**NALINI**

nalini.information@gmail.com

(302) 438 9704

**SUMMARY**

* Over 6 years of Experience as Validation Analyst/ Technical Writer in Validating and maintaining Computer systems, laboratory instruments as per the GxP’s (GMP, GCP, GLP) Rules, 21 CFR Part 11 requirements and worked as Quality Analyst in Health Care Industry
* In depth knowledge of FDA regulations 21 CFR Part 11,50,56,58, 210,211 and participation in implementation of CFR part 11 regulations like Electronic Records, Electronic Signatures and Audit Trails.
* Excellent understanding of Software Development Lifecycles **(SDLC)** and Computer System Validation **(CSV)** lifecycle.
* Experience in reviewing IT project methodologies such as waterfall, agile and V Model.
* Expertise in creating Business process flow Diagrams by using MS Visio
* Proficient in dealing with Laboratory Information Management System**(LIMS)**, Enterprise Document Management System **(EDMS)**, Adverse event reporting system**( AERS),** Change Control Management System.
* Extensive working experience with Track wise.
* Experience in reviewing Validation Master Plan **(VMP)**.
* Proficient in reviewing, approving and Documenting User Requirements Specifications **(URS)**, Functional Requirements Specification **(FRS)**, Design Specification **(DS)**.
* Expertise in preparing all Protocols of Installation Qualification **(IQ)**, Operational Qualification **(OQ)**, Performance Qualification **(PQ)** and Validation Summary Report **(VSR).**
* Experience in Reviewing Deliverables.
* Experience in developing Standard Operating Procedures **(SOP’s),** policies and working instructions to comply with FDA regulations
* Experience in reviewing Corrective and Preventive Actions **(CAPA)** and emphasizing and suggesting the remediation plans to mitigate the non-compliance.
* Executed the workflows for different CAPAs such as Low, Medium and High risks
* Experience in performing GAP Analysis, Risk Analysis and Preparing Remediation plan.
* Expertise in preparing Data Migration Plan.
* Expertise in preparing test plans, defining test cases, developing test scripts, resolving bugs.
* Proficient in various types of testing: End-to-End testing, Performance testing and Positive testing, Negative testing, User Acceptance Testing, Load / stress testing and Unit testing using manual and automated tools.
* Strong Experience in preparing and reviewing Requirement Traceability Matrix (RTM)
* Practical knowledge working with laboratory analytical instruments including Gas Chromatograph, Mass Spectroscopy, Micro Plates.
* Good knowledge on database languages like SQL and VB Script.
* Excellent problem solving skills, quick learner and capability to perform well under pressure.
* Possess excellent documentation skills with good structured writing.

**Technical Skills:**

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| Regulations | FDA Quality System Regulation, 21 CFR Part(11,210,211,820), cGxP (cGMP, cGCP, cGLP) SOPs, LIMS, AERS, |
| Validation Deliverables | Validation master plan (VMP) , Validation test plan, URS, FRS, DS, IQ,OQ,PQ Protocols, Requirement Traceability Matrix (RTM), Validation summary reports, Test summary Report, system release report and Retirement plan. |
| Testing tools | Quality Center, clear Quest, Track wise, Quick Test Professional, Test Director. |
| Operating Systems | Windows 98, Vista, XP |
| Methodologies | Waterfall, Agile, Scrum, V Model |
| Database Languages | SQL, VB script |
| MS Office | Excel, Word, PowerPoint, Visio, Project, Outlook |
| Document Management Systems | SharePoint, Documentum. |

**PROFESSIONAL EXPEREINCE:**

**Abbott Laboratories, North Chicago, IL Apr 12 – Sep 13**

**Sr. Validation Analyst / Technical Writer**

**Project: Laboratory Information Management system.**

Abbott Laboratories is an American global Pharmaceuticals and health care products company. The project was on **LIMS** which is to validate the data collected from various Lab instruments through LIMS Application interface by testing the data and the resultsand Implementation of Plateau Learning Mangement system.

