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Summary:

- 8 plus, years of extensive experience as a business analyst with strong experience in Healthcare Insuranceclaims, Pharmaceuticals and Hospital Domains with a solid understanding of Business Process Flows, and Business Analysis. Detail-oriented and good documentation and process management skills.
- Extensive experience in analyzing and requirements gathering and writing system functional specifications including use cases.
- Extensive practical knowledge of various SDLC methodologies like Waterfall, Rational Unified Process, Agile and Scrum.
- Extensive experience in gathering Business and Functional Requirements, performing Gap Analysis and Impact Analysis
- Excellent in Developing and evaluating business process Models.
- Good experience working with Clinical Trials Databases.
- Clinical trials understanding with hands-on project experience in handling data for CRO.
- Have considerable expertise in Metadata Management, Data Profiling & Quality, Data Governance and Master Data management (MDM).
- Creating user requirements document by interacting with the end users and developers
- Experience in preparation of business requirement documents (BRD), Use cases, UML, Process Flows (BPM), Test Plans, Test cases, Data Mapping, etc.
- Understanding of and experience with different types of commercial pharmaceutical data.
- Knowledge and working experience in GLP, GMP and GCP suites
- Participation in 21 CFR Part 11 and GxP compliance assessments.
- Understanding of GxP and Computer Systems / Automation role in support of GxP compliance
- Extensive experience in preparing and executing qualification protocols (IQ, OQ, PQ)
- Proficient in dealing with Standard Operating Procedures (SOPs), Test plan, Laboratory information management system (LIMS).
- Knowledge of industry practices and regulatory expectations as they relate to commissioning, qualification, and validation programs.
- Proven success as a business analyst through the years, providing a well-balanced understanding of business relationships, business requirements, and technical solutions.
- Strong understanding of information technology capabilities and dependencies, including platforms, content management, e-document strategies and process mapping.
- Excellent skills in forming and facilitating Joint Application Design (JAD) for eliciting data requirements that support the business requirements and documenting data flows.
- Strong experience in Agile and RUP Business Process Modeling.
- Experience with data migration (ETL development), document data manipulation processes and scripts.
- Strong experience of working with the Salesforce platform, including Sales Cloud, Service Cloud, Community Cloud.
- Directly managed multiple projects involving multiple team sizes. One of the key projects involved Clinical Trial using SCRUM development methodology handling highly sensitive data. Recommendations established new firm wide coding and testing standards.
- Extensive working knowledge in validating systems like Inventory management, LIMS, CMS and EDM.
- Proficient in Technical and Business Writing, Business Process Flow, Business Process Modeling, Business Analysis and Testing various methodologies.
- Excellent in Developing and evaluating business process Models.
- Good Exposure to Query Analyzer, Execution Plan to optimize SQL Queries.
- Experienced in RESTful andSOAP Application Program Interface (API) testing using Postman and to check the API response data in JSON or XML as required by workflow to resolve discrepancies and used Swagger for API documentation.
- Proficient in MS Office Excel (pivot tables, vlookups, hlookups, macro), Access, PowerPoint, Visio.

- Design 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) and testing documents
- Effective in executing multiple tasks and assignments ahead of schedule. Created and maintained effective budgets.
- Exposure to Client/Server, Web Application developmental tools and Software development and design.

Professional Experience:

Sr. Business systems Analyst

Halo Pharmaceutical, Parsippany NJ **March 2020 to present**

Responsibilities:

