**Ananya Jain**

E-mail: [ananyajain03@gmail.com](mailto:ananyajain03@gmail.com)

Contact # (818)-610-9352

Github account: - <https://github.com/AakashTamang>

Linkedin account: - <https://www.linkedin.com/in/aakash-tamang-5a6bb7170/>

Zip code: - 12345-6789

**SUMMARY**

* **6+ years of experience with Information Technology Systems inFDA regulated industries** with emphasis on **Business Analysis**, Project Management, Validation and Quality Assurance.
* **Hands on with various applications/systems touching different business areas including** Clinical Research, Drug Development, Supply Chain, Packaging and Labeling, **R&D, Regulatory Compliance/Submissions, Laboratory Information**, Audit, **CRM (Customer relationship management)** and Document Management.
* **Significant business analysis and business process modeling experience with various IT initiatives including data warehousing/business intelligence projects, web-based applications, client/server-based applications, content management, and custom development projects.**
* **Hands on Data Analysis and Data Mining skills for creating and maintain Data Maps, Reference Cards and Enterprise Data Dictionary.**
* **Excellent SQL skills for creating and modifying queries for data validation / backend testing.**
* Strong understanding of **FDA regulations, 21 CFR part 11, Annex 11, 21 CFR 820, USP 1058, Pharmacovigilance, Electronic Records/ Electronic Signatures, cGXP (GMP, GLP, GCP), ISPE, GAMP 4, GAMP 5, MHRA, ISO9001, Sunshine Act, ITIL and ICH.**
* Extensive knowledge of Software Development Life cycle **(SDLC)** methodologies including **RUP, Waterfall and Agile.**
* **Applied industry best practices for requirement gathering, stakeholder management, meeting facilitation, project management, project scope definition, risk & issue identification and other areas of SDLC.**
* Expert in creating **Process Flow Charts, Swim Lane Diagrams, Activity Flow Diagrams and Data Flow Diagrams using MS Visio.**
* Specialist in authoring and reviewing **validation artifacts** such as **Change Request**, **Quality Assurance Plan, Validation Strategy Document, Design/Configuration Specifications, Traceability Matrix (RTM), UAT, Qualification Protocols (IQ, OQ, PQ), Validation Summary Report, Standard Operating Procedures (SOP), User Guide and Training Manual.**
* **Experience in designing Test Plan, defining Test Cases, developing and maintaining Test Scripts, analyzing defects and interacting with development team members in fixing the defects.**
* Excellent knowledge of **HIPAA standards, EDI** (Electronic data interchange) Transaction syntax like ANSI X12, Implementation and Knowledge of HIPAA code sets, ICD-9, ICD-10 coding and HL7.
* Modeled requirements, managed and communicated requirements throughout the project life cycle, performed Gap and Impact Analysis against requirements specifications to determine fit.
* Experience in working with cross-functional groups, different levels of management and liaison between system users, company management and development team.
* Actively involved in developing, executing and managing **User Acceptance Testing** (UAT)
* Highly skilled in using **Microsoft Excel** data analysis techniques viz., **V-Lookup, Pivot Tables, VBA macro development**
* Experience in reviewing documentation of developed solutions and authoring of basic user guides or instructions and help files to assist in end user training & support.
* Excellent **interpersonal, verbal & communication skills**.

