**ANKUR CHAURASIA**

**SUMMARY** Experienced Sr. Systems Analyst/Project Lead in Agile Project & Product Life Cycle Management (PPLM) for Pharmaceutical, Life Sciences, Drugs Discovery Phases & Healthcare Projects & Products. Offering over ten years of success leading, planning and managing multimillion-dollar projects aligning business goals with technology solutions to drive process improvements, competitive advantage and bottom-line gains by communicating effectively with stakeholders, clients, executives, and cross functional teams. Expert in Agile PPLM and waterfall project management methodologies for various ERP Systems – **SAP (SCM, MM, QM), Oracle EBS, R12 Financial, Oracle JD Edward EnterpriseOne 9.2, 8.1, Salesforce CRM, ServiceNow, Change Management, LabVantage, LIMS, CDS (Empower 3, Atlas), ELN, NuGenesis** etc. and the Big Data Systems – **Hadoop, HIVE** etc. Able to manage large project teams and known for high-quality deliverables that meet or exceed timeline and budgetary targets.

**EDUCATION** **Illinois Institute of Technology**, Chicago, IL

MS Computer Science

**Rajiv Gandhi Technical University**

BS Computer Science & Engineering

**CERTIFICATIONS** LabWare Laboratory Information Management System (**LIMS**) V5 & V6 Administrator.

WATERS Scientific Data Management System (SDMS) NuGenesis Administrator.

WATERS Empower 3 Chromatography Data System (CDS) System Administrator.

ITIL Foundation v3 Software Professional.

CBAP - Certified Business Analyst Professional (Expected Certification: - December 2019)

**TECHNICAL SKILLS**

**Pharmaceutical/Healthcare Laboratory IT & Manufacturing Systems Expertise**: -

**Global Lab Systems & Retail Ops**: - Laboratory Information Management Systems (**LIMS**) **v5/v6** Thermo Fisher ScientificSample Manager 2004 R2, Sample Manager 11, Chromatography Data Systems (CDS) – Empower 3, Atlas, IDBS ELN, SDMS NuGenesis.

**Quality Assurance/Control (QA/QC)**: - CAPA Documentation & Reporting, **Lean Six Sigma** - Green Belt, Gap Analysis, Failure Mode Effect Analysis **Process** Expertise & Documentation **(FMEA),** Corrective Action (CA), Incident/Exception Report (I/E R), Quality Assurance Document Management Systems **(DMS/VMS/QDMS)** andQuality Management Software **(QUMAS)**

**FDA Regulations**: 21 CFR PART 11 (FDA Data Integrity), EU ANNEX 11, ICH Q7/Q8, 810, 820, 410(k), 420(k), 480(k), 510(k), IDE, Pre-Market Approval etc. filings procedures and requirements **for Class I and Class II Medical Devices.** **cGxP** (cGMP, cGCP, cGLP) Compliance.

**Programming:** C# 4.0, Java, .Net 4.0, Web Services (REST, WSDL), Apache Suite, CSS, ExtJs, Macros, MS Studio 2016, MVC Framework 4.0

**Databases:** SQL PLUS, TOAD, Teradata, MYSQL, SQL Server 2012/16 (SSAS, SSIS, SSRS), **Oracle 10g and 11g**, **PL/SQL Developer**, T-SQL, PL/SQL (Stored Procedure & Packages), **Data Warehousing & Optimization**, **ETL** Data transformation and management, **Query** tuning and optimization.

**Big Data Systems:** Hadoop, HIVE, Datameer

**Reporting/Analytical Tools:** Tableau, Microsoft **Jet 4.0,** Discoverant, SSRS, Base SAS software suite, BI suite, Cognos, QlikView, Crystal Report, Pivot tables, Power BI, Informatica.

**Project Management/BA Tools:** RAPID & JAD sessions, MS Project, MS Office Package, MS Test Manager, Client Vantage, Gantt Chart for Project, SharePoint, Trackwise, JIRA, RequisitePro, DOORS.