- Created Validation plan for Laboratory Data system and Computer Systems (CDS, SDMS, ELN) interfaced with LIMS.
- Actively involved in creating and updating the templates for the different folders and eCRFs in each application based on phase IV trials from CTMS.
- Implement CTMS to centralize all trial-related information, and improve clinical data management by equipping staff, including biostatisticians and database administrators.
- Performed Requirement Gathering & Analysis by actively soliciting, analysing and negotiating customer requirements and prepared the requirements specification document for the application using MS Word.
- Used ISI Toolbox Pharma Edition efficiently for FDA submissions.
- 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.
- Participated in process of preparing VMP (verification master plan) to describe clearly and concisely the company's philosophy, expectation and approach to be followed Structured workflow for entire content lifecycle from early research and development (R&D) through eSubmission.
- Documented all aspects of the computer system validation lifecycle, in accordance with FDA regulation which includes validation plan and protocol, Installation Qualification (IQ), Operational Qualification (OQ) and specification performance
- Involved in validation of Labware LIMS and OpenLab 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.
- Structured workflow for entire content lifecycle from early research and development (R&D) through eSubmission.
- Defined charter, scope, schedule, and resources for projects productizing R&D programs, managing (and often defining and delivering) customer needs via marketing requirement documents (MRD).
- Responsible for working on multiple R&D environments where bulk chemicals were tested for Quality Control, CISPro was integrated with STIS(TM) Sample Tracking and Inventory System.
- Involved in creating a validation plan to validate SaaS Veeva CRM system, a Salesforce integrated solution with Sample Management and Signature Capture functionality to be compliant with 21 CFR Part 11 and Prescription Drug Market Act (PDMA) detailed in 21 CFR Part 203 regulations.
- Performed 21 CFR Part 11 GA-P Analysis, Risk Analysis, Developed Requirements, Traceability Matrix (RTM) to track requirements for the software application module. Validated LabWare LIMS to meet 21 CFR Part 11 FDA Regulations.
- Worked with project manager, SMEs and assisted with the implementation of the Labware LIMS
- Gathered Business/Functional Requirements from Business/R&D Users.
- Developed business and system requirements, program functions, best practices (GMP, GLP), FDA validation, and 21 CFR Part 11 conditions in a highly regulated environment, for submission of regulatory documents pertaining to drug development
- Worked on project life cycle and SDLC methodologies including RUP, RAD, Waterfall and Agile.
- Wrote PL/SQL statement and stored procedures in Oracle for extracting as well as writing data.
- Involved in Functional, Positive, Negative, and Regression testing of Workstation/Equipment automation with LIMS and Empower.
- Conducting Internal Audits for each department and related processes to ensure the adherence to Quality Management System (QMS).

- The user reported that the Good Manufacturing Practice (GMP) checkbox is checked which is preventing from dynamic referencing - Remediation successful.
- Extensively worked with Case Report Forms (CRF) during database design and developed various macros to filter data for phase II and phase III of clinical trials.
- Prepare presentation slides in MS Project, which was extensively used in different JAD sessions and to track progress.
- Prepare graphical depictions of Use Cases, Use Case Diagrams, State Diagrams, Activity Diagrams, Sequence Diagrams, Component Based Diagrams, and Collateral Diagrams and creation of technical design (UI screen) using Microsoft Visio
- Collaborate with UI/UX, API and System teams to support development initiatives and Knowledge of APIs involved.
- Reviewed Stored Procedures for reports and wrote test queries against the source system (SQL Server) to match the results with the actual report against the Data mart (Oracle).
- Worked with ETL team during the upload process.
- Helped with Data Mapping between the data mart and the Source Systems
- Worked with the UX team to develop UX wireframes, navigation flows and interaction rules using UX design principles and best practices
- Involved in validation of LabWare LIMS by developing, executing and documenting SOPs, Test Plans and Test Scripts.
- Involved in preparing the compliance report featuring the existing status of the cGLP, cGMP sensitive computerized systems.
- Prepared FDA/Regulatory Readiness Reports for IT supported GMP systems that included SDLC documentation assessment, Training completion assessment, Physical and Logical Security, Change Control, Deviations, Disaster and Recovery Planning.
- Extracted data from disparate sources by SAS/ACCESS.
- Developed Traceability Matrix matching URS and UAT for various release efforts for Labware LIMS. Executed OQ and PQ test scripts and generated Test Summary Reports. Interacted with the Lead user and wrote PQ scripts and was responsible for User Acceptance Testing (UAT).
- Participated in performing and communicating Risk Assessment pertaining to Labwrae LIMS validation to the quality team and higher management
- Conducted internal audits of the Quality Management System (QMS) per the documented audit plans and operating procedures
- Developed Use Cases, Activity Diagrams, Sequence Diagrams, OOAD using UML and Business Process Modeling.
- Clarified QA team issues and reviewed test plans and test scripts developed by QA team to make sure that all requirements will be covered in scripts and tested properly.
- Organized meetings to discuss outstanding issues with QA and developers.
- Wrote test scripts for User Acceptance Testing (UAT).