**EDUCATION**

* **Bachelors in Pharmaceutical Science**

**SKILLS**

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| --- | --- |
| **Software** | **CRM (Salesforce),** CTMS (Oracle Siebel), AERS (Argus Safety), IT Service Management (ServiceNow, BMC Remedy), IDBS ELN (Electronic Lab Notebook), Accelrys ELN, Empower, Nugenesis SDMS, TrackWise, LabWare LIMS, Test Director, Tableau, Crystal ball |
| **Ticket management** | Remedy, ServiceNow |
| **Technical Writing Tools** | MS Word, MS Excel, MS PowerPoint, MS Visio, MS Project |
| **EDMS** | SharePoint, Documentum, QUMAS, ISOtrain |
| **Project Management Tools** | MS Project, Clarity, Rally, Data Analysis |
| **Database** | **MS Access, MS SQL, Oracle** |
| **Software Development Methodologies:** | Object Oriented Programming, Joint Application Design (JAD), AGILE (Extreme Programming, and Scrum), Rapid Application Development (RAD), Incremental, V-Model, Waterfall, Spiral, Rational Unified Process (RUP), UML |
| **Testing Tools:** | QTP, WinRunner, Load Runner, Mercury Suite, Rational Suite. |
| **Applications:** | Rational Rose, MS-Visio, MS Excel, MS-PowerPoint, MS-SharePoint |

**PROFESSIONAL EXPERIENCE**

**Client: Optum Government Solutions March 2014 – Present**

**Location: WILMINGTON, DE**

**Senior Business Analyst**

**Optum Health** serves the physical, emotional and financial needs of more than 77 million individuals, enabling consumer health management and collaborative care delivery through programs offered by employers, payers, government entities and, increasingly, directly with the care delivery system. Optum Health’s solutions reduce costs for customers, improve workforce productivity and consumer satisfaction and optimize the overall health and well-being of populations.

**Responsibilities:**

* **Acted as Senior IT representative** for projects which are implementing new COTS systems and/or implementing changes, upgrades, enhancements or fixes to existing systems.
* **Majority of tenure was spent on project which was aimed at configuring SFDC (Salesforce.com)** as per changing business needs and requirements.
* **Built requirements to register the wet signed or docu signed documents to the Spring CM feature in Salesforce** to ensure proper filing and validation of all the contracts and PO through the legal department.
* **Built configuration requirement for Salesforce chatter functionality to bring various cross functional teams on one communication channel.**
* **Analyzed current state and futures state of the system to build high level process map.**
* **Organized and lead JAD sessions with client and the development team** to define and document the business requirements (BRD) as well as functional requirements (FRD).
* **Utilized Documentum based EDMS (Electronic Document Management System)** to manage the document work flow.
* **Assisted with data preparation for analysis and reporting purposes**; responsible for data pre-processing, creating data model and regression studies
* **Provided GMP compliance subject matter expertise** for library management, data management, software development, and instrument troubleshooting
* **Actively participated in group training and coaching efforts**; acting as a recognized technical and procedural resource for peers.
* Ensured proper understanding of the system by giving training to the SME’s and troubleshooting the problems till and after UAT.

**ENVIRONMENT:** Rational Requisite pro, Agile waterfall hybrid, HP Quality Center, MS Office, MS Visio, Salesforce, EDMS, CFR part 11, HIPPA

**Client: BCBS April 2013 – February 2014**

**Location: Jacksonville, FL**

**Business Analyst**

**The Blue Cross Blue Shield (BCBS)** is a federation of 36 separate United States health insurance organizations and companies, providing health insurance to more than 106 million Americans.

**Responsibilities:**

* Managed the requirements gathering process including scheduling interview and brainstorming sessions with user groups to gather, prioritize, and to decompose business and technical requirements
* Conducting analysis, configuring, testing, quality assuring and documenting configuration solutions for all applications in the **FACETS** system.
* Worked on configuration of **FACETS** with Benefits, Claim processing and Enrollment
* Configured benefit summary views and translated business message into simple English for Customer support view
* Queried claim information to identify any discrepancies with the working of the system. (i.e. making sure that the system is processing claims as it is supposed to.)
* Met with SME’s (Subject Matter Experts) to identify impacts to the system in order to incorporate new enhancements to the system.
* Worked on loading the benefits configuration data into **FACETS** table.
* Created and configured benefits, components, riders and benefit plans
* Conducted Gap Analysis on the AS-IS and TO-BE business processes and technology; and identified potential pitfalls, risks, and issues. Mitigated risks and developed contingency plans for risk management.
* Prepared the detailed work flow diagram based on the proposed enhancement for the system using Business Process Modeling Language.
* Configured benefit summary views and translated business message into simple English for Customer support view Queried claim information to identify any discrepancies with the working of the systems.
* Performed configuration and testing (**test plan, test cases, audit, UAT** etc.) tasks, support implementation and production deployment, review tasks and resolve issues independently.
* Ensured and Coordinated efforts for compliance with **HIPAA, CLIA and OSHA regulations; improved patient care/satisfaction.**

