**Summary:**

* Overall 7 Years of Professional Experience as Quality Analyst with strong knowledge of Pharmacy industry including Validating and maintaining Computer systems, laboratory instruments as per the GxP’s (GMP, GCP, GLP) Rules, 21 CFR Part 11 requirements.
* Extensive experience in analyzing and requirements gathering and writing system functional specifications including use cases.
* Excellent in Developing and evaluating business process Models.
* Validating and maintaining Computer systems, laboratory instruments as per the GxP’s (GMP, GCP, GLP) Rules, 21 CFR Part 11 requirements and worked as Quality Analyst in Health Care Industry
* Expertise in Oracle table data manipulations using SQL queries and UNIX commands/UNIX scripts.
* Strong experience in Back-End Testing for Oracle databases using complex SQL queries.
* Experience in developing Test Plans, Test Cases based upon the business requirements.
* Experience testing in different environments- QA, UAT and Production environment.
* Extensive experience with working knowledge of SDLC, CSV, 21 CFR Part 11, GLP, GCP, GMP, GAMP 5 standards.
* Experience in Black Box, Positive, negative, Data-driven, Unit, System, Front-End and Back-End Testing.
* Good documentation and Process Management skills with an ability to effectively understand the business requirements to develop a quality product.
* Experience in full Software Development Life Cycle (SDLC) including requirement analysis, design, development, testing, and implantation and project documentation.
* Proficient in dealing with Laboratory Information Management System(LIMS), Enterprise Document Management System (EDMS), Adverse event reporting system( AERS), Change Control Management System.
* Familiar with FDA and Regulatory Requirements such as Table 21 CFR Part 11 and GxT.
* Managed and performed testing of Web-based application on both Windows and UNIX platforms.
* Strong working Experience with data movement/ Data mining/Data warehousing projects using various ETL process/ data mining tools
* Strong experience in developing Test Plans, Test Cases and Test Scripts from Requirements and Use Cases.
* Strong working Knowledge in different databases i.e. Oracle databases, SQL PL/SQL, Toad, SQL Developer, SQL Assistant for Tara Data
* Have extensive knowledge of Regression testing, Functional testing, System testing, Black Box testing, Integration testing, Back-end testing, Browser Compatibility testing, GUI testing and Volume & Stress testing.
* Experience with Manual/Automated testing using Win Runner, Load Runner, QTP, and Quality center/Application Life Cycle Management (ALM).
* Experience with process documentation and process documentation tools- MS Visio.
* Experienced in interacting with business users and executives to identify information needs, gather Requirements, and authoring Business Requirement Documents (BRD), Use Case Diagrams, Activity Diagrams, Sequence Diagrams using UML modeling.
* Knowledge of SQL and experience of writing SQL commands.
* Strong knowledge of Financial Modeling Techniques using Excel.
* Works closely and effectively with all levels of management to satisfy project/productivity requirements.
* Self-motivated, customer-focused teamwork, oriented and strategically focused experienced professional with strong analytical, pattern detection and problem solving abilities.
* Excellent in communication, problem-solving, and interpersonal skills. Good team player with the ability to lead, manage and work independently in a time sensitive environment.

**Technical Skills:**

Regulations: FDA Quality System Regulation, 21 CFR Part(11,210,211,820), cGxP (cGMP, cGCP, cGLP) SOPs, LIMS, AERS

Software/Hardware: OOAD (OOA/OOD), RUP, UML, SDLC, Agile, Waterfall, QA, WAP, CVS, TEAMMATE, MS Access, SQL Server, MySQL, PL/SQL, Oracle DBA, Java , Windows 98/2000/XP, basic UNIX, HTML, basic DHTML, basic XML, MS Office Suite-Excel Macros, MS Project, MS Visio, Adobe Photoshop, Flash, Rational- Rational Rose, Clear Quest ,Rational XDE,Cobol,Requisite Pro, CaliberRM, Omniture, Crystal Reports, various NIKU products, C, C++, Sharepoint, Docushare, BASIC, Intermediate level-Visual Basic

**Professional Experience:**

**Abbott Laboratories, North Chicago, IL**

**Mar’ 15- Present**

**Sr. QA Analyst**

**Description:** Abbott Laboratories is an American global Pharmaceuticals and health care products company. The project was on LIMS which is to validate the data collected from various Lab instruments through LIMS Application interface by testing the data and the results and Implementation of Plateau Learning Mangement system.The project was on LIMS which is to validate the data collected from various Lab instruments through LIMS Application interface by testing the data and the results and Implementation of Plateau Learning Mangement system.