Konsyl Pharmaceuticals, Easton, MD **Jan 2018 to Feb 2020**

Business Analyst

Responsibilities:

- Created and updated Software Development Life Cycle (SDLC) documentation, such as a Business Requirement
- Document (BRD) and Functional Requirements Document (FRD) and Software Requirements Specifications (SRS).
- Interacted with users, developers, project manager and process analysts to understand the business process, identify enhancements and gather business requirements.
- Prepared and updated Requirements Specification documents, Traceability Matrix, IQ scripts and OQ scripts as per the guidelines to be in compliant with FDA regulations.
- Collaborated with department managers, project manager, and Director of QA to ensure ongoing compliance with SOX, GxP, and all other applicable regulatory requirements.
- Responsible for coordinating with team members in locating, tracking, organizing and verifying validation documentation for GMP compliance, GxP and regulatory requirements.
- Consulted and assisted with FDA content development and compliance regarding pharmacovigilance adverse events and clinical medical claims and content.
- Conducted a CSV audit and prepared a position paper for ensuring compliance for all SOX and GxP servers and applications being migrated to one of three central locations as part of a data center consolidation, and presented findings to all levels of management.

- Involved in design and implementation of enhancements to GxP project within RIS (Radiologically Isolated Syndrome) PreClinical department using Watson LIMS and Crystal Reports.
- Performed 21 CFR Part 11 GAP Analysis, Risk Analysis, Developed Requirements, Traceability Matrix (RTM) to track requirements for the software application module.
- Involved in writing Standard Operating Procedures (SOPs) for all aspects of the validation life cycle, in accordance with FDA regulations, particularly 21 CFR Part 11 and GxP regulations.
- Involved in managing Electronic Document Management System (EDMS) for automating R& D and Regulatory document repositories for submissions to the FDA.
- Involved in the Administration of Clinical R& D software including Oracle clinical, Clinapps PMD, Forecasting and sales and marketing software Spotfire and Cognos.
- Worked on risk assessments, Gap Analysis, Deviations, CAPA and creating templates for various deliverables, procedures (SOPS, Work Instructions
- Responsible for LIMS analysis, configuration and support. Authored and reviewed the validation lifecycle deliverables such as Requirement Specifications (User and Functional), Configuration Specifications, Validation Plan and Testing documents and Summary Report. Review and approve product specification in Laboratory Information Management Systems
- Provided analysis report on the incidents/deviations and participated in corrective actions and preventive actions CAPA.
- 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.
- Prepared detailed user-friendly compliance reports of the documentation for the entire project in agreement to FDA standards.
- Involved in consolidating various legacy system including Salesforce sales, marketing and service cloud into a single global Salesforce instance
- Documented and reviewed all the laboratory records through LIMS and controlled forms following the GLPs.
- Involved in managing and participated in configuration and design of Labvantage LIMS and various lab applications
- 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 with in the LabVantage LIMS application
- Interfaced with Manufacturing, Quality, R& D organizations and integrated new products and processes into the existing manufacturing area.
- Created SDLC documentation to support Clinical Trial Management System (CTMS) and Electronic Data Capture (EDC) tools.
- Defined and documented business process flows for Global Laboratory Information System (LIMs) Lab Vantage implementation / upgrade.
- Worked on L2, L3 and L4 support tickets.
- Reviewed all completed IQs/OQs, checklists, and other documents for accuracy and compliance with GxP and FDA rules and regulations
- Assisted the implementation in GXP environment to adhere to regulatory and risk management compliance.
- Involved in supporting accurate management and financial monitoring of multiple Clinical Trials Support Budgeting, Forecasting and Monthly Reporting Cycles across all R& D
- Responsible for trouble shooting any issues that arise with our current LIMS System and other issues with results shuffling from one lab environment to the other
- Create procedures for Sample manager LIMS system and work with Operations to implement.
- Involved in writing and executing Installation qualification IQ, Operational Qualification OQ and Performance Qualification PQ protocols to check installation and successful operation of the application.
- Reviewed the requirements & user stories in JIRA and ensured its traceability in various applications like JIRA and session recordings. Defects were tracked, reviewed, analyzed and compared using HP Quality Center.
- Worked on pharmacy benefit management (PBM) systems to make use of our existing web applications that provide pharmacy/Rx related member functionality