**ENVIRONMENT:**UML, Microsoft Office, Microsoft Visio, MS SharePoint, Facets, User Stories, Power-point, ERD, RTM, Test Plans, HIPPA

**Client: Verus Pharmaceuticals Oct 2012 – March 2013**

**Location: San Diego, CA**

**Business Analyst**

**Verus Pharmaceuticals** based in San Diego, California was founded in November 2002, with an initial focus on the treatment of asthma, allergies, and related diseases and conditions, specifically in children. Verus is best known for it development and manufacturing of Twinject, the first two-dose epinephrine autoinjector.

**Responsibilities:**

* **This particular project was to enhance legacy database system and other peripheral systems so they are in compliance with Sunshine Act.**
* **Built requirements to enhance systems to accurately track and report physician payments in compliance with the Sunshine Act.**
* **Acted as a liaison with the business owners and technical stake holders** to capture and author business requirements.
* **Created User Stories, Swim Lane Diagrams, Entity Relationship Diagram (ERDs) and Process Flows** using Microsoft Visio to define the new functional work flow within Facets.
* **Identified, researched, investigated, realized, analyzed, defined and documented current business process model and desired business process model.**
* **Created complex Use Cases, Business Processes and Work Flow Diagrams using MS Visio and MS Excel.**
* **Developed number of SDLC deliverables including Business Requirement Document,** Validation Strategy Document, System Design Specifications, **User and Functional Requirement Specifications**, IQ/OQ/PQ, SOPs/Work Instructions and Validation Summary Reports
* **Created Power point deck to present the progress of project** to the higher management in the biweekly project evaluation meetings.
* **Managed the change management process** to clearly document change controls, justifications for the changes, impact analysis and approvals.
* Developed **Test Plan, Test Cases and Test Scripts**.
* Assisted Project Manager in resource management, scoping and planning of validation activities
* Developed Test Cases for Integration Testing
* Developed UAT Cases and performed ‘Dry Run’.

**ENVIRONMENT:** Rational Unified Process (RUP), Waterfall, EDI, MS Visio, Word, Excel, PowerPoint, UML, Axure RP, Microsoft Access, Sunshine Act

**Orley Pharmaceuticals February 2009 – July 2012**

**Ahmedabad, India**

**Validation QA Analyst**

**Orley Labs is one of the largest manufacturers of antimalarial and heparin products along with many other pharma products,** Orley’s Environmental Monitoring Lab processes thousands of plates and bottles through multiple steps each shift. The system intended to minimize the data entry effort required in the lab and therefore the total amount of time to process the samples by introducing automation. **The new system will enable the bulk entry of data into LABWARE LIMS, through the use of instruments like a conveyor and manual barcode readers. LABWARE LIMS (Sample Management, Plate Management) was configured to accept and process new data.**

**Responsibilities:**

* **Performed Vendor Assessments** and reviewed vendor documents in order to ensure compliance to the company policy and validation requirements.
* **Facilitated work sessions with lab personnel and other SMEs to gather changes suggested for Lab System Upgrade.**
* Documented all the aspects of Systems validation life cycle including **Validation Plan and Protocol, Installation Qualification (IQ) Specifications, Operation Qualification (OQ) Specifications, Performance Qualification Specification (PQ)**
* **Executed IQ and OQ protocols and documented results and deviations.**
* **Documented Validation Summary Report and Test Closure Memo.**

**ENVIRONMENT:** MS Visio, Word, Excel, PowerPoint, UML, Microsoft Access.