**Responsibilities:**

* Conducted User Acceptance Testing, System testing and End-to-End testing.
* Used Manual Test Scripts in QC.
* Created a custom library in QTP for utilization.
* Wrote and reviewed Operational Qualification (OQ) and Performance Qualification (PQ) test scripts for different modules of LIMS based on the User and Functional Requirement specifications.
* Performed data queries for backend using complex SQL queries, to validate the consistency of the data.
* Extensive use of backend queries using Sqldeveloper.
* Worked on Gap Analysis Mapping with 21 CFR Part 11 Regulations.
* Performed backend testing for data validation using SQL Queries.
* Wrote numerous test cases based on test strategies.
* Responsible for documentation of all aspects of the SDLC, Computer System Validation Life Cycle in accordance with 21CFR Part11, GLP and GMP.
* Executed SQL statements to check if the data integrity has been maintained.
* Executed SQL statements to test the integration between application and database.
* Enhanced test cases and scripts by adding the required functionality or removing defunct functionality as per the new Business Requirements and Change Request.
* Defect Tracking and Bug Reporting were performed using Quality Center and Jira.
* Assist QA manager to analyzed team performance and implemented the changes if any with respect to raising the efficiency of the entire team.
* Worked closely with system analyst to clarify the user story and acceptance criteria.
* Categorized bugs based on the severity and interacted with developers to resolve them.
* Performed Gap Analysis while maintaining Test Matrix and Traceability matrix.
* Followed Agile Methodology to get quick results.
* Interacted with other teams through walkthroughs, teleconferences, meetings, etc. to resolve various issues.
* Understand user stories and broke it down into functional testing.

**Environment:**Java, J2EE technology, Windows XP Pro, UNIX/Oracle Platform, SQL, SQL Server, Rational Rose and Requisite Pro, MS Visio, MS Project, UML, Rational Clear Quest, Rational Clear Case, RUP, Agile, Microsoft Excel, Microsoft Word, Microsoft Power Point.

**Johnson & Johnson Pharmaceuticals, Bridgewater, NJ**

**Aug’2013– Jan’2015**

**Sr. QA Analyst**

J&JHCS (Johnson and Johnson Health Care Systems) is a distribution center which acts as a distribution hub for 11 of its sister concerns. The project was to design an order management system where in - a customer orders a product in the J&J site and it automatically reflects in the sister companies (called as Operating Companies- OpCo). Worked in the enhancements to a Clinical trial system; this is an application used to collect the patient data who is taking part in the new study for a drug/vaccine. This is a CFR Part 11 validated and Regulated System. I have also worked on a LIMS integration project with Core Dossier.

**Responsibilities:**

* Participated in developing project charter and identifying stakeholders for the project
* Prepare Test plan, Test cases and Test scripts based on the functional specifications.
* Documented all aspects of computer systems life cycle (SDLC), in accordance with FDA regulations, Particularly 21 CFR Part 11.
* Perform functionality testing, system testing, integration testing, regression testing, end-to-end testing, unit testing, user acceptance testing, positive testing and negative testing.
* Involved in discussion with the business analyst and Subject Matter Experts (SME) during creation of test plans and updating of business requirements.
* Expertise in developing and executing Installation, Operational and Performance Qualification (IQ, OQ and PQ) Validation Protocols.
* Developed FRS (Functional Requirement Specification) from the URS (User Requirement Specification).
* Responsible for developing IQ protocols and Validation Summary Report.
* Work on Agile environment.
* Developed Risk assessments and 21 CFR Part 11 assessments.
* Prepared and reviewed User Requirement Specification, Functional Requirement Specification and System Requirement Specification in accordance with 21 CFR Part 11.
* Involved in Scrum meetings, user stories testing and Build releases.
* Created and maintained User stories and Test Plan for Each Build.
* Coordinate with the developers and test lead on Defects Status on a regular basis.
* Responsible for storing and maintaining the documents to comply with 21 CFR Part 11 requirements.
* Using HP Quality Center, submitted the bugs, verified and resolved the bugs, Change Requests and raises the issues.
* Provided support for Unit and UAT testing as required for the application or any other assigned application.
* Performed System, Functional, UAT and Black box Testing.
* Performed Manual Testing as well as Automation Testing.
* Supported documentation across extending testing team as directed by UAT Manager.
* Used Manual Test Cases to create Automation Test Scripts to perform in QTP
* Created batch files for running different QTP scripts in batches.
* Validated the data across the system during UAT.
* Developed Test Script for Functionality, Security, and Regression testing.
* Recorded Regression Testing using scripts using QTP.

**Environment:** UNIX / Oracle Platform, Mainframe, Business Objects, Java, MS Visio, RUP, RUM, Agile, Rational Rose 2002, Rational Clear Quest.

