**Mathew Jose**

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**SUMMARY**

As a Strategic, solutions-oriented Business Analyst with over 8 years of experience in Pharmaceutical and Healthcare industries. Hands- on experience in eliciting, analyzing, documenting, and fulfilling complex functional and business requirements of stakeholders and business users through interviews and JAD sessions. Vast experience in all phases of the Software Development Life Cycle (SDLC), in Agile, Waterfall, RUP methodologies. Primarily in Agile methodology. Handling Scrum team offshore and onsite.

Knowledge of Business Intelligence, Statistical Analysis, Data and Quality Assurance analysis. Lead the effort to effectively communicate and collaborate with external and internal stakeholders to analyze information needs and functional requirements and deliver the following artifacts as needed: Functional Requirements Document, Business Requirements Document, Use Cases, Process Flow Diagrams. Comfortable with managing multiple projects simultaneously while executing project deliverables that meet highest client satisfaction. Continuous learner and experienced in Microsoft Office Suite, Tableau.

* Experience in FDA regulations, GxP suites (GAMP4 & GAMP5, GDP), Computer System (CSV) & Equipment Validation, Documentum, LIMS and Track wise.
* Knowledge of FDA 21 CFR Part 11, 210, 211, 820 and ISO 13485 for medical and pharma industries.
* Experienced in Veeva CRM and Veeva Vault Content Management applications and in validating systems like Inventory management, LIMS, CMS and EDM.
* Experienced in implementation/automation of the clinical trials and different modules of Viva Vault, CTMS. Also, implementation of the LIMS applications this was also moving from the legacy to the LIMS.
* Experience in validating Laboratory Information Management System (LIMS), Adverse Event Reporting System (AERS), and Chromatography Data System (CDS).
* Strong knowledge of FDA QS 21 CFR 820, 211 for Pharmaceutical, Life Science and Health Care Industries and cGMP, GCP, GLP, CAPA, GRP, EMR, EHR & QMS.
* Knowledge in Good Clinical Practices GCP with the Clinical Trials area and GXP for work in R&D areas.
* Experienced in validating Laboratory Information Management System (LIMS) and thorough knowledge of GRC regulation and policies.
* Hands on experience in SharePoint and Outlook integration with Dynamics CRM.
* Experience working on a database driven web based CTMS solution for tracking regulatory and clinical data in a clinical trials environment.
* Excellent experience in working with FDA regulated environment, GxP (GCP/GLP/GMP) guidelines.
* Strong Working Knowledge of SDLC, GRC 21CFR Part 11 and software FDA validation practices.
* In depth knowledge in using Business Process Modeling Tools to visually display the business process and indicate where a possible solution could be implemented.
* Adept in writing SQL queries for data extraction, manipulation, analysis, and validation, generating user reports and on Relational Database Management Systems (RDBMS), and Data Warehousing.
* Extensive experience in reviewing and analyzing functional requirement specifications (FRS) and system requirement specifications (SRS) and writing detailed Test Plans, Test Cases, and Test Scripts.
* Expertise in testing tools (Mercury and Rational Suite of Tools).
* Vast exposure with creation and implementation of test strategy and UAT.

