Sandeep Prabhakaran
Sr Business Analyst
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PROFESSIONAL SUMMARY:

- With 8 years of experience as a pharmaceutical industry business analyst, I bring a robust set of skills in gathering and understanding business requirements.
- Experience in crafting diverse project documents, including Business Requirement Documents (BRD), Functional Requirement Documents (FRD), Software Requirement Specifications (SRS), Data mapping, data definition documents, Data migration-related documents, Test Plans, Test cases, User Acceptance testing (UAT) Document, etc.
- Experience in orchestrating Joint Requirement Planning (JRP) sessions with Business User Groups, conducting Joint Application Development (JAD) sessions with IT Groups, and adeptly managing conflicts among project team members.
- Experience in Project Management, demonstrating skills in scoping, planning, estimation, scheduling, organization, direction, control, budgeting, and devising corrective procedures.
- Experience in utilizing JIRA for User Story requirements management throughout the Agile Sprints and the development life cycle.
- Experience in various development methodologies such as Waterfall, SDLC, Rational Unified Process (RUP), Agile, and Scrum.
- Extensive experience in translating business requirements into functional specifications and creating business models using UML diagrams, including Use Case, Sequence, and Activity diagrams. Proficient in using software tools like Enterprise Architect, MS Visio, and Rational Rose.
- Extensive background in operating within a highly regulated FDA environment, demonstrating a strong commitment to adhering to GXP - Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Good Manufacturing Practice (GMP) guidelines. Committed to ensuring compliance with stringent quality and safety standards to meet regulatory requirements.
- Experience in implementing and ensuring application compliance with 21 CFR Part 11, GxP (Good Practice), and CSV (Computer System Validation) guidelines.
- Experience in using PBM analytics to extract insights into program performance metrics, facilitating data-driven decision-making for continuous improvement.
- Utilized LabWare expertise to optimize laboratory operations, ensuring adherence to industry standards and improving efficiency.
- Experienced in a thorough analysis of TrackWise Digital functionalities, identifying opportunities for customization and enhancement.

- Experience in performing Gap Analysis to ensure compliance with 21 CFR Part 11 and executing subsequent remediation efforts.
- Experience in crafting intricate SQL queries involving multiple tables joins, covering both inner and outer joins, and skilled in creating and optimizing stored procedures.
- Experienced in validating a Laboratory Information Management System (LIMS) to ensure adherence to compliance and optimal functionality, supporting data management, sample tracking, and reporting within a laboratory context.
- Experience in developing business cases while maintaining adherence to GxP and 21 CFR Part 11 regulatory requirements, consistently delivering essential documents to the pharmaceutical sector.
- Experience in LabVantage for optimizing laboratory operations, maintaining industry standards compliance, and improving data management efficiency.
- Skillful in documenting and managing detailed records of CTMS configurations, facilitating knowledge transfer and future system updates.
- Participation in the implementation of test plans for validating LabWare configurations, ensuring system accuracy and reliability.
- Experience in utilizing CTMS analytics to extract meaningful insights into the performance metrics of clinical trials, supporting informed decision-making through data-driven approaches.
- Expertise in monitoring mechanisms for RIM performance, and analyzing data to identify areas for optimization and improvement in regulatory efficiency.
- Experience in reviewing and analyzing the data design and data flow between various interfaces based on Visio documents and Design documents.
- Experience in Implementation of automation for routine reporting tasks using Power BI, resulting in a substantial decrease in manual efforts and a noteworthy improvement in the efficiency of clinical trial data analysis.
- Experience in utilizing Power BI's reporting capabilities to create comprehensive reports on clinical trial performance metrics, enabling data-driven discussions with cross-functional teams.
- Generated detailed documentation outlining LabVantage configurations, workflows, and customizations for future reference and knowledge transfer.
- Experienced in integrating PBM systems with other healthcare information systems, promoting seamless data flow and interoperability.
- Extensive experience in conducting meticulous analysis of defects in pharmaceutical software applications, ensuring a thorough understanding of industry-specific intricacies.
- Proficient in various types of testing, including Functionality Testing, User Acceptance Testing, Database Testing, Regression Testing, and Risk-Based Testing.
- Comprehensive understanding of conducting User Acceptance Testing (UAT), data quality assessments with SQL, gap analysis, and Requirement Traceability.

