**SantSah**

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**PROFESSIONAL SUMMARY:**

I have 6 years of experience as a QualityAnalyst. Expert in obtaining a grasp of the business process and acting as a bridge between theManagement and the Development teams Strong customer/user advocate, apt negotiator withexcellent analytical, collaboration, communication decision-making, and organization skills.Good communication skills coupled with excellent interpersonal skills that helped in developing an excellent rapport with the team members and maintained an inspiringenvironment, which I strongly believe, play a key role in carrying out the given tasks within thetime constraints.

**PROFESSIONAL EXPERTISE:**

* **Prepared Test Plans, Test Scripts and routed the documents for approval by Information Technology Quality (ITQ), business owner, and IT system owner.**
* **Extensive experience with FDA and Regulatory Requirements such as Table 21 CFR Part 11 and GxP.**
* **Prepared, authored, reviewed OQand PQ protocols.**
* Interactingwithstakeholders, gathering requirements, and elicitation techniqueslikeinterviewing, questionnaires, brainstorming, focus groups, cost/benefit analysis andrisk analysis.
* Implemented risk-based approach to validation using principles from GAMP 5.0.
* Conducted GAP analysis against regulatory requirements and prepared remediation plans.
* Hand on experience of Pharmacy Benefits, Claims, Clinical Trial Management system, Clinical Data Management system ( CDMS ) and Electronic Data Capture ( EDC )
* Excellent knowledge of Software Development Life Cycle (SDLC), Iterative SoftwareDevelopment Life Cycle Process as perRationalUnifiedProcess(RUP) and Rational Tools used during various phases of RUP.
* Business Analysis knowledge for business process, the need to understand all aspects of the company's operations. Identify, analyze and design processes to improve the overall flow of information within the company
* Proficient in Rational tools includingRational Rose, and Requisite Pro.Excellentskillsin Business Analysis, Data Analysis, RequirementAnalysis, Business Process ModelingandUseCaseDevelopment usingUML methodology.
* Skilled in creating logical diagrams likeUse Case, Activity, Sequence, Data flow, Collaboration and Deployment UsingCASE ToolslikeRational RoseandMS Visio.
* Experience in conductingJoint Application Development (JAD)JAD sessions
* Withmanagement, SME, vendors, users and other stakeholders to gather business requirements andtranslating the same to the development teams.
* Performed Functional, Integration, Data Validation, User Acceptance, and End-To-End testing and evaluated the test results.
* Expertise in automating the functional and performance test scripts using industry standardlikeWinrunner, Rational Robot and QTP.

**TECHNICAL PROFICIENCY:**

**Business Modeling Tools:**  Rational Rose, MS Project, MS Visio

**Change Management Tools:** Rational Clear Case, Clear Quest, TestDirector

**Languages:** C, C++,SQL, PL/SQL, JAVA, VB

**Operating Systems:** MS Windows NT/98/95/2000, Unix

**Web Technology:**  HTML, DHTML, ASP, HTTP, and JavaScript

**Database:** SQL Server, Oracle, Sybase, MS Access, MySQL

**Utility:** MS Office, Virtual UML, FrontPage

**Automation tools:** Rational Analyst Suite, RUP, RequisitePro and Rose. Mercury Interactive WinRunner, Load Runner, TestDirector, QTP

**PROFESSIONAL EXPERIENCE:**

**BIOGEN IDEC, Cambridge, MA**

**April 2016 – Mar 2017**

**Quality Analyst**

I have worked on 5 different projects for Clinical Trial Data Transparency group and helped them launch different systems which supported their current business needs and also helped them scale to meet evolving industry requirements.

Along with launching different systems, I also provided an IT support to the business on their existing systems by working on help desk calls, creating a change request tickets, and successfully carrying out the changes. The two systems that I provided a support to the business were the Clinical Trials Registration and Results disclosure system, and Clinical Trials Management System (CTMS).

**Responsibilities:**

* **Prepared System Impact Assessment, Test Plans, Test Scripts and routed the documents for approval by Information Technology Quality (ITQ), business owner, and IT system owner.**
* Executed test scripts and tracked any issues in **Test Incident Report (TIR)**, and in some cases in a vendor’s defect tracking tooland worked with the development team to get the issues resolved and close the ticket.
* **Prepared, authored, reviewed OQ and PQ protocols.**
* **Assisted and executed User Acceptance Testing (UAT).**
* Performed Defect Tracking and Change Control Procedures, Configuration Management and Version Control using VMware Service Manager (VSM).
* Wrote basic SQL queries to validate data have been transferred from the source system to the target system.
* Responsible for gathering and documenting User Requirement Specifications (URS) and Functional Requirement Specifications (FRS).
* Lead various requirements gathering workshop sessions to capture and elicit the requirement to prepare URS and FRS documents for various reports and obtain sign off on final documents.
* Lead various business process flow sessions to capture detailed swimlane diagrams using MS Visio which depicted the overall business process.
* Prepared test plan, test scripts to validate system functionalities.
* Prepared data mapping documents that captured field level data elements being integrated to a single target system from multiple source systems.
* Worked with third party software development team to identify gaps between requirements and the functionality of the SaaS solutions and helped develop a workaround process for the business.
* Worked with third party software development team to resolve any issue found with any system that is in production.
* Used SharePoint for storing URS, FRS other project documentation and Assisted Project Manager with the development of project schedules.
* Extensive experience with working knowledge of SDLC, CSV, 21 CFR Part 11, GLP, GCP, GMP, GAMP 5 standards.
* Performed Regression Testing to ensure that bugs fixed did not generate new defects

**PURDUE PHARMA, Wilson, NC**

**QualityAnalyst/Validation Analyst**

**January 2015 – April 2016**

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.