**EXPERIENCE**

**Role: Sr Business Analyst**

**Company: Boston Clinical Trials - Boston, Massachusetts July 2021 – Till Date**

**Roles & Responsibilities:**

* Structured workflow for entire content lifecycle from early research and development (R&D).
* Gathered requirements and designed an inventory control system for the R&D labs.
* Created validation transfer plans for separate assays while collaborating with Marketing, R&D and Manufacturing.
* Establish documentation for agile methodology for implementation with a very water-fall-centric development team.
* Worked as a part of scrum team, in an agile methodology with sprint cycles, daily stand ups and story implementation. large cross functional project and support teams.
* Serve as a point of contact for the client’s stakeholders and provided customer support in addition to team building with on and offshore agile teams.
* Worked on requirement gathering, data analysis, FRD, BRD, process flow diagrams. UX, database designing, user acceptance testing, plan product roadmap. And Designed process flowcharts for BRD.
* Create story board of back log items in Agile and develop item according to business needs.
* Worked on business needs, rules, requirement gathering, End-User Manuals, user acceptance testing (UAT) and Gap analysis.
* Performed gap analysis between a client's requirements and the functionality within Microsoft Dynamics gather requirements, schedule vendor demos for the products and gave industry best practices to the customer.
* Created Custom Entities, Custom attributes for individual Business Units in MS Dynamics CRM 365 as per the Business Process.
* Worked with User Experience (UX) and User Interface (UI) teams while driving the functional requirements and Wireframes.
* Involved in requirement elicitation and conducting requirement discovery meetings with SMEs, product owners, UX and the technical teams.
* Used MS Visio/UML to model Use Case Diagrams, Activity Diagrams, business flow diagrams, work flow diagrams sequence diagrams for the applications design.
* Documented Claims assignment details in Vision and Business Requirement Documents (BRDs), Functional Organize requirements into high level Use Cases and low-level Use Case Specifications and modelled them into UC, Activity and Sequence Diagrams using Rational Rose and MS Visio.
* Compile business and functional requirements in the BRD and user stories.
* Reviewed tools for LIMS decision support to be used by the site. Analysis of LIMS enhancements, troubleshooting issues, second tier application support and routine master data configuration as required within the LabVantage LIMS application.
* Gathered URS and FRS for the Software and its integration with Labvantage LIMS.
* Work directly with business owners to gather requirements for Veeva Vault and translate those business requirements into technical specifications and solution.
* Created reports and dashboards in Veeva Vault as per the business requirement.
* Involved in implementing and validating 21 CFR Part 11 compliance strategies for LabVantage LIMS.
* Reviewed User Requirements to create Validation Plan and define the validation strategy, Roles and Responsibilities and all deliverables required for Validation of LabVantage LIMS.
* Conducted operational testing of LabVantage LIMS software and involved in writing of Operational Qualification of various LIMS modules.
* Collaborated with developers to automate supply chain processes, saving time and money while decreasing errors. Collected and analyzed data to improve supply chain operations.
* Involved in the computer system validation (CSV) lifecycle, which matches with FDA regulations particularly 21 CFR part 11 and validation requirements like reporting features, password regulatory rules, password aging and session time-out for the LIMS system.
* Performed cost benefit analysis for supplier efficiency programs and other supply chain projects that may affect Supply Chain KPIs.
* Created defect tracking using HP QC and JIRA and reviewed them in subsequent iterations of the application development process.
* Involved in project scope meetings with the Pricing manager to understand the type of requests and issues handled by the pricing team and documented the high-level business requirements to the product backlog using JIRA
* Involved in Joint Application Development sessions with SMEs and development teams and documented functional business requirements as product backlogs using JIRA.
* Identifies, analyzes and interprets in Supply chain both technical and business opportunities.
* Involved in the documentation of various artifacts as per the FDA 21 CFR Part 11considerations as well as Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP).
* Preparing Weekly action report & QA feedback to QA team & Manager.
* Conducted UAT testing for confidential SharePoint repository site project.
* Performed User Acceptance Testing to the check the various functionalities of LIMS.
* Involved in writing and executing test cases and test scripts to validate certain functionalities of LIMS.