**IT Enterprise Resource Planning (ERP): -**

**SAP –** Manufacturing (**MM**), Project Planning (**PP**), Supply Chain Management (**SCM**), Warehouse Management (**WM**), Finance & Quality Management (**QM)** modules.

**Oracle (ERP Suite)** – Agile **PLM** 9.3.5, JDE Enterprise One 9.2, EBS Supply Chain Management (**SCM**) & Quality Management (**QM**), Contract management, Pricing, Rebate processing, Chargeback Processing, Customer Relationship Management (**CRM**), Master Data Management (**MDM**), R12 Financial Application (Oracle Modules: - Purchasing, **AR, AP, GL**)

**EXPERIENCE**

March 2019 to ERP CLOUD TECHNOLOGIES INC, Client: **Baxter Pharmaceuticals, Deerfield, IL**

Present

Project Details: - 1. Gather requirements, perform System Design and build out the testing strategy

for implementing Global ERP Platform for Riversand Product Information

Management (PIM) system.

2. Perform data analytics, trending, demand forecasting and lay-out

Optimization strategies by identifying KPIs (**Key Performance Indicators**)

used by executives showcasing Data Analytics, business trend charts,

Demand v/s Supply analysis, Cost trending, ROI Analysis, at an organization

level.

3. Created and Performed Data Models and Data Integrations between multiple

ERP Systems like PIM, Oracle EBS and JD Edwards with Laboratory Testing

Systems like BaxLIMS (LabWare LIMS v5/v6), ELN and CDS Empower 3.

4. Created, Updated and Validated the SQL, ETL scripts, Data Model, data &

field mapping spec design and documentation, workflows design and

integration etc.

*Role: -* ***SR BUSINESS SYSTEMS ANALYST/SR DATA ANALYST***

Technology: - ServiceNow, BMC Remedy, RequisitePro, DOORS, JIRA, Oracle JD Edwards (SCM, Finance, WM), Siebel CRM, SAP ECC 6.0 (MM and QM), HP ALM, Tableau, Informatica PowerCenter 8.6

Responsibilities: -

* Gather complex requirements, rules/validation criteria and functionalities required from Business Organization to translate complex requirements in IT terminology and workflow to the IT implementation /Delivery team.
* Review assigned business processes from end-to-end to identify and address operational, financial, technological risks and improve efficiency by developing Scientific and Mathematical models like **Use Case**, Activity, Sequence, Process Flow, and Entity Relationship (**ER**) Diagrams, Pie Charts (Decision Making and Making Predictions).
* Gather Business Requirements using Agile methodology by conducting brainstorming sessions, **Master Scrum, User Stories** documentation and JAD approach with the cross-functional teams to finalize the requirements and scope of the projects by using Rational RequisitePro, DOORS and JIRA tools and creating/updating the deliverables like URS, FRS,

Test Plan and Test Cases.