- Worked as an active member of PDP team, interacting with developers, business users and subject matter experts SME to analyze and configure PBM Web-Portal functionality based on Business Requirement.
- Involved in performing Regression testing on both internets PBF and Intranet PBM Web-portals to check compatibility between two code releases.
- Participated in requirement gathering sessions with business stakeholders in capturing the requirement and technical feasibility with Salesforce/Veeva responsible for capturing, analyzing, and designing of different
- integration points involved in the system with external systems.
- Worked on change control documentation such as Change Request Form CRF's, Change Control
- Implementation Plan, Change Control Summary Report.
- Documented user and functional requirements for a healthcare professional HCP look-up tool between Veeva CRM and Customer Data Management (CDM).
- Involved in defining and implementing the QMS standards and policies.
- Created Gate Documentations including RACI matrix, Project Management Plan and Project Charter
- Coordinate with business stakeholders and SMEs to ensure timely completion of all testing activities as per the project plan.
- Implement MES solutions and integration with ERP and or/control equipment.
- Worked with the Remediation team to identify and analyze the ISA Information Security Administration functions to check for compliance and open CAP Corrective Action Plan, RA Risk Acceptance or RE Risk
- Exception for AML Anti Money Laundering, Bond trading and Fraud prevention applications.
- Documenting IQ, OQ and PQ test scripts for new functionality and modifying existing test scripts, execution and SOP development.
- Involved in executing the test scripts to test the interface between SAP and LIMS system.
- Involved in developing and analyzed test plans and test scripts to check functionalities of application of 21 CFR Part 11 compliance and FDA regulations, GAMP 4&5, cGXPs (cGMP, cGLP, cGDP).
- Involved in testing Labvantage LIMS system in which is a Laboratory Information Management System involving functional and user-acceptance testing

Genaissance Pharmaceuticals, CT **March 2016 to Dec 2017**

Business Analyst

Responsibilities:

- Extensively involved in gaining knowledge in patient and protocol compliance in clinical Trials. FDA guidelines and ensuring 21 CFR part 11 compliant and capable of capturing detailed audit trail of user activity on the system.
- Used Data Integrator to load data from various sources such as MS Access, MS Excel, CSV files to MS SQL Server.
- Responsible for working on multiple R&D environments where bulk chemicals were tested for Quality Control, CISPro was integrated with STIS(TM) Sample Tracking and Inventory System.
- 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
- Responsible for all the activities related to configuring Data Loader, uploading data in CSV files into salesforce.com, checking for integrity of the data.
- Converted CSV flat files into HL7 messages.
- Rigidly followed FDA's 21 CFR Part 11 to create, modify, maintain, archive and retrieve electronic records required throughout all the phases of SDLC.
- Developed strategic plans that enabled the enhancement of application by reducing document approval and delivery process across R&D, quality, procurement and manufacturing partners.
- Suggested and implemented innovative tools like RAID (Risk-Assumptions-Issues-Dependencies) and RACI (Responsible-Accountable-Consulted-Informed) in MS Excel to track and monitor these 8 performance parameters for any deliverables, tasks or milestones that can otherwise prove as a show-stopper.
- Coordinate and qualify potential eQMS suppliers for eQMS implementation.
- Analyzing the internal and external processes, dependencies, SOPs, interfaces, and, mapping them to specific business needs, objectives and desired functionalities.

