**RABINDRA LAMICHHANE**

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# CAREER SUMMARY

* A results oriented professional with 6plus years of diversified experience with Medical device and Pharmacy /biotech Industries
* Strong experience with different phases of Software Development Life Cycle (SDLC). Experienced in full life cycle of system development like Agile (Scrum), Waterfall, and RUP
* In-depth knowledge compliance with Pharmaceuticals Policy, which were written to comply with the rules and regulations of FDA 21 CFR Part 11.
* Provided technical expertise to resolve issues related to lab methodology and set lab standards.
* Knowledge of industry standards governing clinical trials such as CDISC, SDTM and HL7. Knowledge of lab methodology and set lab standards.
* Expertise in translating user requirements into System Specifications, mapping process design, and work flows for SDLC while documenting and managing business requirements.
* Experience in Project Planning, Project Design, creating functional specifications and data flow diagrams.
* Developing Use Case diagrams, Sequence diagrams, Data Flow diagrams and Class diagrams.
* Possess excellent organizational, interpersonal, communication and documentation skills with good process management skills along with an outstanding ability to gather requirements to bring out quality product.
* Strong analytical and problem solving skills with the ability to adapt to a new environment and meet stringent deadlines.
* Ability to excel and succeed in a diverse environment or project using strong determination, dedication, and a commitment towards customer satisfaction.
* Conducted requirement analysis using techniques such as Business Process Automation, Business Process Improvement, and Business Process Re-engineering.
* Conducted Joint Application Development (JAD) sessions and interviewed Subject Matter Experts (SMEs), asking detailed functionality aspects of business process and carefully updating the information to the requirements in an easy and understandable format.

**TECHNICAL SKILLS**

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| **CATEGORY** | **DESCRIPTION** |
| **Operating Systems** | Windows, Unix |
| **Application Software** | MS Office suite, Rational Suite, MS Project |
| **Databases** | SQL Server, Oracle, MS Access, DB2 |
| **Web Technologies** | HTML, XML, XSLT, web services, SOAP, SOA, HTML, .NET |
| **Methodologies** | RUP, OOAD, UML & Business/Data Modeling, ER modeling |
| **Requirements Management Tools** | Requisite Pro, MS Visio |
| **Testing Tools** | Microsoft Test Manager(MTM), Team Foundation Server(TFS), HP ALM/ Quality Center, Quick Test Pro |
| **Process Modeling** | MS Visio, Rational Rose |
| **Programming Languages** | Java, J2EE, SQL, ASP.NET, UML, Visual Basic, C, C++ |
| **Documents & Processes** | SRS, Use Cases, UML diagrams, FRS, UAT, Test plans & cases, Business Process Modeling, Project Planning & tracking |

**EXPERIENCE**

**Medtronic Navigation, Inc., Louisville, CO Mar 2016- May 2017**

**Business Analyst**

Medtronic Navigation Inc is company which is contributing to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life. It is one of the world’s largest suppliers to the healthcare industry and a leader in medical imaging, laboratory diagnostics, medical information technology and hearing aids. Medtronic offers its customers products and solutions for the entire lifecycle of patient care – from prevention and early detection, to diagnosis, treatment, and aftercare. I was involving in testing medical devices in web based application, reviewing system behavior under various conduction and manually executed test scripts.

Stealth Connect is a web based version of the cranial application, allowing the surgeon to do the planning for a surgery remotely. This saves a lot of effort and time of the surgeon to be spent in an OR. Stealth Connect allows the surgeon to do many important things remotely like all the planning involved in a Stereotactic Frame DBS procedure, creating platforms and sending them to the manufacturer, merging the pre-operation CT and MRI scans and creating plans and defining the trajectory of the instruments inside the brain.

**Responsibilities:**

* Identified and implemented the processes for developing and documenting detailed business requirements. Collected from end-users and analysts.
* Elicited business requirements through interviews, document analysis, design workshops, surveys, use cases, and workflow analysis.
* Performed Requirements Gathering and Analysis, interacted with the SME (Subject Matter Experts), and ensured that contributors and all key stakeholders were motivated to complete assigned tasks.
* Participated and facilitated Joint Application Development (JAD) Sessions for communicating and managing functional requirements and project expectations.
* Coordinated with the Project Manager to set project activities like keeping track of Project Status reports, Deadlines, and Compliance Issues.
* Manage the Requirements (Business as well as System requirements), performed requirements analysis along with the creation of Use Case Scenarios.
* Created Process Work Flows, Functional Specifications, and was responsible for preparing Software Requirement Specifications (SRS) and the Functional Specification Document (FSD).
* Imported preexisting Microsoft Word and Excel-based requirements and tests for analysis in Quality Center.
* Developed and wrote test cases for the testing efforts in compliance with Pharmaceuticals Policy, which were written to comply with the rules and regulations of FDA 21 CFR Part 11.
* Performed Security Testing on the application. Selected test cases based on an  
  analysis of the specification, for functional and non-functional requirement of a component or system without reference to its internal structure for black box testing.
* Extensively used SQL statements to query the Oracle Database for Data Validation and Data Integrity.
* Executed test cases, found errors, reported defects, determined repair priorities, did regression testing
* Monitored the Defect Tracking Process and generated customized graphs and reports for the client using Jira
* Followed the Agile Methodology Process throughout the project and all artifacts are generated for each discipline.
* Extensively used SQL statements to query the Oracle Database for Data Validation and Data Integrity.