* Plan and update the System Design & Architecture by performing Data Analysis, Data Integrations & Migrations by performing Data Modeling, mapping, integrating multiple DBs by following **Global IT Data Governance model**.
* Acted as liaison between Global Development/Testing team, QA/QC, RA teams and business development group and owners in Belgium by participating in **Sprint Planning, Daily Scrums, testing, retrospectives and Sprint Reviews**.
* Perform Data Analytics, business trend charting, Demand forecasting and Process Optimization by using **Tableau, Informatica Power Center 9.0**. Worked and actively engaged with Operational Enterprise **Risk** Manager (RM) & **Performance Improvement** (PI) to review compliance with firm’s IT policies and procedures around Product Planning, Finance, Development and Release and methodologies for calculating Key Performance Indicators (**KPI**) and Key Risk Indicators (**KRI**). Mitigate the security risk by implementing **Compliance Metric Reporting (CMR)**.
* Performed Global Rollout, Global Data migration, implementation, Development, Conversion, Upgrade, Enhancement, Interface Integration and Data migration Strategy and Support roles for of **Oracle EBS**.
* Configured the Financial Modules like Account Receivable AR, General Ledger GL, Account Payables AP, Cash Management CM, I-Expenses, I-Procurement, Project Accounting PA, Oracle Trade Management OTM and **Oracle Financial R12 e-business suite (EBS) modules** as per the business requirements and QA guidelines. Also, created the test plans and test cases for performing Unit Testing, integration system testing, and user acceptance testing in HP ALM.
* Worked on Configuration, Updates, Creating new functionalities/features for ERP Systems like **Oracle E-Business Suite** R12 Order Management, Pricing modules,Customer Information.
* Involved in planning and delivering GL, and Phase I Reporting module which includes defining calendar, defining security rules, account aliases , roll-up group, journal sources, journal categories and used ADI (general ledger desktop integrator) to integrate the GL module to the excel sheet, designing and developing FSG reports such as Balance Sheet, P& L Accounts and other management reports.
* Interacted with end users and functional architects for mapping the legacy data to the Oracle tables. Created **MD050 (Functional design documents)** specification for Reports. Created **MD070 (Technical design document)** for all enhancement requirements.
* Defined the Setup per the business requirements and Validation Criteria for the Profile Class, Dunning letters, Collectors, Customers, Auto Accounting, Transaction Types, Transaction Sources, Payment methods, Receipt classes, Receipt sources, Payment Terms, Receivable Activities in **Account Receivables**.
* Defined the Setup per the business requirements and Validation Criteria for Payment Options, Payment terms, Distribution Set, Payment Format, Internal Banks, Recurring Invoices, Prepayments, Expense Report Templates, Interest on Invoice report, Matching options, Adjustment of Prepayments in **Account Payables**.
* Created **Data Models/Mappings** and performed **System Integration** between multiple ERP Systems like PIM, Oracle EBS and JD Edwards 9.2 with Laboratory Testing Systems like BaxLIMS (**LabWare LIMS** v5/v6), ELN and CDS Empower 3 for integrating and data flow related to Products/Items, Product Hierarchy, Cost, testing results etc.
* Create business requirements and Test Plans for integrating the new business units with the existing system without any issues for **Oracle JD Enterprise One 9.2** and perform the below activities –Update Package Builds, Full Package Builds (Need based), Trouble Shooting, User Profile Management, Security and Server maintenance and Performance Optimization.
* Create, Update and Execute the **Test Plans & Test Cases** for Unit Testing, UAT, Regression Testing, System Integration Testing (SIT), Stress Testing, Performance Testing, Load Balancing testing (for servers), Validation Protocol Testing (V-model), Acceptance Criteria testing etc. for Oracle JDE, SAP & LIMS using HP ALM, Test Manager, Selenium (for functional testing), HP LoadRunner (for Load and Performance Testing) and JIRA
* Perform Gap Analysis, field mapping, data mapping, interface mappings, mapping and updating the Workflows in Oracle EBS and JD Enterprise One 8.10 for integrating, migration or retiring the JDE modules for consistent data transfer.
* Code and update the **SQL, T-SQL** queries, joints, tables and View, Stored Procedure, Functions and Triggers in PL/SQL and SQL Server 2014. Integrate the SQL and PL/SQL queries and Store Procedures with Oracle JDE application, LIMS system and Web Services

for performing updates and creating the SSRS, Crystal Reports & QlikView reporting as per the business requirements.

* Conduct weekly discussions with Stakeholders, Business & QA groups to analyze the complex business scenarios, critical requirements and priorities and perform complex problem solving by evaluating the pros and cons for the proposed resolution and action items by using tools like Rational RequisitePro and MS Visio.
* Create IDP Plan & Summary Report, Design History File (DHF) using Continuous Deployment tool JENKINS. Create and update the IT Systems documentation for the complicated QA/QC processes listed below using TrackWise 7.0, Veeva Vault Quality Docs and LMS ComplianceWire 3.0., CAPA Documentation & Reporting, Failure Mode Effect Analysis Process Expertise & Documentation (FMEA), Corrective Action (CA) and Incident/Exception Report (I/E R).

