**Name:**

**Email:**

**Phone:**

**ATE Software Validation Engineer – Medical Devices**

### ****Professional Summary****

* **Over 10 years of experience** designing and leading software validation strategies for automated test equipment (ATE) used in testing infusion pumps, patient monitors, and diagnostic devices, leveraging LabVIEW, TestStand, Python, and C/C++ while ensuring full compliance with FDA 21 CFR Part 820 and ISO 13485 regulatory standards.
* Developed, deployed, and executed automated test sequences in LabVIEW and TestStand to validate software and hardware functionality across multiple medical device platforms.
* Architected robust Python and C/C++ test scripts to simulate embedded device behavior and automate end-to-end ATE validation processes for production and R&D environments.
* Collaborated with cross-functional teams including R&D, Quality, and Manufacturing to define risk-based testing strategies that align with IEC 62304 software lifecycle standards and ISO 14971 risk management practices.
* Performed Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) for ATE systems, ensuring traceability from requirements to execution and regulatory compliance.
* Created and maintained comprehensive documentation including validation plans, protocols, test reports, and change control records to support internal and FDA audits.
* Integrated advanced measurement instruments such as oscilloscopes, signal generators, multimeters, and communication analyzers to ensure accurate and repeatable test results.
* Investigated, analyzed, and resolved system-level and software anomalies discovered during validation or production use, providing corrective and preventive actions.
* Developed continuous improvement initiatives for test automation frameworks, ATE methodologies, and software validation best practices to enhance productivity and reliability.
* Led design transfer activities from R&D to manufacturing, ensuring ATE systems meet production readiness and functional requirements.
* Maintained electronic records and signatures in compliance with FDA 21 CFR Part 11 for software validation documentation and reporting.
* Provided mentorship and technical guidance to junior engineers on ATE validation processes, test automation scripting, and documentation standards.
* Executed validation of software updates and patches in controlled environments, confirming adherence to regulatory standards and maintaining risk-based traceability.
* Applied strong analytical, troubleshooting, and documentation skills to improve ATE system reliability and software quality across multiple medical device platforms.
* Supported regulatory submissions and internal quality audits by ensuring all software validation activities meet FDA, ISO 13485, and IEC 62304 requirements.

### ****Technical Skills****

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| --- | --- |
| **Programming & Scripting:** | LabVIEW, TestStand, Python, C/C++, Embedded Scripting |
| **ATE & Test Automation:** | Automated test script development, functional/performance/regression testing, stress testing, test automation frameworks |
| **Test Instruments:** | Oscilloscopes, Multimeters, Signal Generators, Communication Analyzers |
| **Standards & Compliance:** | FDA 21 CFR Part 820 & Part 11, ISO 13485, IEC 62304, ISO 14971, GxP |
| **Validation & Testing:** | IQ/OQ/PQ, design transfer validation, traceability matrices (DOORS, Jama), risk-based testing |
| **Tools & Platforms:** | DOORS, Jama, Agile methodologies, change control, document management, regulatory compliance tracking |
| **Continuous Improvement:** | Root cause analysis, corrective/preventive actions, dashboards, process enhancements |

### ****Professional Experience****

#### ****Client :****

**ATE Software Validation Engineer**

**Responsibilities:**

* Developed and executed LabVIEW-based automated test scripts for infusion pump systems to validate software functionality, ensuring compliance with FDA 21 CFR Part 820 and ISO 13485.
* Implemented TestStand sequences to automate ATE test execution and data logging, enabling consistent and repeatable test results across multiple production lines.
* Collaborated with firmware engineers to synchronize automated test scripts with embedded software, providing comprehensive system coverage and accurate functional validation.
* Integrated advanced instruments including oscilloscopes, signal generators, multimeters, and communication analyzers into ATE systems to capture precise electrical and signal measurements during validation.
* Designed risk-based validation protocols in accordance with ISO 14971, performing thorough testing of software modules in infusion devices to ensure patient safety.
* Created and maintained detailed validation documentation including IQ/OQ/PQ protocols, test execution records, and traceability matrices in DOORS for audit readiness.
* Conducted root cause analysis of ATE failures and implemented corrective and preventive actions to improve test reliability and accuracy.
* Collaborated with cross-functional teams to define software validation requirements, test plans, and acceptance criteria for FDA compliance and production readiness.
* Developed Python automation scripts to simulate device behavior and stress-test ATE systems, enhancing coverage of edge cases and reducing manual intervention.
* Led software lifecycle compliance efforts ensuring adherence to IEC 62304 and ISO 13485 standards across multiple device platforms.
* Maintained change control and document control procedures for all validation artifacts to ensure regulatory compliance and traceability.
* Supported design transfer from R&D to manufacturing by ensuring ATE systems met production throughput and reliability requirements.
* Mentored junior engineers on ATE scripting, test automation strategies, and validation best practices to strengthen team capabilities.
* Continuously improved ATE test methodologies by analyzing results, incorporating lessons learned, and updating automation frameworks to enhance efficiency.