- Experience in guiding the development team and QA team to ensure the timely completion of the project by the specified delivery date.
- Documentation skills, well-versed in all phases of Validated and non-validated testing, such as Test Planning, Test case estimation, Test Strategy, test case scripting, and test case tracking.
- Excellent team player with the ability to work independently, possessing outstanding written communication and interpersonal skills.
- Functional expertise in both Manual and Automated testing tools, encompassing planning, design, and implementation of tests and test cases, as well as integration, system, and regression testing, and the management of test efforts documentation.

PROFESSIONAL EXPEIRENCE:

Client: Boston Scientific, Natick,
MA 2021 July - Present
Business Analyst
Responsibilities:

- Conducted interviews, sessions, and workshops to collect and document business requirements (BRD), subsequently translating them into functional requirements (FRD).
- Developed and conducted training programs on quality systems, Software Development Life Cycle (SDLC), GAMP (Good Automated Manufacturing Practice), as well as general GxP regulations and best practices.
- Facilitated and organized Joint Application Development (JAD) sessions, resulting in the successful identification and comprehensive documentation of critical requirements through a detailed and collaborative analytical process.
- Managed the Defect Tracking and Management processes in JIRA, utilizing the platform to automate daily reporting, enhance project efficiency, and facilitate timely issue resolution.
- Collaborated with Clinical Trial Management Systems (CTMS) to improve daily operational efficiency, involving activities such as study feasibility assessment and optimizing workflows for trial coordinators and investigators.
- Utilized specialized defect tracking tools customized for Pharma operations, guaranteeing accurate logging, continuous monitoring, and precise reporting of defects.
- Integrated Power BI dashboards with other clinical trial management systems, establishing a unified and comprehensive view of trial data.
- Implemented data security measures using SQL to ensure compliance with privacy regulations and industry standards.
- Tailored the STARLIMS application extensively, addressing all facets, including the incorporation of Electronic Laboratory Notebook (ELN) functionality.

- Provided daily support for STARLIMS migration, configuration, and implementation, ensuring adherence to site-specific requirements.
- Conducted data profiling and validation using SQL to guarantee the accuracy and integrity of data.
- Participated in the development and execution of strategies to align TrackWise Digital with evolving regulatory requirements and industry standards.
- Involved in the implementation of upgrades and patches for the Regulatory Information Management (RIM) system, incorporating new functionalities and improvements while staying updated on the latest regulatory standards.
- Proactively identified opportunities for continuous improvement in Electronic Data Interchange (EDI) processes, proposing and implementing enhancements to optimize workflows for data exchange.
- Conducted comprehensive root cause analysis tailored for Pharma processes, providing valuable insights into the fundamental issues leading to defects.
- Involved in the Development and implementation of validation protocols for computerized systems, ensuring compliance with regulatory standards such as GxP, 21 CFR Part 11, and Computer System Validation (CSV).
- Performed validation and configured Laboratory Information Management System (LIMS) modules by 21 CFR Part 11 compliance requirements.
- Managed the Requirements Traceability Matrix (RTM) and skillfully coordinated the adjustment of test cases to align with newly established requirements, demonstrating a systematic and adaptable approach to ensure testing congruence with evolving project demands.
- Engaged in enhancing the efficiency, cost-effectiveness, and overall performance of Pharmacy Benefit Management (PBM) systems by identifying and implementing optimization opportunities.
- Involved in integrating data from diverse sources, including internal clinical data management systems, laboratories, and contract research organizations, and conducted comprehensive data cleansing procedures.
- Engaged in the creation and execution of comprehensive system test plans based on data mapping specifications. These specifications determined the data extraction from an internal data warehouse, its transformation, and transmission to an external entity.
- Ensured compliance with regulatory requirements and industry standards in LabWare operations, particularly focusing on data integrity and security.
- Maintained awareness of the latest LabWare updates and features, implementing upgrades and patches to leverage new functionalities and improvements.
- Participated in the database design phase, actively utilizing Case Report Forms (CRF) and developing customized macros to efficiently filter data for both Phase II and Phase III clinical trials.
- Performed manual testing across various domains, encompassing functionality, integration, and system, as well as positive and negative testing.