January 2018 to KFORCE, Client: **US BANK**

February 2019

Project Details: - 1. Gather requirements and build out the testing strategy of Oracle EBS, Eagle

Financial Investment Systems.

2. Perform the Data Integration and Migration activities for moving data from

Siebel CRM and EFIS to Oracle EBS.

3. Created, Updated and Validated the ETL scripts, mappings, workflows etc.

4. Perform the Data Analytics by using Informatica PowerCenter 8.6, Big Data

Systems like Hadoop and HIVE for Bonds and Mutual Funds market trend.

*Role: -* ***SR BUSINESS SYSTEMS ANALYST/SR DATA ANALYST***

Technology: - RequisitePro, DOORS, JIRA, Oracle EBS, Siebel CRM, Eagle Financial Investment Systems (EFIS), HP ALM, Informatica PowerCenter 8.6

Responsibilities: -

 Managed & Delivered multiple automation projects as Senior Business Systems Analyst by prioritizing critical project tasks, resource allocations, priorities, and ensuring quality project delivery within budget.

 Performed **Requirement gathering** and analysis by following ***Agile/SCRUM technique***, thereby creating requirement phase documents like FRS, URS etc. Led and achieved the results of transforming the business requirements to IT systems design requirements/design for Global IT, Quality, Fund Services in ERP Systems like Eagle Investment Systems, SAP Financials etc.

Acted as a **Liaison** for Business, Clients, Vendors and Quality Assurance (QA) cross-functional teams.

 Created manual and **Automated Test Plans**, Test Cases in HP ALM for Unit tests, UAT, SIT, Performance testing, Acceptance Criteria testing and boundary value testing to ensure the data safety and integrity.

* Configured and Updated the STAR and PACE modules for EAGLE FINANCIAL SYSTEM banking application to process the transactional and non-transactional data for the FUND SERVICES, BONDS etc. Also, implemented the **DATA SAFETY** validations and notifications in case of any failures and to ensure the compliance with the guidelines of the FEDERAL BANKING LAW and Quality Assurance (QA) protocols.
* **Executed** the **Project Plannin**g, Development and Testing timelines for the complex and single/multi-stage project implementation. Conducting **weekly and monthly presentation**s with **Senior and Executive management** to demonstrate the project progress and up-coming major milestones.
* Experienced working for **Oracle E-Business Suite/Oracle Applications**11i/R12 with core expertise on GAP Analysis, Process Mapping, Defining Business Requirements,
* Member of Quality IT ERP Systems - ***Change Control Board (CCB)***. Ensured the **Oracle EBS** and **SAP QM** System configuration & design are in conformity with **QA/QC data compliance** (established procedure for data storage, back-up, and system/data disaster recovery). Worked with internal and external auditors for **Oracle System audits**.
* Performed **Requirements gathering** for **Business Rules/Criteria** and Worked on **11i to OLFM R12 upgrade project**, involving moving the finance modules - GL, AP, AR and FA to R12 version, which included data extraction, conversion and interfacing and validation of trial balances on these modules.
* Created and maintained **BR-100** for above modules and making relevant changes to the same based on changing business requirements, post setup and validation in R12 instance.
* Worked in R12 implementation project (AP, AR, GL and Cash Management) - Responsible for requirement gathering, Fit-Gap Analysis, design of MD-50 for interfaces (AP/AR invoice, Customer/Supplier Interface) and **integrating and migrating legacy data from Info Lease to OLFM r12.**
* Developed and maintained **ETL** (Data Extraction, Transformation and Loading) mappings using Informatica Designer 9.0 to extract the data from multiple source systems that comprise

databases like Oracle 10g, SQL Server 7.2, flat files to the Staging area, EDW and then to the Data Marts using lookups, Source Qualifier, Router, Filter, Expression, Aggregator, Joiner,

Normalizer, Sequence Generator, Update Strategy from varied transformation logics in Informatica.