**Environment:** LabVIEW, TestStand, Python, C/C++, DOORS, Oscilloscopes, Signal Generators, Multimeters, IEC 62304, ISO 13485, FDA 21 CFR Part 820, Agile, GxP

#### ****Client :****

**ATE Software Validation Engineer**

**Responsibilities:**

* Designed and executed automated test sequences in LabVIEW for respiratory care devices, performing software validation in a controlled, FDA-compliant environment.
* Developed TestStand workflows to automate execution of functional and performance tests while collecting precise measurement data for regulatory documentation.
* Implemented Python and C/C++ scripts to simulate device inputs, automate testing, and enhance coverage of critical software paths and embedded modules.
* Executed IQ, OQ, and PQ validation procedures in alignment with ISO 13485, ensuring complete traceability of test execution to software requirements.
* Utilized oscilloscopes, signal generators, multimeters, and communication analyzers to monitor device performance and confirm accurate ATE measurements.
* Collaborated with R&D and Quality teams to define validation strategies, acceptance criteria, and risk-based testing approaches, ensuring compliance with IEC 62304.
* Created and maintained traceability matrices in Jama to track requirements, test cases, and results for audit readiness.
* Investigated and resolved software anomalies discovered during ATE execution, documenting root cause analysis and corrective actions.
* Supported design transfer and production readiness by validating ATE systems and confirming adherence to functional specifications.
* Developed and enhanced ATE automation frameworks to improve test reliability, reproducibility, and system coverage.
* Ensured change control and document control procedures were followed for all validation artifacts, maintaining FDA compliance.
* Trained junior engineers on LabVIEW, TestStand, and Python scripting best practices for software validation and automated test execution.
* Participated in internal and external audits, presenting validation documentation and test results to demonstrate regulatory compliance.
* Contributed to continuous improvement of test methodologies, risk management documentation, and validation strategies across multiple respiratory care devices.

**Environment:** LabVIEW, TestStand, Python, C/C++, Jama, Oscilloscopes, Signal Generators, Multimeters, ISO 13485, IEC 62304, FDA 21 CFR Part 820, Agile, GxP

#### ****Client :****

**Software Validation Engineer**

**Responsibilities:**

* Led validation of ATE systems for patient monitoring devices by designing and executing automated test scripts in LabVIEW for functional and performance verification.
* Developed Python-based test automation scripts to simulate device behavior, enhancing test coverage of embedded software modules.
* Conducted IQ, OQ, and PQ validation activities and maintained detailed documentation of test results, aligning with FDA and ISO 13485 standards.
* Collaborated with cross-functional teams to define validation requirements, acceptance criteria, and risk-based testing strategies, ensuring software lifecycle compliance with IEC 62304.
* Utilized multimeters, oscilloscopes, signal generators, and communication analyzers to capture accurate measurements and validate system functionality.
* Performed root cause analysis for test failures and implemented corrective actions to prevent recurrence and maintain test system reliability.
* Maintained requirements traceability matrices in DOORS to track alignment of test cases with regulatory and functional requirements.
* Participated in internal audits and quality reviews, providing evidence of compliance for regulatory inspections.
* Supported design transfer activities from R&D to manufacturing, ensuring ATE systems met production and functional requirements.
* Developed continuous improvement initiatives for test automation frameworks, validation protocols, and ATE system integration.
* Ensured all validation artifacts were controlled under formal document and change control procedures.
* Provided mentorship and guidance to junior validation engineers on software validation best practices and automated testing.
* Contributed to risk management documentation and hazard analyses following ISO 14971 standards.
* Assisted in the preparation of regulatory submission packages by providing validated ATE test data and reports.