- Evaluated the impact of defects on regulatory compliance within the pharmaceutical sector, ensuring resolutions adhered to strict quality and documentation standards.
- Guaranteed that Standard Operating Procedures (SOPs) were aligned with organizational objectives to ensure procedural consistency across all departments.
- Executed User Acceptance Testing (UAT) with a focus on comprehensive testing and meticulously documented UAT summary reports, ensuring the successful validation and readiness of systems for deployment.
- Managed the coordination of testing activities for external systems that interface with the primary LabWare LIMS application.
- Managed the task of facilitating and documenting scientific content, its usage, adherence to business process standards, and technical requirements.

Client: Astellas Pharma, Farmingdale, NY **2019**

June – 2021 June

Sr Business Analyst

Responsibilities:

- Collaborated with the project manager and subject matter experts (SMEs) to support the implementation of LabWare LIMS.
- Involved in monitoring of systems to assess EDI performance, and scrutinizing transaction data to pinpoint opportunities for optimizing and enhancing the efficiency of data exchange.
- Collaborated with the project manager and subject matter experts (SMEs) to support the LabWare LIMS implementation.
- Diligently documented defects and resolutions specific to the Pharma industry, creating tailored and succinct reports for stakeholders in the pharmaceutical domain.
- Involved in the development of a comprehensive Validation plan for Laboratory Data systems, including Computer Systems (CDS, SDMS, ELN) integrated with LIMS, ensuring seamless functionality and regulatory compliance.
- Conducted Requirement Gathering and Analysis, proactively collecting, analyzing, and negotiating customer needs, and produced the requirements specification document for the application using MS Word.
- Facilitated project initiation meetings with team members to clarify their roles and responsibilities, interdepartmental relationships, deliverables, timelines, task assignments, and progress reporting.
- Created Use Cases, Activity Diagrams, Sequence Diagrams, Object-Oriented Analysis, and Design (OOAD) artifacts using UML, and Business Process Modeling.
- Formulated business and system requirements, and program functions, adhered to GMP and GLP best practices, ensured FDA validation, and met 21 CFR Part 11 compliance in a heavily regulated environment. These efforts supported the submission of regulatory documents for drug development.

- Engaged in the proactive development and maintenance of templates for various folders and electronic Case Report Forms (eCRFs) within each application, tailored to the requirements of Phase IV trials derived from the Clinical Trial Management System (CTMS).
- Applied SQL skills to troubleshoot and resolve database-related issues, ensuring system reliability.
- Maintained adherence to regulatory standards in TrackWise Digital operations, prioritizing data integrity and security.
- Analyzed Regulatory Information Management (RIM) processes, identifying bottlenecks and recommending streamlined workflows to expedite regulatory activities.
- Performed GAP Analysis and Risk Assessment aligned with 21 CFR Part 11, created software requirements, and implemented a Requirement Traceability Matrix (RTM) for compliance monitoring.
- Guided on and executed best practices in Computer System Validation (CSV), fostering a culture of adherence to regulations and ongoing enhancement.
- Executed enhancements in PBM (Pharmacy Benefit Management) workflows, aiming to boost operational efficiency, minimize errors, and streamline the administration of pharmacy benefits.
- Implemented the Clinical Trial Management System CTMS to centralize all trial-related information and improve clinical data management by equipping staff, including biostatisticians and database administrators.
- Integrated data from a broad spectrum of sources, spanning in-house clinical data management systems, laboratories, and contract research organizations, and conducted thorough data cleansing procedures.
- Developed PL/SQL statements and stored procedures within Oracle to extract and write data.
- Engaged in testing Workstation/Equipment automation in collaboration with LIMS and Empower systems, encompassing Functional, Positive, Negative, and Regression testing.
- Contributed to the validation of LabWare LIMS by creating, implementing, and documenting Standard Operating Procedures (SOPs), Test Plans, and Test Scripts.
- Involved in the development of Traceability Matrices for User Requirements Specification (URS) and User Acceptance Testing (UAT) alignment in LabWare LIMS releases. Executed Operational Qualification (OQ) and Performance Qualification (PQ) test scripts, and generated Test Summary Reports. Collaborated with the Lead User and managed User Acceptance Testing (UAT) responsibilities.
- Engaged in the execution and communication of Risk Assessment for LabWare LIMS validation, presenting findings to the quality team and senior management.