* Worked on ***Integration and Data Migration*** of **Oracle E-Business Suite R12** modules with **Siebel CRM** and other financial application like **Eagle Fund Investment Service.** Performed Gap Analysis, field mapping, data mapping, resolved data inconsistencies and duplication.
* Extensive work experience in **SQL and PL/SQL** in Oracle by writing Packages, Stored Procedures, Cursors, Functions, Views, Database Triggers, User-Defined Types, Dynamic SQL, Bulk binding techniques using Rapid SQL and SQL Server Management Studio.
* Constructed and implemented multiple-table links requiring complex join statements, including **Outer-Joins**and**Self-Joins** and database design and development including **Tables, Primary and Foreign Keys, Indexes** and**Stored Procedures**.
* Used principles of Normalization to improve the performance. Involved in **ETL** code using **PL/SQL** in order to meet requirements for Extract, transformation, cleansing and loading of data from source to target **data structures.**

June 2017 to KFORCE, Client: **MILWAUKEE TOOLS INC.**

December 2017

Project Details: - 1. Gather requirements and perform testing for periodic updates to the business

logic/design of **LIMS** and **SAP** (MM, WM and QM modules).

2. Perform the **Data Integration and Migration** activities for **LIMS** and

**SAP ECC R/3** (WM and QM modules). Performed Script Validations,

Business logic Validations, QA documentations and assisted in developing

the Risk Mitigation Plan.

*Role: -* ***SR. LIMS BUSINESS SYSTEMS ANALYST/SR. VALIDATION ENGINEER***

Technology: - LIMS, LabVantage 6, RequisitePro, DOORS, JIRA, Oracle EBS, SAP (MM,

WM and QM modules), HP ALM.

* **Leaded and Achieved** the results of **transforming the business requirements to IT systems requirements/design** for ERP & Lab Operations Systems like – SAP (MM, WM, QM), Oracle CRM, LabWare **LIMS**, CDS etc. using **Agile methodology** by conducting multiple workshops, **SCRUM** master approach, **brain storming** sessions and discussions (**RAPID**, **JAD sessions**) with the cross-functional teams –

**Tools Used: -** RequisitePro, DOORS, JIRA etc.

**Cross-Functional Teams (Lab Operations, R&D, Manufacturing)**: - Business Operations & Stakeholders, Senior & Principal Engineers, Sr. Chemist, R&D Scientist, Laboratory Managers, End Users Community, Product Development & Management, Supply Chain Management (SCM) team, Logistics, Legal & Compliance, Quality Assurance/Control (QA/QC), Regulatory Affairs (RA), 3rd party Vendors, Contractors, IT Infrastructure & Architecture, Global IT Data Back-up & Disaster Recovery team, Subject Matter Experts (**SME**), Auditors.