**Environment:** LabVIEW, TestStand, Python, C/C++, DOORS, Oscilloscopes, Multimeters, Signal Generators, ISO 13485, IEC 62304, FDA 21 CFR Part 820, Agile, GxP

#### ****Client :****

**Software Validation Engineer**

**Responsibilities:**

* Developed and maintained LabVIEW-based automated test scripts to validate hospital bed monitoring and control systems, ensuring adherence to ISO 13485 and FDA 21 CFR Part 820 standards.
* Executed OQ and PQ testing, capturing detailed performance data and documenting results for regulatory compliance.
* Built Python automation scripts for embedded software testing, enabling simulation of device responses and stress-testing of critical functionality.
* Integrated advanced measurement tools including oscilloscopes, signal generators, and multimeters to validate electrical and communication interfaces accurately.
* Collaborated with firmware and hardware teams to ensure seamless integration of ATE systems with embedded device functionality and production requirements.
* Conducted root cause analysis of validation failures and implemented preventive measures to enhance system reliability.
* Maintained requirements traceability using DOORS, ensuring complete alignment of test cases with design and regulatory requirements.
* Participated in internal and external audits, demonstrating compliance with software lifecycle processes, risk management, and document control standards.
* Applied risk-based testing strategies in accordance with ISO 14971, ensuring patient safety and regulatory compliance.
* Supported design transfer activities from R&D to manufacturing, confirming that ATE systems were production-ready.
* Provided training and technical support to junior engineers on automated test scripting, validation best practices, and documentation standards.
* Contributed to continuous improvement of ATE test methodologies, automation frameworks, and validation processes across hospital bed devices.
* Maintained change control and document control procedures for all validation artifacts to ensure audit readiness and regulatory compliance.
* Developed reporting and visualization dashboards to track test execution, results, and validation coverage effectively.

**Environment:** LabVIEW, TestStand, Python, C/C++, DOORS, Oscilloscopes, Signal Generators, Multimeters, ISO 13485, IEC 62304, FDA 21 CFR Part 820, Agile, GxP

#### ****Client :****

**Junior Software Validation Engineer**

**Responsibilities:**

* Assisted in the development and execution of LabVIEW test sequences for infusion systems validation under FDA 21 CFR Part 820 and ISO 13485 standards.
* Executed Installation Qualification (IQ) and Operational Qualification (OQ) procedures, capturing detailed test results and documenting compliance.
* Collaborated with senior engineers to define validation requirements, develop risk-based testing strategies, and maintain traceability matrices in DOORS.
* Developed Python scripts to automate repetitive test cases and simulate device input scenarios for enhanced test coverage.
* Assisted in TestStand sequence development, execution, and integration with ATE hardware systems for reliable testing of embedded software modules.
* Maintained detailed documentation of test protocols, results, and validation reports in accordance with FDA and ISO 13485 guidelines.
* Supported risk management activities and hazard analyses per ISO 14971 to ensure patient safety and regulatory compliance.
* Utilized multimeters, oscilloscopes, and signal generators to capture accurate electrical and communication measurements during test execution.
* Assisted in root cause analysis of ATE failures and implemented corrective actions to improve system performance and reliability.
* Maintained validation artifacts under formal change control and document control procedures to ensure audit readiness.
* Participated in design transfer activities from R&D to manufacturing, validating ATE readiness for production.
* Applied software lifecycle knowledge to support regulatory compliance, traceability, and validation best practices.
* Collaborated with cross-functional teams to plan, execute, and document validation activities for infusion devices.
* Contributed to the continuous improvement of test automation frameworks, reporting, and validation methodologies across the organization.

**Environment:** LabVIEW, TestStand, Python, C/C++, DOORS, Oscilloscopes, Multimeters, Signal Generators, ISO 13485, IEC 62304, FDA 21 CFR Part 820, Agile, GxP