**Role: Business Analyst**

**Company: Akros Pharma - Princeton, New Jersey May 2019 – June 2021**

**Roles & Responsibilities:**

* Utilized corporation developed Agile SDLC methodology. Used Scrum Work Pro and Microsoft Office software to perform required job functions.
* Worked in Agile environment allowing teams to deliver project piece-by-piece and make rapid adjustments as needed. Good understanding working in Agile and bringing projects to completion.
* Prepared process flow/activity diagram for existing system using MS Visio and re-engineer the design based on business requirements.
* Created Process Flow diagrams, Use Case Diagrams, Class Diagrams and Interaction Diagrams using Microsoft Visio and Rational Rose. Created Use cases, activity report, logical components and deployment views to extract business process flows and workflows involved in the project.
* Elicited, analyzed, and documented business requirements; specifically, user stories, process flow diagrams, and wireframes.
* Designed business flows in MS Visio, created IQ/OQ/PQ validation protocols and new master data in xTAB following SDLC change control protocols to implement changes using TrackWise and Veeva Vault following ISO 13485, 21 CFR 11, 21 CFR 210 and 21 CFR 211 regulations.
* Used MS Visio to create Business Flow Diagrams and Workflow Diagrams
* Designed UI screen and layout for patient portal by using MS- Visio.
* Worked on validation of Labware LIMS to be used by Quality Management group to store project related regulatory and non-regulatory documents in a controlled manner.
* Collaborating with the QMO Manager to define and establish the appropriate Quality Management System (QMS), based on project and client requirements; such as Capability Maturity Model Integration (CMMI).
* Implemented Power BI Visualizations to Microsoft Dynamics 365 personal dashboards.
* Involved in Requirements Gathering from user groups and analyzed workflows and UI screen dynamics
* Created SSIS packages using CRM Dynamics.
* Worked with project manager, SMEs and assisted with the implementation of the Labware LIMS.
* Participated in configuration and design of Labware LIMS and various lab applications for the Genetic Quality.
* Generate requirements specifications, use cases, process flow diagrams, user manuals, training materials, and other system documentation.
* Involved in the computer system validation (CSV) lifecycle, which matches with FDA regulations particularly 21 CFR part 11 and validation requirements like reporting features, password regulatory rules, password aging and session time-out for the LIMS system.
* Identified, document business processes for LIMS and captured As-Is and To-be workflow process diagrams to illustrate exchange data between existing CDS and future LIMS.
* Performed validation of Labware LIMS and Open Lab including editing and review of protocols and post execution review for IQ and OQ effort.
* Coordinate testing efforts of external systems interacting with core Labware LIMS application.
* Worked on validating Labware LIMS to meet 21 CFR Part 11 FDA Regulations.
* Ensured all bugs, requirements, mockups and test cases are logged with adequate information into JIRA to assist developers and the team in developing a sound product based on customer standards.
* Created acceptance criteria for functional and technical user stories in JIRA.
* Created test cases for the ACPMS application in JIRA.
* Participated in performing and communicating Risk Assessment pertaining to Labware LIMS validation to the quality team and higher management.
* Involved in validation of Labware LIMS and Open Lab including editing and review of protocols and post execution review for IQ and OQ effort.
* Conducted operational testing of Labware LIMS software and involved in writing of Operational Qualification of various LIMS modules.
* Prepared specification documents for Lab station module of LIMS and created test scripts for positive, negative, regression and the validation of Lab station module for interfacing lab instruments with LIMS.
* Validated Labware LIMS to meet 21 CFR Part 11 FDA Regulations.

**Role: Business Analyst**

**Company: Rowell Laboratories - Orlando, Florida October 2017 – April 2019**

**Roles & Responsibilities:**

* Interacted with the end users in establishing requirements, defining reports, testing, and implementing the new CTMS system.
* Primary contact for setup and testing of new EDC and IVR studies and their interfaces int CTMS.
* Write specification documents, work with vendors on establishing and explaining requirements, setting timelines for testing and implementation, and provide post-go-live support.
* Conducted weekly conference calls on EDC and IVR study status and issues with interface CTMS.
* Worked as a part of scrum team, in an Agile methodology with sprint cycles, daily stand ups and story implementation.
* Interacted with Subject Matter Experts (SME) and end users and established a business analysis around Agile methodology.
* Ensured that relevant UML diagrams and tools were used in all requirement documents and prepared business process models such as Use Case Models, Activity Diagrams, Sequential Diagrams in MS Visio.
* Prepared documents such as Project Scope, Project Vision, Project Success, Business Requirements, Functional Specification, Data Warehouse Process Flow (SQL queries & Crystal Reports) using MS Office (Word, Excel, Visio) and dashboards.
* Created and review of various documents including the Software Requirement Specifications (SRS), Business requirements document (BRD), Use Case Specifications, Functional Specifications (FSD), Systems Design Specification (SDS), Requirement Traceability Matrix (RTM), testing documents and miscellaneous documentation.
* Assists in creating process flow diagrams, solution design documents for various agile projects. And created process flow diagrams to help simplify business requirements.
* Conducted brainstorming sessions with executive sponsors, project champion and stakeholders to document problems with existing CTMS and potential solutions.
* Worked with internal team, CROs and clinical sites to ensure the tracking and timely conduction of clinical studies.
* Attended requirements gathering sessions with the customer based on user feedback and new enhancements, which were entered into JIRA and tracked for future releases.
* Translated high level requirements into functional and technical user stories in JIRA.
* Created mockups for functional user stories implemented in JIRA.
* Worked with CTMS to support day-to-day operations in areas such as conducting study feasibility, streamlining the workflow of the trial coordinators and investigators.
* Created transition requirement document to allow users to be familiar with new CTMS System.
* Involved in development of Clinical Trial Management System (CTMS) integrated with EMR and customized to suit protocols following GCP and other FDA standards.