Client: Abbott Laboratories, Abbott Park, IL 2017

November – 2019 May

Business Analyst

Responsibilities:

- Engaged with users, developers, project managers, and process analysts to gain insights into business processes, pinpoint areas for improvement, and collect business requirements.

- Developed and maintained Software Development Life Cycle (SDLC) documentation, including Business Requirement Document (BRD), Functional Requirements Document (FRD), and Software Requirements Specifications (SRS).
- Engaged proactively in walk-through sessions and meetings with the development team to address relevant concerns and topics.
- Facilitated brainstorming sessions involving executive sponsors, project champions, and stakeholders to identify issues with the existing Clinical Trial Management System (CTMS) and explore prospective solutions.
- Developed and executed strategies in the PBM (Pharmacy Benefit Management) framework to control costs, optimizing pharmacy benefit programs while maintaining service quality.
- Organized and prioritized user stories efficiently within the JIRA platform, collaborating with the development team to address and resolve blockers.
- Utilized dedicated defect tracking tools tailored for Pharma operations, ensuring accurate logging, continuous monitoring, and precise reporting of defects.
- Integrated PBM (Pharmacy Benefit Management) systems with various healthcare information systems to facilitate seamless data flow and ensure interoperability.
- Stayed current with LabVantage updates, implementing upgrades to enhance system functionalities.
- Improved LabVantage configurations to enhance system accuracy and reliability.
- Worked closely with the Lead Developer to create and build the prototype of the application, actively contributing to the initial development stages, technology selection, and overall project foundation.
- Participated in the design and development of the Clinical Trial Management System (CTMS) integrated with EMR and customized to adhere to protocols following CDISC, GCP, and other FDA standards.
- Involved in the Implementation of proactive measures to promptly identify and resolve EDI transaction errors, minimizing disruptions and ensuring the accuracy of exchanged data.
- Leveraged in-depth LabVantage knowledge to enhance laboratory operations and ensure alignment with industry standards.
- Ensured LabVantage operations complied with regulatory requirements and industry standards.
- Involved in Creating and implementing new Standard Operating Procedures (SOPs) and delivered user training on the incorporation and effects of 21 CFR Part 11 compliant data systems on daily functions.
- Evaluated and authorized Computer System Validation (CSV) documentation generated by other teams, guaranteeing thoroughness and alignment with validation standards.
- Authored multiple advanced Oracle queries for data retrieval, while rigorously verifying data integrity to maintain the quality and reliability of extracted information.
- Optimized query response times and enhanced system efficiency through SQL performance tuning.
- Utilized Regulatory Information Management (RIM) analytics to generate insights into regulatory performance metrics, supporting data-driven decision-making for continuous improvement.

- Reviewed and enhanced companywide policies and quality assurance procedures, aligning them with industry standards and regulatory requirements to ensure a robust quality control framework.
- Facilitated the integration of LabVantage with other laboratory instruments, ensuring seamless data flow. Implemented robust data security measures to safeguard sensitive information.
- Created documentation for the Computer Systems Validation Lifecycle, adhering to FDA regulations, including the Validation Plan, Protocol, Operation Qualification (OQ) Specification, and Performance Qualification (PQ) Specification.
- Implemented updates and patches for TrackWise Digital, ensuring alignment with the most recent software enhancements.
- Leveraged SQL proficiency for strategic database design, normalization, and indexing to ensure optimal data organization.
- Formulated a comprehensive Validation Plan precisely tailored to the Project Scope, Testing Objectives, and Testing Plan, ensuring effective quality assurance and validation activities aligned with project goals.
- Collaborated closely with the Lead Developer to establish and manage the Exception Report Database, efficiently addressing and resolving identified bugs for a streamlined debugging process.
- Produced weekly action reports, providing valuable Quality Assurance (QA) feedback to enhance communication and informed decision-making within the team. Developed a Validation Plan by aligning it with the Project Scope, Testing Objectives, and Testing Plan.

