Job Description

TITLE: Software Engineer II

DEPARTMENT: Engineering

REPORTS TO: Director of Engineering

JOB SUMMARY:

This position will participate in all aspects of Software and Firmware engineering and design from the initial feasibility stage to manufacturing release, (Software Development Lifecycle) for next generation in vitro diagnostic medical instrumentation and related infrastructure. This position will be responsible for Software design and development in accordance with Good Manufacturing Practices (GMPs) for Design Controls, e.g., Software architect, coding, code reviews, implementation and test verification and validation of the Software. Design and/or maintain firmware for target PCBs where applicable and verify designs of various test production and test equipment that include software.

GENERAL DESCRIPTION:

Key Responsibilities

- Support all phases of the software development lifecycle including requirements, design, implementation, debug, verification, validation, and transfer to manufacturing.
- Follow Product Design Controls procedures and Software Development lifecycle procedures.
- Develop software to execute product requirements following Agile methodology.
- Develop and document test procedures for software unit, integration and system testing.
- Perform formal risk analysis and develop software mitigations.
- Software build, change control, and development/test process improvement.

Job Requirements

- Actively engages in the design development and review process while driving ongoing process improvement across the software engineering function;
- Strict adherence to design controls in a regulated environment such as, ISO 13485, FDA GMP, and other relevant compliant quality management systems across the medical device spectrum;
- Strong organizational skills with the ability to prioritize tasks, self-driven and independent in performing the engineering processes
- Fundamental understanding of IPC and IEC requirements as well as ISO organization related to software development.

Typical Tools, Technologies

- Interfaces: I2C, SPI, USB Full Speed and High Speed, 802.11, RS-232, Bluetooth (standard and BLE), Ethernet
- Technologies: Embedded Microcontrollers (e.g., ARM), System on Chip (SoC), Real Time Operating System (RTOS)
- Tools: C, C++ (Std 11), Object Oriented Design, Design Patterns, Configuration Management (CM), Modern IDE's (Such as Keil and IAR), gdb, unit testing and mocking frameworks.
- Proficient in standard design and development tools such as Confluence, Jira, Bitbucket, Microsoft Office, and the Agile approach to software development life cycle.
- Software test methods such as unit testing, black box/white box testing, integration testing, and regression testing.

Experience and Education:

- B.S. or M.S. in Software Engineering, Electrical Engineering, or related field.
- Requires a minimum of 3-5 years of relevant experience.
- Working knowledge of electronic design principles and medical device design control methods.
- Working knowledge of UL, IEC, and CE Requirements is a plus.
- Real Time or Safety Critical Systems a plus
- Experience with designing software products in an FDA or other regulated industry.
- Familiar with concepts of design input, design output, traceability, and risk analysis.
- Able to debug software and hardware/schematics at higher level using logic analyzers, oscilloscopes, and simulators.