**Responsibilities:**

* Involved in the entire SDLC and ensured that the application is in compliance with 21 CFR part 11, GLP, and internal company quality Regulations.
* Developed Business Process flow for LIMS application using **MS Visio.**
* Responsible in preparing Validation Plan, Test plan, User Requirement Specifications **(URS)**.
* Wrote and reviewed **Operational Qualification (OQ)** and **Performance Qualification (PQ) test scripts** for different modules of **LIMS** based on the **User and Functional Requirement specifications.**
* Developed **Gap Analysis** Mapping with **21 CFR Part 11** Regulations.
* Responsible for performing **Risk Assessment**.
* Developed and updated the **Requirements Traceability Matrix (RTM**) to track requirements during the QA Testing Phase.
* Developed **Test Strategies**.
* Wrote Test Cases.
* Extensively involved in testing phase, which include various testing activities, like **Regression Testing**, **Black box Testing**.
* Logged errors on the **Quality center** and re executed the test cases upon resolution.
* Developed Test summary Report.
* Responsible for validating the reports generated by the LIMS application in compliance with 21 CFR part 11 requirements.
* Attended **weekly status meetings** with **Team lead, Project Manager** and **Subject Matter Experts** to update work progress.
* Defined various scenarios for testing the application to meet the critical requirements.
* Interacted with the **Developers and Subject Matter Experts (SME)** to better understand the workflow and functionalities on different modules.
* Responsible for documentation of all aspects of the SDLC, **Computer System Validation Life Cycle in accordance with 21CFR Part11, GLP and GMP.**
* Responsible for writing **Work Instructions** for **Change control**.
* Interacted with developers to resolve technical issues and investigated the bugs in the application using **Quality center.**

**Blistex, Oak Brook, IL Sept 11 – Apr12**

**Validation Engineer / QA Analyst**

**Project: Enterprise Documents Management System.**

**Blistex** is a small family company in 1947. Its focuses mainly to develop and market lip care products in the United States. The scope of the project is to validate Enterprise Document Management System (EDMS). EDMS was used to support management of Electronic Submissions, validation documents, quality and manufacturing documents.

**Responsibilities:**

* Documented all aspects of computer systems life cycle (SDLC), in accordance with FDA regulations, Particularly 21 CFR Part 11.
* Developed Validation Plan.
* Developed FRS (Functional Requirement Specification) from the URS (User Requirement Specification).
* Responsible for developing **IQ protocols** and **Validation Summary Report**.
* Utilized **Documentum** and created documentation in all phases of the **SDLC**.
* Developed **Risk assessments** and **21 CFR Part 11** assessments.
* Expertise in developing and executing **Installation**, **Operational** and **Performance Qualification** **(IQ, OQ and PQ)** Validation Protocols.
* Created and maintained the **Requirement Traceability Matrix (RTM) for the** application.
* Documented CAPA by using Track wise.
* Responsible for storing and maintaining the documents to comply with **21 CFR Part 11** requirements.
* Responsible for developing the **Data Migration Plan**.
* Involved in creating System operational and Administration SOP’s.
* Involved in Preparing User Guides.
* Performed **Periodic Reviews** on regulated production computer systems
* Developed **test plans, test strategies for validation testing** along with the **Test** **Summary Report.**
* Executed test cases based on the test plan and in accordance with **Good Documentation Practices (GDP)**
* Responsible for performing **User Acceptance Testing (UAT)** for the application.
* Developed procedure manuals and Training manuals.

#### **Roche, Branchburg, NJ Dec 10 – Aug 11**

##### **Validation Engineer / Technical Writer**

**Project: Adverse Event Reporting System.**

The company provides highest quality pharmaceuticals and health care products to enhance human life. The adverse events caused during the clinical trials must be reported and should be in compliance with FDA regulations. **AERS** was used as the solution. The scope of the project is to validate **Adverse Event Reporting System (AERS**).

**Responsibilities:**

* Involved in gathering the **User Requirements** from the **System Owners** document for all the software components.
* Responsible for reviewing Validation Plan.
* Developed FRS (Functional Requirements Specification) and DS (Design Specification) from the URS (User Requirement Specification)
* Responsible for reviewing and documenting **OQ/PQ** protocols and **Validation Summary Report**.
* Actively involved with the application developers in developing the high level **System Design Specifications (SDS) documents.**
* Used Track wise to Automate workflow.
* Used **MS Visio** for pictorial representation of the **Design Specifications** and workflow of the process.
* Involved in documenting **Vendor Assessment Report** from a list of **AERS** suppliers.
* Developed Requirements Traceability Matrix (RTM) to track requirements during the QA Testing Phase.
* Checked the modules of the application and used SQL queries to extract the data from database.
* Involved with the development team to verify bug fixing and update bug report status using **Mercury Quality Center**.
* Responsible for writing **change control** **SOP’s** to comply with 21 CFR Part 11 requirements.
* Developed **test plans, test strategies, test scripts for validation testing.**
* Responsible for developing test protocols for **audit trail, time stamp** and electronic signature for the work flow of documents.
* Prepared training documentation for the various SOP training.
* Involved in writing audit plans for the quality department
* Expertise in audits and assessments on documents and systems.
* Hands on experience in documents review and approvals in QA aspects.
* Successfully coordinated meeting with the users, management and vendors