* Leaded & Managed the successful **SDLC/Agile Project deliverables** for highly complicated and integrated ERP applications like – SAP (MM, WM, QM) and **LabWare LIMS Systems** –
  + User Requirement Specification (**URS**), Functional Requirement Specification (**FRS**), System Design Document (**SDD**), Project Plan (**PP**), Test Plan & Test Cases (HP ALM), Validation Protocol Testing (**V-model**), Incident & Exception (**I/ER**) Reports, Traceability Matrix ™, Validation Summary Report, Implementation & Deployment Plan (**IDP**)
* Leaded and Managed **following multi-platform and integration applications** testing’s **for LabWare LIMS, CDS and ERP Systems like** – **SAP** (MM, WM, QM), **Oracle** for the accuracy and performance of the **applications, JAVA Web Services and server configuration**.
  + Unit Testing (**UT**), User Acceptance Testing (**UAT**), System Integration Testing (**SIT**), Acceptance Criteria Testing (**AT**), Performance Testing, Regression Testing, Server Load Balancer Testing (**L/BR**), **V-model** (Validation Protocol Testing, Validation Summary Report), Automated (**HP ALM, Rationale Rose Suite**) & Manual Testing.
* **Integrated** the **LIMS and SAP ECC 6.0 WM and QM modules** creating an interface for sending the Laboratory Sample Testing Results from the LIMS System to SAP – QM and WM, so that the “***Quality Decision***” to determine release of lot/batch in SAP QM could be made.
* Analyze, create and maintain **Enterprise LIMS Master Data** (EMD) supporting quote to cash process. Communicate with internal & external customers to address issues and provide support on data quality and integrity improvements.
* Configured & Implemented the **Templates** like Job, Sample, Tests and Results **Templates**, **Specifications, Components, Units,** **Lab Station Configurations**, **Equipment Calibration functionalities** for the **LIMS & Sample Manager systems** across various testing laboratories. Validated custom configurations including **database tables** and **reports**, **labeling** and **bar-code systems** and instrument interfaces with **LabWare LIMS V5 & V6**.
* Implemented the Complex Requirements for multiple platforms, O/S, applications by performing analysis of systems requirements, configurations of **Specifications**, Validation Criteria’s, designing, coding, testing, debugging and documenting the LabWare LIMS templates, modules, Lab Stations, Equipment, labels etc.
* Maintained **24X7 “Un-Interrupted”** Laboratory Testing Schedule, by scheduling **Equipment/Instrument** maintenance/calibration schedule in LIMS & CDS Systems. Resolved the conflict by creating and updating procedures and documentation by working with SMEs, Lab Managers and Senior Engineers etc.
* Designed & Developed software applications with**Microsoft .NET Framework 3.0/3.5/4.0 using C#, MVC Framework 4.0 ASP.NET and ADO.Net**. Developed several **REST web services** supporting both XML and JSON to perform demand-response management task. REST web services leveraged by both web and mobile applications.
* Created and Executed **Validation Documentation** (Requirements; Design Specifications; Risk Assessment; IQ, OQ, PQ; RTM; and Reports) for application upgrades, Databases and Data Warehouses.
* Worked and Co-ordinated with **Quality Assurance (QA)** for creating the **Traceability Matrix** ™, **CAPA**, **FMEA**, Incident Reports, **Risk Mitigation Plan (RMP)**, Conditional Production Release docs, **Validation Documentation** (Requirements; Design Specifications; Risk Assessment; IQ, OQ, PQ; RTM; and Reports) for the **Oracle EBS, SAP modules (WM and QM)** and ***Lab Systems like LIMS, Empower 3, ELN* for Continuous Improvement (CI)** process andto ensure the safety, traceability and recovery of critical data by calculating Key Performance Indicators (**KPI**) and Key Risk Indicators (**KRI**). Mitigate the security risk by implementing **Compliance Metric Reporting (CMR)**.
* Leaded and Worked with the **business & IT cross functional teams** like -- Laboratory Quality Assurance (QA), Software Quality Assurance (SQA), legal, Audit & Compliance IT security for testing and documenting IT security control and compliance requirements as per **HITRUST and HIPAA** across **IT Change Management**, Operations, and application development.
* Experience with SQL-LIMS, Oracle 10g/11g, SQL Server, MySQL, PL/SQL, RDMS, Normalization and T-SQL in constructing Triggers, Tables, implementing **Packages**, **Stored Procedures**, Functions, Views, User Profiles, Data Dictionaries and Data Integrity.

May 2016 to KFORCE, **SHIRE/BAXALTA PHARMACEUTICAL INC**

May 2017 ***SENIOR LIMS & CDS BUSINESS SYSTEMS ANALYST/SR VALIDATION ENGINEER***

 Conducted Requirements Analysis, System Designing, Test Plans, test cases, gap analysis, data analysis, data mapping, data compliance, data back-up, disaster recovery for SAP - Product Planning (PP), Quality Management (QM), Warehouse Management (WM), Human Capital Management (HCM), Oracle Suite, Laboratory Operation Systems (like Thermo Scientific **Sample Manager** **11**, LabWare **LIMS v5/v6** & CDS Systems **Empower 3, ELN, SDMS)** to construct system best suited for company needs in compliance with the Quality Assurance/Center.

