* 6 years of experience in software Validation, Technical Documentation, Quality Assurance as a Validation Engineer and Quality Analyst.
* In depth knowledge of SDLC- Software Development Life Cycle and various methodology such as Agile, Waterfall model, V model.
* Well versed with all stages of validation and testing of application
* Hand on experience of 508 – compliance & Regulation.
* Strong experience with development and reviewing of Validation Deliverable such as Validation Master Plan, Requirement Traceability Matrix, Validation Protocols (IQ, OQ, PQ), Validation Summary Report.
* Abundant experience in generating and reviewing Computer Systems Validations (CSV) Deliverables according to 21 CFR Part 11 and FDA regulations for the Pharmaceutical industries
* Extensive knowledge and experience in validating computer systems following Software Development Life Cycle (**SDLC**) as per FDA regulations and **cGXP (GLP/GCP/GMP)** guidelines.
* Strong expertise in FDA regulations, GxP suites **(GAMP4 & GAMP5, GDP),** Computer System **(CSV)** & Equipment Validation, Documentum, **LIMS** and Trackwise.
* Strong knowledge and experience in developing **Validation Mater Plan (VM P), Requirements (URS/FRS), Qualification Documents (IQ, OQ & PQ), Validation Summary Report (VSR) and Requirements Traceability Matrix (RTM).**
* Knowledge and competent in Quality system and standard (cGLPs, cGCPs and cGMPs), 21 CFR Part (11, 210, 211, 820), Gap Analysis and Remediation Plans.
* Performed system compliance assessments, procedural and technical gap identification and **remediation planning** for pharmaceutical analytical research and development laboratories.
* Experience in authoring and reviewing **Qualification documents (IQ, OQ & PQ),** Standard Operating Procedures (SOPs) to be compliant as per FDA Regulations. Experience in Defect tracking from Test protocol using ALM – defect module.
* Strong experience of Database Testing using various joins in SQL Queries.
* Thorough knowledge of various phases of Validation Life Cycle.
* Expertise in System testing, Integration Testing, smoke testing and Regression Testing.
* Capable to work independent as well as team player.

**Test Management Tools** JIRA 6.4, HP ALM 11.0, HP Quality Center 8.2/9.2, Version one

**Automation Test Tools**  HP Quick Testing Pro 9.2/ 11, UFT 12.5, Selenium IDE 2.27

**Graphical User Interface** MS window , Visual Basic

**Defect Tracking tool** JIRA 6.4, ALM 11.0

**Web Technology** HTML, .NET, beyond Compare 4.0

**508 compliance tool**  Dragon, Jaw, Magic, NVDA

**Web Service tool** SOAP UI

**Terumo Cardiovascular, Ann arbor, MI July 2016– Till Date                        
Role: Validation Engineer / QA Tester  
Project Description:  
·**Validation of the CTspace Electronic Data Management System (EDMS) platform to manage documents from     
·                Analytical, manufacturing and drug safety department to comply with FDA 21 CFR Part 11 Guidelines.

**Environment: FDA, GMP, cGMP, 21 CFR Part 11, IQ, OQ, PQ, Manual Test Script**

**Responsibilities:**

* Detail gap analysis of requirement and verification of scoping for case request IPT.
* Creation of functional test case, End-to-End test case, and smoke test on development build based on specification as part of Agile Team.
* Experience with leading short team 3-4 member for Test Execution and Defect reporting
* Execution of Test protocols using test automation tool HP ALM
* Creation of issues and tracking status using JIRA.
* Assessed **21 CFR Part 11** requirements for Electronic Records and Electronic Signatures to access data security issues like authorization and login.
* Updated of Defect and Test Case Status execution in Version 1 tool at the end of each sprint.
* Performed 508 –federal regulation compliance verification using MAGIC, JAWS tool.
* Created 508 test cases and execution as per guideline for 508 compliances – Dragon
* Smoke test execution on Development build and reporting build verification status.
* Performed functional test for NVF interaction with DCPS using SOAP UI.
* Database Record retrieval and verification as per UI information by creating & executing SQL query.
* Updating data table and deleting duplicate record using Delete/Update –SQL query.
* Test data –risk assessment and manipulation as per request from Validation team using execution script.
* Assistance to development team for re-verification of scenario in pre-development environment.
* Creation SIT scenario as per system requirement for Task Request module.

**AstraZeneca Hamilton, OH July 2014 – June 2016**

**Role: Sr. Validation Analyst**

**Environment: GMP/GLP, Traceability Matrix, URS, FRS, 21 CFR Part11**

**Responsibilities:**

* Developing and implementing validation protocols and documents for system specifications, vendor recommendations and client requirements in GMP/GLP environment
* Writing functional requirements, traceability matrix, test case objectives and test cases for each version of Simple Forms to ensure that all the requirements are covered by the test cases
* Reviewing and Understanding User Requirements and Functional Requirements
* Reviewing, recommending, and implementing process improvement techniques to increase test quality and improve test productivity.
* Developing Standard Operating Procedures that support Computer Systems Validation
* Introducing test scripts, testing methodologies and user manuals for Adverse Event Reporting System to ensure compliance in accordance with 21 CFR Part 11
* Interacting with production team and R&D to resolve the issues during product development so as to meet the client’s requirement for a better quality product.
* Designing and developing validation protocols to ensure product developed as intended and according to design
* Taking responsibilities for Validating the control of report laboratory information.

**Bayer Pharmaceuticals, West Haven, CT Nov 2012 – June 2014**

**Role: Validation Analyst**

**Environment: SLC, IQ, OQ, PQ, FDA Regulations, 21 CFR Part 11, SOP, Risk Assessment, GDP**

**Responsibilities:**

* Coordinating validation activities in support of assigned validation projects
* Maintaining procedures to regulate change implementation and Change Control Procedures to ensure system compliance through its life cycle
* Responsible for writing and executing Installation qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) protocols to check installation and successful operation of the application.
* Provided validation support for reviewing and designing of new systems and modifications to existing systems to ensure designs comply with current validation standards and are able to be adequately validated and maintained within validated control
* Writing documentation for validation in accordance with FDA regulation particularly 21 CFR part11 validation plan and protocol.
* Reviewing, revising and implementing Standard Operating Procedures as per the new user requirement specification and functional requirement specifications.
* Executing and leading risk assessments activities for high-risk materials in support of validation activities
* Supporting Regulatory inspections, internal and partner audits, and implement corrective actions as needed. Providing computer system validation related responses to inspectors/auditors.
* Involved in developing the Validation Plans for the applications.

**Lexicon Pharmaceuticals, Inc. - The Woodlands, TX Oct 2010 – Nov 2012**

**Role: Validation Analyst**

**Environment: FDA, GMP, cGMP, 21 CFR Part 11, IQ, OQ, PQ, Manual Test Script**

**Responsibilities:**

* Involving in writing IQ/OQ Test Plan, Scripts & Summary Report for Test as well as in Production environments
* Performing the validation of LIMS for 21CFR part11 compliance by reviewing IQ, OQ, and End to End testing scripts
* Good Knowledge in writing and reviewing Computer System Validation Plan/Remediation.
* Performing Functionality, System testing and regression testing according to the SOPs and departmental guidelines.
* Ensuring computer systems validation meet internal and external regulatory requirements such as FDA, GMP, cGMP, etc
* Developing and implementing validation Strategy and Approach to document validation plans
* Reviewing and approving written and manually executed test scripts to support technical projects, regulatory submissions and coordinate the validation activities to meet critical project deadlines and and/or launch dates.