SHAKILA SHANKAR

TEST & VALIDATION ENGINEER

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Professional Summary

Test & Validation Engineer with over 5.9+ years of experience at Xybion Corporation, focusing on Computer System Validation (CSV) and manual testing. Proven ability to execute OQ/PQ protocols while ensuring GxP compliance. Proficient in defect tracking with JIRA and effective collaboration within Agile teams to deliver high-quality results.

Experience

Test & Validation Engineer, 09/2019 to Current
Xybion Corporation
- Experience in Computer System Validation (CSV) and manual testing in pharmaceutical and healthcare domains.

Skills

- Manual Testing (Black box Testing)
- Bill review knowledge (UB04, HCFA 1500)
- Verification & Validation (V&V) Lifecycle
- Technical Impact Document (TIA), Verification Summary Report (VSR), Release Notes (RN)
- Requirement Traceability Matrix (RTM)
- Defect Life Cycle
- ALCOA+ Principles for Data Integrity
- 21 CFR Part 11.
- Agile/Scrum Methodology

- Test case development and execution
- Computer System Validation (CSV)
- OQ/PQ Protocol Preparation & Execution
- User Requirement Specification (URS), FRS, CS, Functional Risk Assessment Documentation
- Defect tracking with JIRA
- Good knowledge on STLC.
- GxP Compliance
- GAMP framework knowledge
- CAPA / Deviation Handling Systems

Tools

JIRA, Postman, Balance Tester, FileZilla

Detailed Experience

#1. Verification and Computer System Validation (CSV): (56 Months)
- Validated products to be delivered to clients using both **Traditional(paper-based) & Computerized validation** method, following Good Documentation Practice (GDP) and standard procedures.
- Performed verification for GxP-regulated systems in Pharma and healthcare domains.
- Involved in validation ensuring compliance with **21 CFR Part 11, GxP** , and FDA guidelines.
- Executed **OQ** and **PQ** test cases of high quality, resulting in zero defect leakage during product delivery.
- Reported and tracked bugs using JIRA, supporting timely resolution.
- Ensured thorough validation of products for flawless delivery to clients.

- **L3 Support (11 Months):**
- Worked on 70+ patch releases for key projects including **Internal and Client projects.**
- Actively participated in **daily Scrum meetings** , involved in **client calls** to discuss requirement clarifications, issue resolutions, and deliverables
- There are no issues leaked from the customer after the patch release. Ensured 100% quality in deliverable.

#2. Sun Pharma – Pharmaceuticals (1.5 Months)

- Prepared a data integrity checklist to ensure user-entered values during drug preparation complied with ALCOA+ principles.
- Conducted internal Data Integrity Audits in alignment with SOPs, GxP, and regulatory standards.
- Guided users to follow FDA-compliant ALCOA+ practices for secure and validated computerized systems.
- Assessed organizational adherence to data integrity policies and identified areas for improvement

Projects

LIMS/BI Aqua/NBR/CytomX

- Inventory Management
- Test Management
- Storage /Stability /Sample / Study Management
- Results Management
- Audit Management
- QMS/DMS
- Support Modules
- Medical Bills

Education

Institution: Ethiraj college for Women
B.Sc. Mathematics with Computer Application - 2016-2019 (79.34)
School: ST. Antony's Girl's Higher secondary school.
HSC – 2016 (88.92%)
SSLC – 2014 (93%)

Language

Tamil/ English