ROBERT SMITH

Software Consultant II

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SUMMARY

Software Consultant II with 15+ years of experience in the field of Medical Device Validation/Verification, CSV, DFMEA, Risk Analysis, QA/V&V/IV&V for Embedded RTOS Systems, in the Pharmaceuticals, Healthcare, Medical Device, DOD, and Financials industries. Knowledge in Java Design Patterns, Spring (MVC), JavaScript, TypeScript. Good team player with clear knowledge of technical details, business rules and having excellent communication skills.

SKILLS

C/C++ Development, C#, Visual Basic, Websphere, Java, Java Script, HTML, IBM Lombardi

WORK EXPERIENCE

Software Consultant II

Boston Scientific - 2006 – 2019

- Authored Test Requirements, Test Strategy, Test Plan, Test Cases, Test Procedures, Unit Level Test Strategy & reports for 510K Submission.
- Served as a Team Member/Technical Lead of the Retrospective Evaluation Team for the retrospective evaluation of the Oxygen Level Sensors Provided regulatory compliance guidance for software applications.
- Lead, performed, consulted & provided leadership for the QSR System/Record implementation.
- Wrote and executed Validation Plan, URS, FRS, RTMs (Requirements Trace Matrix), IQs and PQs for packaging/assembly lines, which included validation of PLCs, Vision Systems, Operating Systems/Networks, COTS software packages, Micro Controllers, Configurable software packages (SCADA, LAS and MRP), as well as Custom Built Systems.
- Performed Requirements Analysis, in order to, understand the user needs for Oxygen Level Sensors Facilitated Test Readiness discussion sessions with users, analyzed information from users, survey FDA/customer responses, and user behavior on internal and FDA web sites Developed system test requirements based on user and functional needs.
- Supported the test architecture for web-based "telemetry applications" for the Pacemakers for physician monitoring.
- Validated and verified the satisfaction of requirements for Software Design & Unit Level Testing.

Software Consultant

ABC Corporation - August 2002 – October 2004

- Review and approved Functional Requirement documents (FRS) in HP Quality Center (QC)-ALM 11 as per Validation Policy and SOPs Review and approve Validation Test plans (VTP) in HP

Quality Center (QC) ALM 11 within following Quality Assurance Library guidelines Review and approve Process description document (PDD) in Solution Manager (SAP) system.

- Wrote and executed QRA, [] 21 CFR Part 11 Assessment, Supplier Quality Audit, Risk Management Plan, Change Control Plan, URS, FRS, DSs, RTMs, Design Validation Protocols, Issue Tracking, Training Material, Updated SOPs, Updated.
- Authored Test Requirements Analysis scenarios, in order to, to understand user & define the needs for the Garbo Production Line concerning the Sporanox, Propulsid, and Risperdal product line.
- Review and approve Functional design document (FDS) in Solution Manager (SAP) system Work with Release management team for authoring Incident reports, review and approve on timely basis Author System certification and present it to review board.
- Peer review and approve Validation Change request documents (VCRs) in GIS Packet Tracker Application (PTA) Write Traceability matrix report, Test Summary reports and present it to review board.
- Conduct test review meetings with testers and provide review comments.
- This is Dummy Description data, Replace with job description relevant to your current role.

SCHOLASTICS

- BA in Mathematics - 2000 (Guilford College/University of North Carolina)