- Identified business rules supporting the ICD codes related to processing of claims, remediation of other business processes that may use ICD codes, including group and member enrollment, provider pricing configuration, product configuration, and medical policy configuration must be in place.
- Support CDC team with document reviews in preparation for document releases to ensure the CDC standards is adhered to.
- Manages concurrent Phase I-IV adult and pediatric global clinical trials throughout various phases of the project lifecycle including set up, verification, maintenance and decommissioning in a number of therapeutic areas
- Conducted technology comparison, tool/solution assessment and solution selection from several potential solutions, including SharePoint, Clinical Trial Management System CTMS and customized systems.
- Worked on Healthcare system implementation including enterprise Electronic Medical Records (EMR) and Electronic Health Records (EHR) software.
- Executed Operational Qualification for various components of Lab Vantage LIMS by utilizing in-house and vendor test scripts.
- Validation of Lab Vantage Laboratory Information Management System (LIMS) to be used by Quality Management group to store project related regulatory and non-regulatory documents in a controlled manner.
- Created validation plan to validate SaaS Veeva CRM system, a Salesforce integrated solution with Sample Management and Signature Capture functionality to be compliant with 21 CFR Part 11 and Prescription Drug Market Act (PDMA) detailed in 21 CFR Part 203 regulations.
- Follow 21CFR Part 11 methodologies for validated systems in a structured SDLC environment. Trained in Good Clinical Practices (GCP) for work with the Clinical Trials area and GXP for work in R&D areas.
- Execute business analysis processes to facilitate the user/function/design relationships within the LIMS system including documentation and test scripting.
- Worked on pharmacy benefit management systems (PBM) to make use of our existing web applications that provide pharmacy/Rx related member functionality.

DSM Pharmaceutical Products Inc, Greenville, NC **March 2014 to Feb 2016**

Business Analyst

Responsibilities:

- Conducted brainstorming sessions with executive sponsors, project champion and stakeholders to document problems with existing CTMS and potential solutions.
- Involved in design and development of Clinical Trial Management System (CTMS) integrated with EMR and customized to suit protocols following CDISC, GCP and other FDA standards.
- Member of assessment team to study the 21 CFR Part 11 requirements.
- Wrote the Validation Assessment for the management to understand the importance of validation of core business functionality.
- 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
- Gathered the User Requirements from the Business Users and the Business Sponsor.
- Developed the Functional Specifications based on the Business User Requirements along with the Lead Developer.
- Coordinated with the Lead Developer to set up and build the prototype of the application.
  Created a Validation Plan based on the Project Scope, Testing Objectives and Testing Plan.
- Wrote documentation for all aspects of the Computer Systems Validation Lifecycle, in accordance with FDA regulations, particularly Part 11, including: Validation Plan and Protocol, Operation Qualification (OQ) Specification, Performance Qualification (PQ) Specification.
- Created the Test Plan for Protocol Execution and conducted Tester Training for the Test Script Execution.
- Set up the Exception Report Database and coordinated with the Lead Developer to resolve the bugs that was found.
- Reviewed Vendor Audit and Vendor Compliance report for LIMS software
- Supervised, executed and reviewed scripts for the formal validation process with implementation of cGMP.
- Maintained the Requirements Traceability Matrix (RTM).
- Drafted new SOPs and trained all users on the systems, implications and impact of 21CFR Part 11 compliant data systems on day-to-day functions.
- Actively participated in project meetings and discussions.
- Peer review deliverables from project team members.
- Scheduled and documented the formal and informal software design reviews.