**Debapriya**

**Summary**A result-oriented Business Systems Analyst with 4+ years of experience in the Pharmaceutical domain. Experience ranges from project planning, executing and implementation to timely delivery of products in every sprint. Have in-depth knowledge of Software Development Cycle (SDLC) methodologies primarily Agile while handling and assisting the Scrum master, also including RUP and waterfall methodologies. Experienced in data auditing and mapping for ETL and data warehouse implementation projects. Excellent communication, interpersonal and collaboration skills with cross-functional teams in complex projects.

**Expertise**

* Proficient in all phases of **requirement management** including gathering, **eliciting, analyzing, detailing testing and tracking requirements**, with extensive knowledge of conducting **JAD sessions**.
* Extensive knowledge of **process flows and UML creation** with **use case models, activity diagrams and flowcharts in MS Visio.**
* Good working experience in FDA regulated environment including 21CFR part11. Good working Knowledge of the GMP, GCP, GLP and GDP standards.
* Providing data insights through presentations to clients and higher management by performing virtual analysis through tools like **Tableau.**
* Create and manage **SQL databases** including **complex DBMS queries** and extraction from multiple data sources and reconciling.
* Perform **SQL analysis** to create meaningful dashboards and data reports.
* Performed **SQL** to **Extract, Transfer and Load (ETL)** to generate reports and verify data.
* Managed meetings to review FDA validation protocols and procedures regarding 21 CFR part 11 guidance for the industry.
* Exposure to different validation practices with a good experience in computer system validations (CSV) according to 21 CFR part 11,210, 211, 820 and FDA regulations.
* Focused on enhancing **UI/UX** experience by working on tools like MS visio, Lucidcharts and Balsamiq.
* Good working experience in FDA regulated environment including 21CFR part11. Good working Knowledge of the GMP, GCP, GLP and GDP standards.
* Strong understanding of different API’s like **REST and SOAP.**
* Experience in **Tableau** for creating storytelling dashboards and reporting.
* Experience in **JIRA and Confluence** for defect and bugs tracking and prioritizing user stories and requirements with the project team, with extensive knowledge of defect life cycle.
* Expertise in conducting **Integration, Functional, Regression, Smoke, Sanity and User Acceptance Testing (UAT).**
* Extensive experience in performing **GAP analysis and Feasibility Analysis for the Change advisory board (CAB)**.
* Worked in **Waterfall - Scrum transition environment** and made sure the team understood and enacted the agile philosophies meanwhile did not fall back to traditional documentation, rigid scope-change control methodology.

**Technical Skills**

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| Operating Systems | Windows 7/8/10, MacOS |
| Management Tools | JIRA, HPALM, Rational Req Pro |
| Project Methodologies | Waterfall, RUP, Agile Scrum, V Model |
| Modelling and Visualization tools | Microsoft Visio, Rational Rose, Lucid Charts, Tableau |
| Databases and DB language | Oracle, MySQL |
| Testing Tools | HP QC, Postman, SOAP UI |
| Programming Languages | SQL and SAS |
| ERP Tools | SAP and ORACLE |
| Others | MS Office, MS Excel, MS Access, SharePoint, MS PowerPoint |

**Professional Experience**

**Role: Business Systems Analyst August 2017 – July 2019  
Client: Biogen Inc., Cambridge, MA**

The goal of the project was to validate, re-design and enhance existing systems and implement new systems to support the launch of a new drug. Worked on different systems supporting clinical studies, member management, marketing and document management.

* Conducting regular meetings with Stakeholders and Subject Matter Experts (SME’s) to elicit and analyze business requirements.
* Working with Agile methodology for enhancing the system.
* Prepared all documentation with compliance to the SOPs (Standard Operating Procedures) and the federal code for maintaining electronic records & electronic signature (FDA CFR Title 21 Part11).
* Used SQL to query the data sources for fetching results.
* Assisted the Testing and stakeholders team for conducting UAT’s.
* Worked closely with QA and IS core team to clarify/understand functionality, resolve issues and provided feedback to nail down the bugs.
* Executed the test cases and test scenarios using HP Quality center.
* Developed data flow diagrams for better understanding of the overall business and system architecture.
* Wrote documentation for all aspects of the computer systems validation lifecycle, in accordance with FDA regulations, particularly CFR 21, Part 11.
* Conducted JAD sessions to gain consensus on various issues related to the project. Acted as a facilitator on different occasions.
* Use HP Quality Center to house all test documentation and report/track all issues and defects Defect Management.

**Role: Business Systems Analyst May 2016- June 2017  
Client: Avanir Pharmaceuticals, Aliso Viejo, CA**

The project involved validation of the SaaS System for compliance with FDA regulations. Reviewed regulations and guidance documents issued by regulatory agencies and interpret Pharmaceutical Regulations (21 CFR Part 11 and Predicate Rules, GCP, GLP, GMP) as applicable to the system.

* Gathered requirements from stakeholders, planning, finance, Asset protection, Legal, Business Manage Content team, Customer contact center and Warehouse operations teams and creation of scope and deliverables, implementing change control, time and cost management.
* Conducted UAT in the pre-production environment.
* Ensured that testing practices are in compliance with regulatory requirements like 21 CFR Part 11 and Good Laboratory Practices (GLP).
* Developed As-Is flow diagrams and To-Be process flow diagrams then, assessed the changes from current state to identify and deliver the training needs of business users
* Grooming the user stories and defining the user acceptance criteria for Base Data management project.
* Was involved in documentation during various stages of validation lifecycle, in accordance with FDA regulations, including 21CFR Part 11.
* Assessed 21 CFR Part 11, 820 requirements and ensured validation of Core components and Custom components of Argus in compliance with FDA regulations.
* Worked closely with the QA team for working with APIs and tested them in Postman.
* Expertise in conducting User Acceptance Tests UAT , GAP analysis and Impact analysis to aid in the calculation of the Critical Success Factor CSF of the project.
* Created multivariate PIVOT tables on data from customer questionnaires for evaluation and presentation to the Sales and Marketing teams.
* Created Requirement Traceability Matrix (RTM) in HPALM to track progress in project.
* Assisted the development team in translating and interpreting the Requirements.
* Translated stakeholder requirements into deliverables such as functional specifications, use cases, workflow diagrams and data model diagrams using MS Visio.

**Education**Master’s in Public Administration (Finance) ’19