Client: Biogen, Cambridge, MA **2016 April – 2017 October**

Business Analyst

Responsibilities:

- Created and sustained the Business Requirements Document (BRD) and Functional Specification Document (FSD), actively engaging in user story acceptance and defect resolution.
- Accountable for comprehensively grasping user needs and articulating them accurately in a meticulously documented software functional specifications document.
- Supported Project Management in creating essential deliverables like the Vision Document and Project Scope document to define the project's timeline and capacity.
- Collaborated with users, designers, developers, project manager, and QA team to gain an in-depth understanding of business processes and efficiently gather and prioritize business requirements.
- Initiated Release Planning, Sprint Planning, User Stories Estimation, and Backlog grooming sessions to discuss business requirements and analyze the scope of the Project.
- Implemented security updates for LabWare LIMS, including tasks such as creating new user accounts, adjusting security levels based on authorization, and maintaining comprehensive documentation.
- Conducted operational testing of LabWare LIMS software and contributed to crafting the Operational Qualification for various LIMS modules.

- Actively identified opportunities for continuous improvement in TrackWise Digital, participating in its enhancement.
- Ensured compliance with regulatory requirements and industry standards in Regulatory Information Management (RIM) operations, with a specific focus on data integrity and security.
- Ensured PBM (Pharmacy Benefit Management) operations adhered to regulatory requirements and standards, including those related to privacy and data protection.
- Participated in the Computer System Validation (CSV) lifecycle, aligning with FDA regulations, particularly 21 CFR Part 11, and addressed validation criteria such as reporting features, password governance, password aging, and session time-out for the LIMS system.
- Conducted interviews and designed tailored questionnaires to engage with Clinical Stakeholders and End Clients, fostering a comprehensive understanding of end-user needs and business processes.
- Conducted essential GAP analyses at various project stages to identify disparities between the current status and desired end objectives.
- Contributed to enhanced interoperability by integrating EDI solutions with existing pharmaceutical systems, ensuring seamless data flow and reducing errors associated with manual data entry.
- Managed the requirements traceability matrix (RTM) involves overseeing and organizing the matrix that links every requirement to the corresponding test cases. This ensures that each aspect of the software or system is tested by the specified requirements.
- Formulated a transition requirement document to ease the assimilation of users into the new Clinical Trial Management System (CTMS). This document serves as a comprehensive guide to ensure a smooth transition, providing detailed information and guidelines.
- Coordinated LabWare LIMS specifications in the Change Control System, overseeing the formal process for systematic evaluation, approval, and implementation of modifications or updates.
- Documented all phases of the computer systems validation lifecycle, ensuring compliance with FDA regulations, specifically CFR 21, part 11, and GxP regulations.
- Supported the LabWare LIMS development team by actively participating in the generation of test scripts for validation and change control.
- Demonstrated proficiency in overseeing and documenting User Acceptance Testing (UAT), with a focus on thorough Test Case development and documentation.
- Contributed to Test Management and Planning by assisting with Automation strategy, coordinating cross-team planning, resolving issues, and serving as a Subject Matter Expert (SME) for the entire product.
- Proficiently utilized Quality Center as a key tool for managing and overseeing various aspects of the testing process, demonstrating a strong aptitude for Test Management.
- Engaged in comprehensive Back-End Testing, which included crafting SQL queries and PL/SQL stored procedures to efficiently extract data from a SQL Database using SQL Developer.

Client: Gilead Sciences, Inc., California, FL 2015 March – 2016 March

Business Analyst

Responsibilities:

- Engaged in the collection and analysis of internal business requirements through interviews, and workflow analyses, and facilitated user discussions.
- Translated user business requirements into detailed functional designs for development, testing, and implementation.
- Applied methodologies such as Unified Modeling Language (UML) and Rational Unified Process (RUP), preparing detailed specifications using case statements and related documentation.
- Identified and communicated risks and issues impacting business rules, functional requirements, and specifications.
- Contributed to quality assurance through reviews of functional test cases.
- Collaborated with stakeholders to evaluate the feasibility, effort, and costs of implementing requirements.
- Worked closely with database administrators to create and deploy SQL database structures aligned with project needs.
- Managed release processes, including feature management, roadmap creation, and milestone markers.
- Developed workflows for sending alerts and notifications to user case roles, case owners, supervisors, and participant case roles (primary client, service supplier, and representatives).
- Defined and developed use cases based on requirements.
- Documented business rules for financials, product provider, and service authorization.
- Participated in troubleshooting and resolving technical issues within the LabVantage system.
- Contributed to Test Planning, Test Case development, and test script execution. Involved in creating Test plans and test cases, and executing Test scripts. Participated in Integration, Regression, Performance, Functional, and System Testing, as well as User Acceptance Testing (UAT).