**Sheffield Pharmaceuticals, New London, Connecticut Feb 2014- Feb 2016**

**Business Analyst**

Sheffield Pharmaceuticals is a manufacturer of over the counter pharmaceutical products to retailers in the United States.[[1]](https://en.wikipedia.org/wiki/Sheffield_Pharmaceuticals#cite_note-sph1-1) It manufactures and sells products both under its own labels and privately for other companies, and is an FDA registered cGMP facility. I worked as a business analyst in Operational Data Warehouse (ODW) integrated under Clinical Aggregation Layer (CAL) program. ODW stands on the Clinical Scientific Data Warehouse (CSDW) that allows r to perform the metric reporting across Clinical study operational Data executed by business partners as well as itself.

**Responsibilities:**

* Involved in preparing documentation for all aspects of the computer system validation life cycle, in accordance with FDA design control and regulations, particularly 21 CFR Part 11
* Contributed towards the initial analysis of the vast project definition document.
* Defined and documented the vision and scope of the project for each Wave.
* Worked with the clients on the verification process for the requirement phase documents.
* Coordinated with Business Process Re-engineering team to work on integration plans.
* Facilitated project meetings and compiled meeting minutes.
* Defined and documented the vision and scope of the project.
* Analyzed the “As is” and “To be” system documents to show the current and proposed functionalities of the system using MS VISIO.
* Met with various groups, including business owners, SMEs and marketing team, for requirements gathering in definition Stage.
* Facilitated JAD/JAR and brainstorming sessions to gather requirements.
* Analyzed, elicited and documented User and System requirements for each functional area.
* Coordinate with Development and Business team to develop high level Business and Technical documents.
* Performed data analysis and prepared data flow diagrams and wire frame using MS Visio.
* Responsible for functional requirements and design documents (with SRS).
* Involved in writing and implementation of the test plan, and various test cases.
* Conducted Web Meetings with Off-Shore team members to ensure that everybody is on the same page.
* Collected weekly status reports to ensure that all deliverables are met on time and on schedule.
* Created Use Cases from the list of requirements and prepared use case diagrams using Rational Rose.
* Assisted QA team in creating Test Cases and performed User Acceptance Testing, documented the in detail defects using the Defect Tracking report.
* Prepared detailed test scripts and test plan and assisted in integration testing.
* Responsible for weekly status reporting and project planning

**Watson Pharmaceuticals, Corona, CA May 2011 – Dec 2013**

**Business Analyst**

Watson Pharmaceuticals, Inc. is a leading specialty pharmaceutical company that uses innovative science and market insight to develop responsive products for a changing world. The project involved remediation of lab instruments and bringing them into compliance with FDA regulations. I analyzed and synthesized documents related to requirements gathered from stakeholders meetings to design use case diagrams.

**Responsibilities:**

* Helped the Project Manager in creating Project Charter Document to define the scope and purpose of the project.
* Worked in Agile methodology of system development.
* Identified and conducted stakeholder analysis to gather Business Requirements, interacting with stakeholders, gathering requirements and assigning priorities to each of them.
* Prepared Business Requirement Specification Document (BRD) and converted into Functional requirement specifications document (FRD).
* Involvement of overseeing quality assurance process, data integration mapping for exports of data from citation to client records management system and implementation software training for the client.
* Involved in data mapping, field mapping of the data elements responsible for the migration BRD.
* Performed GAP analysis of business rules, business and system process flows, user administration to be used for the new migration platform.
* Conduct complex documentation and user needs analysis. Interface with team and staff to develop HL7 integration. Participated in the application scrum meetings and the sessions.
* Created and maintained a project schedule using MS Project showing all target dates for deliverables.
* Successfully conducted JAD sessions, which helped synchronize the different stakeholders on their objectives and helped the developers to have a clear-cut picture of the project.
* Conducted UAT (User Acceptance Testing) to make sure that all the user requirements are catered by the application
* Prepared test cases, test scripts, test summary reports for overall product, part wise assessment and improvement, report concerns if any to the suppliers
* Extensively used Enterprise Data Management platform Documentum for maintaining validation life cycle documents
* Performed production data analysis and suggested process parameters for process optimization, process control and product development