**Osi Pharmaceuticals, Northbrook, IL May 09 – Oct 10**

**Validation Analyst/ Technical writer**

**Project: Enterprise Document Management System.**

**OSI** is a pharmaceutical company specializes in the discovery and development of molecular target therapies. The project was to validate the manufacturing and electronic submission documents using Enterprise Document Management System (EDMS)

**Responsibilities:**

* Performed Validation based on the Company’s Validation Policy for Computer Systems Validation.
* Participated in all phases of SDLC starting from Validation Plan to Validation Summary Report.
* Prepared and reviewed Requirement Specifications in accordance with 21 CFR Part 11.
* Validated Audit Trail functionality for learning records and courses to facilitate accurate and ready retrieval of documents.
* Developed Test Plans and executed Test scripts, prepared Test Summary Report.
* Prepared and Executed Validation Protocol documents like IQ, OQ, PQ and User Acceptance Test.
* Developed Traceability Matrix to track requirements for the software application module.
* Developed Data Migration Plan.
* Involved in SOP creation and modification effort for Operational Support SOP, Backup and Restore SOP, and System Admin/Support SOP.
* Involved in Meetings with subject matter experts to gain In depth knowledge on Application.
* Revised and verified change control methodologies for system upgrades.
* Involved in document management and project management through Documentum.
* Involved in Documenting Training Materials and User Guides.

**Sri Krishna Pharmaceuticals, Hyderabad, India June 08– Mar 09**

**Validation Analyst/ Technical Writer**

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**Project : Validation of chromatography Equipements like HPLC, GC**

Sri Krishna Pharmaceuticals is one of the leading company in the manufacturing of Paracetamol. It is active in the business of API’s, direct compression granules, drug delivery systems. Worked as a Validation Analyst validating chromatography equipment’s HPLC, GC and preparing validation reports.

**Responsibilities:**

* Validated LIMS applications and customizations, including database tables and reports, labeling and barcode systems, and interfacing with laboratory instruments.
* Documented IQ, OQ and PQ protocols for new laboratory equipment’s.
* Validated networked Chromatography equipment’s such as HPLC, GC.
* Involved in creation of SOP’s for operation of new laboratory equipment’s such as HPLC, GC and Autoclave etc.
* Used Track wise for Bug reporting.
* Prepared SOP’s describing validation policies, change control procedures and system requirements.
* Coordinated with the team members and the scientists for developing the SOPs for the equipment’s
* Developed Validation reports to summarize deviations from requirements, problems discovered and actions to be taken to fix them.

**Darwin Pharma Pvt. Ltd, Vijayawada, India Jan 07- Apr 08**

**Technical Writer/ QA Analyst**

Darwin group of companies Ltd is one of the largest privately held pharmaceutical companies in India. Over the last decades, it has been developing and manufacturing pharmaceutical products and selling and distributing these all over India.

**Project: Change Control Management system**

**Change Control Management System** is an application that provides proactive, automated and integrated approach to infrastructure. All changes to the system must be controlled and documented by a formal change control procedures.

**Responsibilities:**

* Developed User Requirement Specification (URS).
* Helped Sr. Validation Engineer in developing/writing a Validation Plan, SOP’s and Work Instructions.
* Wrote Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) scripts.
* Validated the Change Control Forms for QA and Production moves and ensured the overall risks of all the transports met the Business Criticality.
* Initiated Good Documentation practice guidelines and workflow diagrams for performing Change Control Management.
* Developed Test cases and Executed.
* Performed a role in pre-reviewing and post-reviewing of the scripts both on paper and Quality Center.
* Involved in the executing of test protocol, reviewing and verifying the test results and documenting the deviations found during the execution.
* Verified the Quality Center Defect Reports, Test Problem Reports/Incident Reports, Production Problem Reports and Scope Change Requests.
* Involved in writing the test summary report.
* Gathered Traceability Matrix and performed Gap Analysis in order to meet the User Business Requirements and identified Risk Assessment for all the requirements.
* Worked both independently and cooperatively with other team members to meet deadlines.

**Education:**

Bachelors in Chemical Engineering, Acharya Nagarjuna University, India.