* Involved in creating **URS (User Requirement Specification)**, **FS (Functional Specification)** based on BPRS (Business Process Requirements Specifications) and PFD (Process Flow Diagram).
* Designed **Use Case diagrams**, **Activity diagrams** and **Sequence diagrams** to analyze the system using UML.
* Wrote **Test Plan**, **Validation Protocols (IQ, OQ, PQ)**, **Traceability Matrix, Test Summary Report**.
* Performed system and functional **risk analysis**. Performed risk analysis for new modules as well as system changes to existing modules to expose all the risks associated with the requirements and to define testing required for mitigating those risks.
* Participated in the preparation of **Standard Operation Procedures (SOPs)**.
* Drafted the Remediation Plan for the Project Management approval after **Gap Analysis**.
* Prepared and used the **Requirement Traceability Matrix (RTM)** to gauge the progress on a regular basis.
* Conducted **JAD sessions** and worked with the data modeler and database developer to create the logic of implementing Labware LIMS V6.
* Responsible for pre and post formation review of **Unit Test scripts, Performance /Automated Test Scripts, Regression Test Scripts, IQ/OQ/PQ Test Scripts**.
* Helped and trained the remote team responsible for creating LoadRunner scripts, for performance/load testing of LIMS.
* Constantly communicated with business and developers to develop test cases for testing complex requirements and functionalities. Guided users in execution of test scripts.

**Versa Pharm, Inc., Marietta, GA**

**July 2013 – December 2014**

**Validation/QA Engineer**

VersaPharm Inc. is a pharmaceutical developer and marketer of specialty prescription products to the United States and its territories.

As a Validation Engineer, my role was to design and to troubleshoot the laboratory instrument control system equipments application and the documentation process involved in validating the IT and Laboratory Equipment systems in compliance with 21CFR Part 11 and cGMP guidelines.

**Responsibilities:**

* Worked in a strictly regulated **GxP (cGMP and cGLP)** environment.
* Provided IT technical expertise to Engineering and Manufacturing operations.
* Reviewed and analyzed **User requirements, Function Specifications** based on flow diagrams and business requirements.
* Conducted meetings to discuss compliances with the FDA rules and regulations.
* Experience with client operating systems (Windows 2000, XP, Vista).
* Involved in up-gradation of the software’s of the laboratory instrumentation and overcame the technical obstacles.
* Defined solution system boundary & identified all regulatory constraints as identified by **GxP, GCP, and 21 CFR Part 11** and technical constraints as documented.
* Developed **Validation Master Plan** and **Test Plan** of this project.
* Involved in maintaining the electronic records in compliance with 21 CFR Part 11 regulations.
* Ensured strict compliance with standards and templates in relation to the writing of Technical Documentation.
* Maintained all the logs, documents through a document management system known as Documentum.
* Developed **IQs, OQs, and PQs** for validating LIMS environment and laboratory instrumentation for FDA compliance in a strictly regulated environment.
* Ensured validation of Core components and Custom components of LIMS in compliance with FDA regulations.
* Developed **SOPs** for all the laboratory equipments in a strict compliance with FDA regulations.
* Performed **Gap Analysis** and developed **Remediation Plan** so that the system was in compliance with both cGLP and cGCP.
* Used **Documentum** to store and retrieve LIMS data and other components.
* Coordinated the entire **Validation Life Cycle**.
* Manual testing for LIMS software used to manage large volume of data of laboratories in compliance with cGLP.
* Reported bugs and change request with the help of the change request form.
* Created **Requirement Traceability Matrix** which helped to see whether the User Requirements were met with the Functional Requirements and traced URS and FRS to UAT and Functional Test Scripts respectively.
* Conducted **User Acceptance Testing** and documented **UAT Summary Reports**.
* Organized, developed, and managed multiple tasks with effective time management.

**Cytokinetics, Inc, San Francisco, CA**

**October 2011 – June 2013**

**Validation Analyst**

CytokineticsInc focuses on the discovery and development of novel and safe small drug molecules targeted at the cytoskeleton for the treatment of cardiovascular diseases and cancer.

My project at Cytokinetics involved validation of **LIMS** for tracking drug samples in regulated compliance, preparation of validation protocols, performing execution of validation protocols, and preparation of summary reports. The analytical data for the drug samples was input into the database and the application provided options for monitoring the composition of the drug and the test results.

**Responsibilities:**

* Gathered and finalized **Business Requirements** and **Functional Requirements** for the project.
* Involved in developing **Use Case** and creating flowcharts using MS VISIO to understand the flow of application and overview of the software system to be validated.
* Created **Installation Qualification (IQ)**, **Operational Qualification (OQ)** and **Performance Qualification (PQ)** protocols, and **SOPs**.
* Facilitated the implementation of the software to meet the requirements of **21 CFR Part 11**.
* Developed **Test Plan** and **Test Scripts**to verify application functionality.
* Involved in **Regression Testing** after bug fixing and changes in the application.
* Analyzed Test Scripts to be compliant with 21 CFR Part 11 to test the Audit Trail, Data Integrity and Data Security of the application.
* Performed **GUI and Functionality Testing** using WinRunner to ensure proper functioning of the application.
* Maintained **Requirement Traceability Matrix (RTM)** for the application.
* Performed **Stress Testing** using LoadRunner.
* Involved in **End to End Manual Testing** of the application.
* **Data Driven Testing** was done using different sets of data in WinRunner.
* Participated in **JAD sessions** and meetings to discuss the issues of the applications and follow up with the developer.
* Wrote **SQL queries** for database testing.