**Kunal Shah**

**848 230 7461**

**analyst.qa215@gmail.com**

**Professional Summary:**

* Quality Analyst/Validation Engineer/LIMS Consultant/ **Computer System Validation** (**CSV**), Technical Writer with Over 6 years of experience in the pharmaceutical and medical device industries with expertise in **Equipment Qualification** and **Quality Assurance** with strict adherence to **GAMP** & **cGMP** regulations.
* 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 (VMP), 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 writing protocols, executing test scripts and constructing Summary Reports for **IQ, OQ and PQ.**
* Experience in **Data Migration, Periodic Review, Change Controls, Change Reporting, GAP Analysis, and Risk analysis**, **CAPA, FMEA** and Remediation Process.
* Expert level experience with Computer System Validation **(CSV)** in developing/reviewing/approving Validation documents, including URS, FRS, Risk Assessments, Design Specifications, Validation Master Plans, Test Protocols **(IQ/OQ/PQ),** Validation Summary Reports, **SOP’s,** and Training Material for variety of laboratory and enterprise systems including **Empower, NuGenesis, LIMS, SAP, LMS, Trackwise and EDMS (Documentum).**
* Good knowledge on **GMP/QSR/FDA regulations** including **21 CFR Part 11, 210, 211, 820, IS0 13485 & 14971.**
* Oversees qualification of laboratory equipment, including **IQ/OQ/PQ** and **Calibration/Maintenance** programs.
* Specialize in developing and implementing appropriate standard operating procedures (SOP), Standard working Practices (SWP), Operation and Administration Manuals
* Proficient in **manual and automated testing tools** and to perform integration testing, user acceptance testing, black box testing, functional testing, load/performance testing, security testing, back-end and regression testing
* Proficiency in **Defect Management**, including Defect creation, modification, tracking, and reporting using Industry standard Tools like **HP Quality Center**
* Proficient in working with systems such as Track wise, **LIMS** (Laboratory Information Management Systems), Documentum and **SAP.**
* Hands on experience in working with HP Quality Center.

**Key Skills**

|  |  |
| --- | --- |
| Computer System Validation | 21 CFR Part (11, 50, 56,210,211,820), cGxP (cGMP, cGDP, cGLP), GAMP5, IQ, OQ, PQ, RTM, Summary Reports, Audit Trails, Gap Analysis and Remediation Plans, FMEA,LIMS |
| Testing and Tracking Tools | HP Quality Center(HPQC), Win Runner, Trackwise EQMS, Documentum (PDOCs), Solution Manager, JIRA,QTP, SAS |
| Databases | Oracle |
| Methodologies | Waterfall, RUP, Agile, SDLC and GRC |
| Scientific Software | Working Exposure to Lab view, MATLAB, Eagle 4.13 and Tina Pro |
| Languages | C, C++,HTML, SQL |
| Other Tools | MS Office, MS Visio, Sharepoint |

**Professional experience:**

**Terumo Cardiovascular, Ann arbor, MI Feb 2015 – Present**

**QA/** **Validation Tester**

Terumo Cardiovascular Group develops, manufacture and distribute medical devices for cardiac and vascular surgery with an emphasis on cardiopulmonary bypass, intra-operative monitoring and vascular grafting. As a CSV Consultant I was Responsible to carry out Q-CSV activities Responsible for the implementation of Remediation Plan according to Terumo Cardiovascular in compliance within FDA audit. Working hands to hands on technical support to the manufacturing and laboratory operations.