* Integrated the **LIMS and SAP ECC 6.0 WM and QM modules** creating an interface for sending the Laboratory Sample Testing Results from the LIMS System to SAP – QM and WM, so that the “***Quality Decision***” to determine release of lot/batch in SAP QM could be made.
* Worked with R&D, QA/QC SMEs & Senior Scientists to analyze and extract the **Clinical data** by performing **data mining & analysis** for report development and presentations, evaluating healthcare cost effectiveness, system impact and other related purposes by using the Data Analytical & Visualization Tool like **Tableau**.
* Configured & Implemented the **Templates** like Job, Sample, Tests and Results Templates, Specifications, Components, Units, Lab Station Configurations, Equipment Calibration functionalities for the LIMS & Sample Manager systems across various testing laboratories. Validated custom configurations including database tables and reports, labeling and bar-code systems and **Lab Instrument**s interfaces with **LabWare LIMS V5 & V6**.
* Maintained **24X7 “Un-Interrupted” Laboratory Testing Schedule**, by scheduling **Equipment/Instrument maintenance/calibration schedule** in LIMS & CDS Systems. Resolved the conflict by creating and updating procedures and documentation by working with SMEs, Lab Managers and Senior Engineers etc.
* **Waters Empower Chromatography Integration** with **LabVantage**, allowing bidirectional data transfer with Analytical Quality Control module and Chromatography results.
* Involved in preparation of Operational Qualification (OQ) test scripts as part of OQ test cycle to ensure that the system is compliant with 21 CFR Part 11 and GMP regulations. Conducted routing Internal inspections of regulated systems (GMP, GCP, GLP) to assure validation procedures have been followed in compliance with company, divisional and departmental policies and predicated rules.
* Led & Managed New Product Development and Analysis for **pharmaceutical drugs**, Class I, II and III medical devices by performing -- Risk Management (RM), **failure mode and effects analysis** (FMEA), essential requirements checklist, reviewing **Design History File** (DHF), **Design verification / validation** (Design V&V), Compliance and Acceptance Criteria Testing, for compliance to quality requirements.

 Performed tasks like - **gap analysis, data analysis, data tuning, data mapping, data compliance, data back-up, disaster recovery plan** on Sample Manager (LIMS), CDS Systems and **SAP-LIMS Integration** to continuously monitor the data security and performance.

 Fast phased the project by authoring **LIMS & ELN** templates by participating in specification setting meetings, reviewing stability protocols, providing method validation instructions, review and approval of ELN methods, functions etc. and integration Lab Instruments like HPLC, FTIR, UV-VIS, Spectrometer etc.

April 2013 to **AbbVie Inc**

April 2016 *SR. BUSINESS SYSTEMS ANALYST)/SR. LIMS DEVELOPER (QUALTIY IT LAB OPERATIONS)*

 Worked on gathering, analyzing and managing the requirements for complex **Analytical Process and Reporting**. Translated the Clinical Analytical concepts to IT systems & data mapping by serving as **liaison** between IT, Business, Vendors and Customers for implementing enterprise level Clinical data analytics and visualization reporting project.

 Worked on Abbott/AbbVie "Transition Service Agreement (TSA)" to move and archive the Lab, Quality and Manufacturing data from legacy Abbott systems like **Sample Manager** **2004 R2**, POMS, Soltraq to new and upgraded AbbVie IT **Sample Manager** **11** Databases and applications.

