

Job Title: Senior Software Quality Engineer; (Full Time Role)

Job Location: Austin, Texas

### **Job Summary**

The Senior SW Quality Assurance Engineer will support every phase of the SW development process and post-market activities to ensure that the design and sustaining activities of products adhere to company Quality Management System and Regulatory standards. This role will work cross functionally to ensure compliance and implementation of the Quality Management System in all processes for the company. Within the design control framework, the candidate shall lead efforts to develop deliverables for risk management. This role will provide additional support for engineering outputs including engineering test plans/protocols/reports, requirement documentation and traceability, engineering test methods and test result review, and defect tracking and resolution.

### **Essential Duties & Responsibilities**

- Review company quality system procedures and work instructions relating to the development, management, control of software and products
- Monitor and audit software related activities governed by quality management system procedures
- Review quality specifications and technical design documents to provide timely and meaningful feedback
- Review and assist software related design documentation including risk management documents and software verification and validation testing protocols, plans, and reports
- Identify any potential problems that users might encounter
- Research and analyze product features under test
- Review user interfaces for consistency and functionality
- Assist in writing and reviewing product acceptance documentation relating to product software and product interfacing software, as well as software used in the manufacturing, installing, and servicing of the product.
- Review process software validation protocols and reports for software systems used in support of quality system management operations
- Experience with requirements analysis and technical design and documentation
- Working experience with system architecture and engineering
- Drive progress and collaborate across domains of hardware, software, systems, and regulatory compliance
- Provide clarification and guidance to teams on the overall quality system with emphasis on design controls
- Responsible for quality design transfer activities including test method validation/measurement systems analysis and incoming inspection, and process validation.
- Responsible for assuring departmental compliance with ISO and FDA requirements through supporting internal and external audits.

- Provide statistical support and expertise and analytical problem solving for product development and manufacturing.
- Participate in risk management deliverables by facilitating the creation of product design failure modes analysis, and hazard risk analysis and associated deliverables.
- Participate in cadaveric labs to build understanding of user needs and conduct design validation/usability.
- Responsible for reviewing product design input/user need traceability
- Support regulatory pathway determination 510(k) vs Letter to File activities

## **Qualifications**

- BS in an engineering field with an understanding of software, mechanical, and electrical engineering
- 7 years of experience working in Quality with direct experience in Verification and Validation
- At least 5 years of experience with medical devices
- Experience working with robotics preferred.
- Strong analytical, communication, and time management skills
- Working knowledge of applicable regulatory standards including but not limited to (21 CFR Part 820, ISO 13485, ISO 14971, IEC 62304)
- Working Experience with the following tools (preferred): Atlassian Products (Jira, Confluence), Jama, Greenlight Guru, expertise in MS Excel macros, FMEA tool management
- Working experience with Cybersecurity for Medical Devices is a preferred
- Intermediate to advanced working knowledge of MS Office suite tools
- Understanding and working knowledge on various SDLC methodologies including Agile/Scrum