**Responsibilities:**

* Assisted functional team in updating various project Deliverables and provided CSV guidelines as necessary
* Implemented and validated 21 CFR Part 11 compliance strategies for **LabWare LIMS.**
* Followed Computer Systems Validation (CSV) Master Plan to author, review and approve CSV deliverables for systems as per GxP (GLP, GCP and GMP) FDA Assessment.
* Requirement analysis, developed strategic, designing test plan, identified test conditions, designed test cases, reviewed test cases, test scripts and executed test cases.
* Played a major role in performing Part 11 Assessments, especially contributing to the components involved in maintenance of Electronic Records (ER), Electronic Signatures (ES) and Audit Trails in accordance with **21 CFR Part 11 regulations.**
* Developed and executed the Remediation Plan. Reviewed all equipment documentation and directed required remediation activities.
* Involved in writing Standard Operating Procedures **(SOPs)** for all aspects of the Validation life cycle in accordance with FDA 21CFR Part 11 and GxP regulations
* Involved in Quality Management system TrackWise Validation for Non-conformance, Complaint, Change control modules.
* Worked in concurrence with FDA compliance in a highly regulated environment for all the aspects of Computer System Validation (CSV).
* Verified the closure of Event and CAPA Records.
* Participated as admin to **Empower CDS** (Chromatography Data System), Standalone Laboratory Software, ChemStation systems to **R&D.**
* Support **LabWare LIMS** implementation in a corporate Pharma environment including Requirements, OQ, PQ, Trace Matrix, and Test Case.
* Provided guidance on CSV, Computer System Regulatory Assessment and SDLC Risk Assessment.
* Generated and reviewed standards of **CSV deliverables,** documented those deliverables in compliance with 21CFR Part11, with the help of the team.
* Worked on IQ/OQ technical writing and execution, commissioning, change control administration and**SOP** adherence
* Developed and reviewed **Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) protocols** for the LIMS application.
* Worked to provide a secure and managing solution for  Environmental Monitoring **(EM)** sampling for the Biological Quality lab Participated in internal and external audits including **FDA and EMEA**
* Identified discrepancies causing failure in the **OQ** scripts and re-writing the **OQ** scripts.
* Re-executed the **OQ** scripts to make sure the scripts are updated with the current system specification and the system meets the functionalities specified in the **URS and FRS.**
* Analyzed Business, User and Functional requirements to develop Test Plans, Test Cases and Test Scripts and organized requirement coverage using **HP Quality Center.**
* Prepared Traceability Matrix between the Business Requirements and Functional Specifications
* Used **Quick Test Professional** (QTP) to automate the Regression Test cases and executed for different releases.
* Reviewed **Corrective and Preventive Action** (CAPA) and drafting Remediation Plans for the project management approval after the **GAP analysis.**

**Fresenius Medical Care, Durham, NC Oct 2012 – Feb 2015**

**QA/Validation Engineer**

Fresenius Medical Care is a German company specializing in the production of medical supplies, primarily to facilitate or aid renal dialysis. Our team was involved making sure application Laboratory Information Management System **(LIMS) version 5** from Lab Ware in the company was compliant with FDA regulations. I am responsible in preparing **documentation for validation of LIMS as per 21 CFR Part 11 and FDA regulations.** In addition, I have also worked towards cleaning validation of lab equipment. Involved in Laboratory Equipment Qualification/Cleaning Validation.

**Responsibilities:**

* As a member of Computer Systems Validation team, responsible for documenting and reviewing all the validation deliverables as part of validation package.
* Involved in executing the test scripts to test the interface between **SAP and LIMS system.**
* Worked on **GAMP, GMAP5, GxP’s (GCP, GLP, GDP and GMP),** and **21-CFR Part 11** regulation of Electronic Records, Electronic Signatures and Audit Trails.
* Responsible for generating and reviewing CSV deliverables in compliance with 21CFR Part 11 and GxP FDA Compliance Regulations.
* Execute**CSV** for packaging lines equipment's.
* Develop and execute Commissioning, **IQ/ OQ/CSV protocols.**
* Guide **remediation activities** to correct compliance gaps related to method validations.
* Participated in all the phases of SDLC and involved in creating **Validation protocols.**
* Wrote, updated and ensured that the **SOP’s** are followed during operation.
* Developed FRS (Functional Requirements Specification) and DS (Design Specification) from the URS (User Requirement Specification) for NuGenesis (Scientific data management system)
* Involved with a team leading the **remediation** and gap analysis of validations for legacy equipment
* Involved in preparing, executing and defending Remediation Plans, Change Controls, Change reporting Requirements, Design Specs, Traceability Matrices, **IQ, OQ and PQ** protocols and summary reports for spreadsheets.
* Worked particularly on **LIMS**, handling data for lab and also processing, tracking, storing and reporting various analytical data and records. I worked both on static data and dynamic data.
* Documented and reviewed all the laboratory records through **LIMS** and controlled forms following the GLPs.
* Developed test plans and **test cases for Functional and Regression Testing**
* Implemented GxP and GAMP guidelines in the systems.
* Developed the Test Execution Guidelines to train the business users to execute the scripts as part of **User Acceptance Testing (UAT).**
* Authored and **reviewed Requirement Traceability Matrix (RTM).**
* Developed the test scripts to test the Security User Profiles and Audit Trail to meet the **21 CFR Part 11 regulations.**