**Pharmacia & Upjohn, Kalamazoo, MI**

**Jan’2012 – July’ 2013**

**QA Analyst**

Pharmacia and Upjohn is one of the largest pharmacy companies in the US. The company has a number of divisions each of which produce different products pertaining to medical supplies and lab instruments for use within US and different parts of the world. In order to keep track of the huge amounts of data generated in clinical trials and with respect to sales and expenses, a data warehouse was developed. Based on the warehouse, the management was able to take sound decisions regarding budgets and forecasting the company business decisions. Also, the project also involved remediation of lab instruments and bringing them into compliance with FDA regulations.

**Responsibilities:**

* Actively participated in all phases of SDLC.
* Execution of Test Plans and Test cases on builds and new features, if any. Reporting the bugs found into Project Tracking System.
* Run the scripts on multiple environments (QA, UAT and Production) to ensure that requirements were still met.
* Created repositories to save object in QTP both local and shared.
* Responsible for reviewing and documenting OQ/PQ protocols and Validation Summary Report.
* Actively involved with the application developers in developing the high level System Design Specifications (SDS) documents.
* Assisted the business partner in preparing UAT plan/scripts and assured project manager has taken steps for alignment of Operational Quality Checklist.
* Performed User Acceptance Testing. Defined the scope of Testing for User Acceptance Testing (UAT).
* Involved in pre-production support and testing each sprints since we were following the agile methodology.
* Created Requirements Traceability Matrix (RTM) to track requirements.
* Responsible for writing change control SOP’s to comply with 21 CFR Part 11 requirements.
* Performed both Manual and Automated testing of the application.
* Used QTP for GUI testing and tested GUI Standards of the application.
* Created test scripts for Functionality, Security, Positive, Negative and User Acceptance Testing (UAT) using QTP.
* Performed Back End Testing and Data Driven Testing using QTP
* Analyzing system requirements and developing test plans.
* Wrote several test cases for functionality, system and integration testing and tested the application manually in UNIX environment.
* Enhanced test cases by adding the required functionality as per the new business requirements.
* Defect Tracking and Bug Reporting was performed using Quality Center.
* Investigated software bugs and categorized based on severity

**Environment:** SQL Server 2000, Pl/SQL, UNIX, Rational Suite, Agile, Crystal Reports, Oracle, UML, MS Office, MS Visio.

**PFIZER,GROTON, CT**

**Dec’2010 – Dec’2011**

**QA Analyst**

Pfizer boasts the industry's largest pharmaceutical R & D organization: Pfizer Global Research and Development ý *The MAPS Project*. The application was an Accounts Receivable and Billing System, the data feeds from different Databases which stores client details, Eligibility Database which stores insured details and Rates database where you to enter rates allows. Billing System is mainly designed to add and modify statements, assign billing lines, updating administrative adjustments, Reconciliation, generating and scheduling Invoices.

* Use Cases and other Process Flow Models were designed using Visio and Rational Rose.
* Interacted with business analysts, users and developers to prioritize user functionality issues.
* Querying various databases for data validation by executing SQL queries.
* Tested the custom point of sales program and interface to handle the windows stations including, file serving, database, security, user account management, sales, logon authorization and web services.
* Performed Regression testing to ensure that bugs where fixed and enhanced builds.
* Participated in various meetings to discuss Enhancement and Modification Request issues.
* Prepared test cases, test strategy and test plans for different business functional areas.
* Worked on System Testing as well as UAT Testing.
* Attended daily scrum meeting as a part of agile methodology.
* Assisted Team Lead, Communicated and collaborated information flow between QA Team and Developers.
* Involved in documentation as to how to maintain and run scripts for future enhancements.
* Involved in analyzing business requirements and writing Test Plans and Test Cases as per the specifications
* Consistently made efforts to streamline the testing process and increase the productivity of the testing team.
* Created and Executed Test Scenarios.
* Publishing UAT test strategy for each release.
* Ensure that traceability matrix is developed kept up to date.
* Involved in performing Negative and Positive testing by executing various test cases.
* Conducted Data Driven Testing to test the application with different sets of data.
* Performed the Back-End testing to ensure data consistency on front-end.
* Customize and administer multiple Quality Center projects, using workflow where necessary.
* Responsible for updating the QA manager with weekly status updates for the progress of testing efforts and open issues to be resolved.
* Involved in preparing test data/ Test script for UAT and participated in UAT signoff.
* Support day-to-day Quality Center activities such as maintain QC users' access, customizing QC entities etc.
* Performed Integration testing, GUI testing and system is testing.

**Environment:**Rational Rose and Requisite Pro, Omniture, MS Visio, MS Project, UML, RUM, XML, Java, J2EE technology, Rational Clear Quest, Rational Clear Case, RUP, Business Objects, Mainframe, Microsoft Excel, Microsoft Word, Microsoft Power Point.