

To achieve a challenging position in the area of Computer system validation where my capabilities and skills can be utilized and an opportunity to continue to develop professionally with the company and to attain organizational and personal goal effectively.

SKILLS

Knowledge of QMS: Deviation management with Trackwise, Incidents, Out of specification (OOS), Change Control and CAPA.

Knowledge of ALCOA +, Data integrity, 21 CFR PART 11, EU Annexure 11, GAMP 5, ICH Guidelines

Knowledge on Software Development Lifecycle, Waterfall & Agile Methodology.

Periodic Review

Communication skills

Exposure to internal and external audits like EMA, Health Canada, WHO, USFDA.

Training imparted to new joiners

Softwares for Validation known: Jira, eVLS (ValGenesis)

Risk assessment

Lean six sigma

Power BI

Pivot chart, V lookup, H look up

MS Excel

WORK EXPERIENCE

Senior executive

Biocon Biologics

06/2020 - Present

Bangalore

Achievements/Tasks

- Computer System Validation of GxP systems as per Title 21 CFR Part 11, Annex 11 and V-Model (VP, URS, RTM, DS, FS, CS, FAT/SAT, DQ, IQ, OQ, PQ) approach as advocated by GAMP-5 guidelines, followed by preparation of TSR/VSR
- Functional Test cases execution using eVLS of various GxP systems.
- Reviewing Vendor Qualification Documents according to regulatory requirement.
- Preparation & Execution of Test Cases for Qualification of software, Execution of IQ/OQ/PQ Protocols for Equipments, System risk assessment and preparation of risk mitigation reports using tools like FMEA, HAZOP, FTA.
- Perform GxP system Risk assessment using tool like FMEA, HAZOP and Fault tree analysis.
- Performing HLRA (GxP assessment, ERES applicability, GAMP categorisation, System Criticality, Confidential System assessment, System availability check) for software.
- Usage of Agile and Waterfall frameworks for SDLC.
- Work in cGMP compliance environment and support audits.
- Study and analysis of business requirement and make sure GxP guidelines are followed stringently. Alongside, Performed GxP assessment and Data integrity activity and propose mitigation activity.

Research Associate Junior

Steerlife India Pvt. Ltd.

12/2017 - 05/2020

Bangalore

Achievements/Tasks

- Equipment Validation, Qualification, Calibration.
- Conducted validation testing, including IQ, OQ, and PQ, and ensured that all validation activities were documented and executed in accordance with regulatory guidelines.
- Calibration and verification of equipments
- Participated in risk assessment activities.
- Preparation of SOPs, Validation Protocols, Study Protocols, Study Reports, Review of Documents.
- Work in cGMP compliance environment.
- Prepared validation summary report IQ, OQ, PQ.
- Prepared and updated requirement traceability matrix.

WORK EXPERIENCE

Executive

Shrushti Pharma Pvt. Ltd.

07/2015 - 03/2017

Bangalore

Achievements/Tasks

- Keeping quality documentation up to date.
- Adherence to CGMP, CGLP and GDP.
- Successfully handled a wide range of QMS documents like Incident, deviation, Change Control.
- Coordinate the investigation of customer complaints.
- Performed IP compliance activities in manufacturing area.

CERTIFICATES

Certified LEAN SIX SIGMA GREEN BELT.

ACHIEVEMENTS

Achieved Rising star award 2023 (Biocon)

LANGUAGES

English

Full Professional Proficiency

Hindi

Full Professional Proficiency

EDUCATION

M.Pharma

Rajiv Gandhi University Of Health Science

2015

Bangalore

B.Pharma

Rajiv Gandhi University Of Health Science

2013

Bangalore