* Integrated the **LIMS and SAP ECC 6.0 WM and QM modules** using ***SM-IDI*** creating an interface for sending the Laboratory Sample Testing Results from the LIMS System to SAP – QM and WM, so that the “***Quality Decision***” to determine release of lot/batch in SAP QM could be made and validate the transactions and modules to be complaint with **21 CFR Part 11 and GMP** regulations. Prepared Test Summary Reports and **Validation Summary Report** (VSR) to summarize all the activities performed during system validation.
* Created, Updated and Implemented the **Business Rules**, Lab and Manufacturing Process **Workflows**, **notifications**, **Specification Validations**, Automated **Triggers**, Customized Coding **Integration** with PL/SQL Stored Procedures and Packages etc. for Sample Manager (LIMS System).

 Leaded & Accomplished the Configuration and development of the Laboratory Information Management System (LIMS V5/V6), **Thermo-Fisher Sample Manager 2004 R2, Sample Manger 11**, Electronic Laboratory Notebook (ELN) Quality Operations Laboratory IT applications/systems which is used for pharmaceutical drugs testing during the Manufacturing stages and R&D to ensure the compliance of drugs as per the standard and norms prescribed by FDA and EU Annex 11, contributing contributes towards company's vision of being paperless and accurate in data mining and documentation that can be viewed consistent across the company and presented to the Auditors and FDA officials.

 Leaded, Implemented & Accomplished the architecture, configuration and implementation of Scientific Data Management System (SDMS) NuGenesis for the Lab instruments data archiving to fulfill and comply with the Laboratory/Quality Data Integrity requirements for **FDA 21CFR Part11 and EU Annex 11 Compliance**.

 Leaded and Assisted the business cross functional teams like R&D, Manufacturing, Laboratory Operations, Architecture, Laboratory Quality Assurance (QA), Software Quality Assurance (SQA), legal, Audit & Compliance etc. to create a streamline process for Laboratory testing like **Raw Material** testing, **Good Receipt** testing, In-Process testing, Finished Good testing, Release testing and Stability testing of the pharmaceutical drugs during manufacturing life cycle.

* Investigated, created, and developed new methods and technologies to improve effectiveness of development workflows by following **Activity Diagram**, **ER relationship model** for creating robust products and improve process performance. Establishes and manages QC metric, data trending, and drives actions for improvement.

February 2008 to **Underwriters Laboratories, Inc**

May 2013 *SR. APPLICATION SYSTEMS ANALYST/BUSINESS SYSTEMS ANALYST*

LIMS (v5/v6) ADMINISTRATOR SPECIALIST (Concurrent Position)

 Interviewed senior engineers and stakeholders for **gathering project requirements** to support and update the complex business processes. Analyzed and provided technical support and development of new features and functionality. Configured laboratory information management system (LIMS), external components, and services for data transfer between source system and J2EE Server.

 Reviewed and provided recommendations and feedback for the increasing efficiency and accuracy for the existing business process requirements and connected process flows between custom applications and components. Acted as a **Liaison** for Business, Clients, Vendors and Quality Assurance (QA) cross-functional teams.

 Created and Updated the **System Design Document** (SDD) for the required technical updates which needs to be fulfilled to comply and implement the approved functional requirements (FRS) of the project.

 Performed Field Mapping, Data Mapping, Gap Analysis, Data Specification configuration, Data Optimization and tuning for efficient data flow between the Front-End application and the Databases.

 Created test plans and test cases for Unit Testing, UAT, SIT, Performance Testing for applications, and designed SharePoint applications.

 Generated interface between custom and legacy application, maintained PL and SQL scripts, and ensured proper data loading and extraction from application systems, servers, and NAS Storage.

 Conducted bi-weekly and monthly presentation to direct manager and cross-functional team leaders to demonstrate the weekly progress of the projects, next steps and discuss any roadblocks or risks. Identified, documented, and provided Process Improvement recommendations to managers.

 Designed/developed automation applications; increased efficiency by 90%+. **Earned Mark of Excellence award.**

 Configured LAB Instrument Specifications in IT applications, performing Validation & Documentations.

2005 to **IBM**

2006 *PROGRAMMER, SERVICE ENGINEER*

 Built web services, developed data model and security model, and created deployment packages for applications.

 Developed web-enable ordering and receiving Electronic Data Interchange (EDI) system.