**GE Healthcare, Noblesville, IN Feb 2011 – Sept 2012**

**CSV/Validation Engineer**

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care.GE is broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help its customers to deliver better care to more

**Documentum** was used to support management of validation documents, quality, manufacturing documents and Electronic Submissions.

**Responsibilities:**

* Authored VMP (Validation Master Plan) with **risk based approach** for validation, leveraging documented risk assessments.
* Excellent working knowledge of Computer System Validation (CSV), developing and reviewing Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).
* Responsible for developing **Functional Requirement Specifications** from the User requirements.
* Responsibilities include system qualification assist in the design, analysis and approval of **IQ, OQ, and PQ protocol scripts.**
* **Performed Quality Assurance responsibilities by reviewing validation deliverables for various projects for compliance with SDLC, CSV, 21 CFR Part 11 requirements and GxP regulations.**
* Conducted routine internal inspections of regulated systems **(GMP, GLP, and GCP)** to assure validation procedures have been followed in compliance with company, divisional and department policies
* Reviewed and updated all applicable **SOP's** and Quality Procedures based on CFR 21Part 11 initiatives
* Created and maintained the **Requirements Traceability Matrix (RTM)** for the application.
* Developed **test plans, test strategies, test scripts** for validation testing along with the Test Summary Reports.
* Executed Positive testing, Negative testing, Regression testing for **LIMS**.
* Responsible for reviewing and executing **IQ/OQ/PQ test scripts.**
* Responsible for storing and maintaining the documents to comply with **21 CFR Part 11.**
* Involved in the **User Acceptance Testing** to validate the customized LIMS module.
* In-depth knowledge of methodologies, specifications and change control of **LIMS** (Laboratory Information Management System) in pharmaceutical manufacturing.
* Performed **regulatory and risk assessment** of the computer systems.
* Involved in writing and executing test cases and test scripts to validate certain functionalities of **LIMS**.
* Responsible to get QA approval for validation deliverables and Vendor Audit.
* Responsible for mapping of **IQ to Design Specification, OQ to Functional Specification and PQ to URS.**
* Maintained the **Traceability Matrix** between Requirements, Test cases and Defects

**Kem Pharma, North Liberty, IA Feb 2010 – Nov 2011**

**Validation/ Quality Manufacturing Analyst**

Key Focus:Provided guidance and support to Production, Manufacturing, and Equipment Engineering subject matter experts (SMEs) for the development, implementation, and execution of validation lifecycle activities.

**Responsibilities:**

* Designed procedures and test methods which comply with business, Regulatory, FDA, and industry best-practice guidelines: **FDA 21 CFR Part 820 and Part 11, ISO 14971 and 13485, cGMP, GAMP4.**
* Developed validation documentation (Requirements; Design Specifications; Risk Assessment; **IQ, OQ, PQ; RTM,** and Reports) for manufacturing processes, systems, and equipment.
* Supervised and participated in the implementation of quality assurance procedures and test processes.
* Identified and assessed impact of Change Control activities for validated equipment, software, and systems.