Shaik Jafer sadiq
Mobile: 91- 9739900380
Email id: jafersadiqshaik@gmail.com

Profile Summary:

- Experience in validation practices with good knowledge on 21 CFR Part 11,EU Annex 11 and GAMP 5 Guidelines and GxP (GMP,GDP,GCP,GLP) Standards.
- Hands on Experience and understanding in Software Development Life Cycle (SDLC) methodologies like Waterfall, Agile, and V-model.
- Experience in Validation with strong background in CSV, Process Validation, Test Method Validation.
- Strong understanding of 21 CFR Part 11, drug cGxP requirements including electronic records, electronic signatures, system validation strategies, Audit trails and documentation.
- In depth knowledge ofGAMP5,GxP (GMP,GDP, GLP and GCP) standards.
- Expertise in pharmaceutical industries using modern analytical methods and techniques in the field of Quality Assurance, Quality Compliance and Manufacturing.
- Expertise in development, review and approval of IT SOP's, Computer System Validation Master Plans (VMP).
- Document Laboratory work through LIMS in detailed, timely in Compliance with GLP/GMP.
- Good knowledge on Risk based approach to GxP Computerized systems.
- Preparation, Review and Execution of SDLC documents as per based on GAMP5 Guidelines. (Validation Plan, User Requirement Specification, Design Qualification (DQ), Risk Assessment (RA), IQ, OQ, PQ, Traceability Matrix (TM), Compliance Report (CR), & Validation Report(VR)).
- Checking the Functions like Security policy, Authority checks, Audit trail, Data Integrity, communication loss and power failure based on 21CFR part 11, GAMP5 and cGMP Guidelines.
- Conducts risk assessments and determine revalidation or qualification needs based on gap analysis.

Work Experience:

Total **5 years 7 months** of Experience

- Presently working as Sr. Consultant at **Company Connect Consultancy** in CSV department at Hyderabad since **07-Oct-2019 till date**.

- Three years experience as Sr. Associate in **Cipla Limited** in at Bangalore from October 2015 – May 2018.

- One year experience as Sr.Associate in **Sterile gene Life Sciences P Ltd,** in Quality Assurance Department at Pondicherry from March 2014 – June 2015.

Professional Experience:

Senior Consultant –Company Connect Consultancy, Hyderabad October 2019 – Till date
Roles & Responsibilities:

- Active team member for validation analysis, preparing test protocols, test summary reports and validation summary reports in accordance with US FDA as well as local regulatory bodies.
- Conducting GxP review of validation deliverables like User requirement specifications, Functional design specifications, configuration documents, test scripts, test results
- Good Exposure to Change Management Tool , Document Navigator & Deviation Tracker Tool
- Involved in Review and Approval of Test Plan Documents Using the above Tools.

- Perform validation of systems for Data Integrity and make sure they are compliant according to Global Procedures (GQPs).
- Review and Execution of SDLC documents as per based on GAMP5 Guidelines.

Projects Handling:

- **Data acquisition system (DAS)** Validation for acquiring process data from various manufacturing equipments to generate the report from office clients along with audit trail functionality.
- Document Management System (DocStore-Diary) validation for generation, review and approval of record.
- Experience in validating wide variety of Laboratory applications such as Laboratory Information Management System (LIMS), Empower 3, Chromeleon, Standalone applications (Lab Instruments).

Quality Management System:

- Review, approval and closure of change control through the SAP system.
- Investigation, Review, approval and closure of incident through SAP system.
- Quality risk management handling.

Senior Associate – Cipla Limited, **Bangalore** **October 2015 – May 2018**
Roles & Responsibilities:

- Involved in the computer system validation (CSV) of Lab ware LIMS, in adherence to FDA regulations particularly 21 CFR part 11.
- Participated throughout SDLC in planning, implementation and documentation of all materials during testing phase.
- Validated the Electronic Records and Electronic Signatures in accordance with FDA guideline's.
- Developed Trace Matrix document for mapping the URS, FS, DS (Design Specification), IQ, OQ and PQ
- Participated in the team meetings to discuss the issues arising out of testing.
- Performed Gap Analysis and also developed the corresponding Remediation plan.
- Working with QA team, designing, reviewing and approving Test Plans, systems and UAT test scripts and test procedures for LIMS applications.

Senior Associate – Sterile gene Life Sciences P Ltd, Pondicherry
March2014 – June 2015
Roles & Responsibilities:

- Perform validation of systems for Data Integrity and make sure they are compliant according to Global Procedures (GQPs).
- Coordinated the validation activities with departments, while providing support services.
- Checking the Functions like Security policy, Authority checks, Audit trail, Data Integrity based on 21CFR part 11, GAMP5 and Guidelines.
- Coordination with other departments to comply Audit observations.

<u>Technical Skills:</u>

Life Sciences Applications Worked: LIMS,Argus,Track wise
Operating Systems: Windows 7 professional,
Functional Experience: Computer System Validation, Risk Assessment, Technical Writing - IQ, OQ, PQ, User Requirements, Change Control Process.

Validation	21 CFR part (11, 210, 211), GAMP, GxP, Validation Protocol (IQ, OQ, PQ), SOPs, GAP analysis, RTM, Risk Assessment, Incidents, Audit trails, Summary Reports.

SDLC	V-Model, Waterfall Model
Defect Tracking Tools	HP Quality Center
MSOffice Tools	MS Office (Outlook,Word, Excel, Power Point, Access, Visio)
Laboratory equipments	HPLC,Spectrophotometer,GC,I.R,
Operating Systems	Windows,

Personal Profile:

Gender	:	Male
Marital Status	:	Married
Nationality	:	Indian
Languages known	:	Telugu, English, Hindi
Permanent Address	:	20/107,BR Street, Jammalamadugu,AP-516434.
Present Address	:	Hyderabad.

Declaration:

I hereby declare that above mentioned information is true to the best of my knowledge and belief.

SHAIK JAFER SADIQ