**Role: Business Analyst**

**Company: Reata Pharmaceuticals - Plano, Texas March 2016 – September 2017**

**Roles & Responsibilities:**

* Interfaced with Manufacturing, Quality, R&D organizations and integrated new products and processes into the existing manufacturing.
* Managed internal R&D and client sponsored web-based projects.
* Worked on validate, test, and implement software tools to maximize efficiency in R&D laboratories.
* Performed R&D stability testing and method transfers to QC.
* Used MS Visio for Process modelling and Business Process flow diagrams.
* Worked in Agile environment and was able to bring projects to completion. And assisted QA team by reviewing test cases and clarifying requirements to ensure complete coverage of requirements,
* Worked in Agile environment allowing teams to deliver project piece-by-piece and make rapid adjustments as needed.
* Developed strategic plans that enabled the enhancement of application by reducing document approval and delivery process across R&D, quality, procurement and manufacturing partners.
* Worked in compliance with FDA regulations and GxP guidelines in all the aspects of Computer Systems Validation.
* Conducted validation and configuration of LIMS module as per 21 CFR part 11 Compliance.
* Involved in documenting the Validation Master Plan in accordance with FDA regulations, particularly 21 CFR Part 11, GLP and GMP.
* Communicated pertinent LIMS Requirements to site/system owners and gained consensus with management, IT, QA and scientists of departmental requirements.
* Assisted in initiating and conducting Gap Analysis and Remediation Plan for lab equipment and software interfaced with LIMS for 21 CFR Part 11 compliance and prepared Deviation Reports.
* Worked with project managers and assisted with the implementation of the LIMS software in compliance with the FDA 21 CFR Part 11 requirements, using GAMP guidelines.
* Worked on creating required documentation (URS, TDS, and FS) in highly regulated FDA GxP environment.
* Performed 21 CFR Part 11 GA-P Analysis, Risk Analysis, Developed Requirements, Traceability Matrix (RTM) to track requirements for the software application module.

**Role: Business Analyst**

**Company: MVP HealthCare - Schenectady, New York January 2015 – February 2016**

**Roles & Responsibilities:**

* Interacted with business heads to finalize the Business Requirements for the application.
* Performed the requirement analysis and documented the requirements using Rational Requisite Pro.
* Created use cases that defined the role of customers, medical practitioners, clearing house Administrators and healthcare plans such as: Medicare, Medicaid insurance plan.
* Used the Agile methodology to build the different phases of Software development life cycle.
* Assist Medicaid staff in designing/modifying MMIS processing cycle reports.
* Used SDLC (System Development Life Cycle) methodologies like the RUP and the waterfall.
* Understand the As Is system and develop the To Be system concept and also prepare the System Process Maps.
* Analyzed plan requirements and then contributed further defining the plan requirements with their Project Manager. Observed the compliance of the requirements with federal and state government regulations Medicaid, Medicare, and accreditation body requirements.
* Analyzed user and data issues related to Medicaid eligibility determination system.
* Prepared and documented System Requirements and workflows for the Content Management Application tool.

**EDUCATION:**

Bachelors in Computer Science – 2014.