and writing training manual templates, design formatting, and project planning and writing technical documents.
* Used MS Visio to create Test use case and other artifacts.

**Environment**: Windows, JIRA, Microsoft Office suit, MS Visio, Oracle, SQL, SIT, UAT, Quality Center, Regression Testing, GUI Testing.

# Education

Master of Science in Management Information System

Bachelors in Business Administration