ROBERT SMITH

Quality/ Validation Engineer

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SUMMARY

Quality/ Validation Engineer with over 2 years of Information Technology experience with expertise in Computer System Validation (CSV) and Software Development Life cycle (SDLC) in FDA regulated Biotechnology and Pharmaceutical industry. Good working experience in FDA regulated environment with expertise in implementing 21CFR part11 compliance requirements and Annex 11, 21 CFR Part 210 / 211and 820. Experience in developing and reviewing User Requirements Specification (URS) and Functional Requirements Specification (FRS) documents.

CORE COMPETENCIES

SolidWorks, AutoCAD, CATIA, ANSYS, Minitab, Matlab, 5S, Kaizen, Poka-Yoke, Root Cause Analysis

PROFESSIONAL EXPERIENCE

Quality/ Validation Engineer

ABC Corporation - August 2009 – June 2010

Key Deliverables:

- Prepared a Validation Master Plan (VMP) for validating the Trackwise application.
- Involved in the complete system development life cycle and documentation.
- Authored User Requirement Specifications (URS) and Functional Requirement Specifications (FRS) by closely working with Business Analyst.
- Developed and reviewed Standard Operating Procedures (SOPs) for various functionalities of the system Reviewed the Test Strategy document prepared by the testing team and provided input on the validation requirements.
- Involved in creation, execution and responsible for pre and post-execution review of Unit Test scripts, Performance/Automated Test Scripts, Regression Test Scripts, IQ/OQ/PQ Test Scripts and UAT Test Scripts.
- Analyzed test scripts to check whether all functionalities have been covered within the compliance of 21 CFR Part 11 Responsible for Test Case Development, Execution and summarizing the results following strict FDA regulation - 21 CFR Part 11.
- Participated in system test script execution and documented results.

Validation Engineer

Optical Cable Corporation - 2008 – 2009

Key Deliverables:

- Collaborate with design engineer to define, develop and document special tools and equipment to support product verification and manufacturing test.
- Collaborate in development of first article assembly builds, prototypes, and evaluate testing specifications.

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- Utilize knowledge of testing and military standards to maintain and support QPL products for fiber optics.
- Conduct extensive fiber optics testing in compliance with military and EIA/TIA standards.
- Create test fixtures and procedures and support test tools for new product development.
- Perform fiber optic system root cause analysis.
- Prepare all protocols and reports for validation work.

EDUCATION

Bachelor Of Science - 2007

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