



## Job Description – Senior/Embedded Software Engineer

Reports To – Director, Software Engineering OR Manager, Software Engineering

### Job Responsibilities

This position is responsible for the design, development and manufacturability of software related product(s)/system(s) in accordance with the company's Quality System and customer requirements. This position complies with Quality System by engaging in appropriate levels of GMP/ISO test methodologies, adherence to Quality System Design Controls, and applies proper documentation skills.

### General Description and Duties:

*To perform this job successfully, an individual must be able to perform each essential job task satisfactorily. The tasks listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.*

- **Software Engineering:** Establishes functional requirements, deliverables, timelines, budgets and develops corporate status reports of projects/products. Works with project team to develop detail specifications, construction of prototypes, pre-clinical trials for new products or current product enhancements. Prepares and delivers status reports. Develops, sets up, and runs product testing and protocols in accordance with project plans. Recommends and/or selects vendor and material choices for product. Ensures product documentation is in accordance with Quality System requirements. Assists in the reaction and maintenance of software specifications. Participates in software risk hazard analyses. Complies with software validation requirements. Participates in appropriate test plans and reports for software verification and validation work as necessary. Provides for evolution of requirements, stress test coverage and maintain verification trace matrices. Performs software unit/integration testing, white box testing, and code inspections.
- **Product Enhancements:** Provides feedback to the development staff on client specific enhancements as well as new applications for base product. Acts independently to research design and develop new products and current product enhancements.
- **Manufacturability:** Designs new software or software enhancements in a cost effective and timely manner and with an understanding of how the product will be manufactured and used. Contributes to or leads the process of transferring product from development to manufacturing.
- **Sales:** Participates in customer meetings, trade shows, etc. upon request. Keeps abreast of competition and trends in the field and market.
- **Regulatory Acceptance:** Provides engineering testing and documentation that is in accordance with regulatory requirements for approvals of products by the U.S. and foreign regulatory agencies.
- **Intellectual Property:** Works with senior staff and/or attorneys in writing and researching patents. Participates in and contributes to brainstorming sessions to generate new intellectual property.
- **Safety:** Performs job functions in a safe and effective manner. Helps ensure employees are adhering to the safety procedures of the company.

### **Projects and Other Duties:**

- Perform other duties as assigned.

### **Position Qualifications**

- Experience using oscilloscopes, logic analyzers, and other related tools.
- Experience working with domestic and international regulatory agencies. Knowledge of ISO 13485 and FDA QSR is desired.
- Strong project management and communication skills.
- Detail-oriented and well organized.

### **Minimum Education:**

- Bachelor's Degree in Computer Science, Computer Engineering, or other appropriate engineering science field.

### **Minimum Experience:**

- 2 years working on Class III medical device embedded software development, or software development or other highly regulated industry.
- For Senior Embedded Software Engineer, 5 years working on Class III medical device embedded software development or other highly regulated industry.
- 3 years programming and test on complex software systems.