**Job Description – Sr. R&D Engineer**

**Reports To – Manager, Biomedical Engineering or Chief Technology Officer**

## Job Responsibilities

This position is responsible for contributing to the R&D activities of specific product(s) in accordance with the company's Quality System and customer requirements. This position supports in obtaining regulatory approval and complies with the Quality System by engaging in appropriate levels of GMP/ISO test methodologies, adherence to Quality System Design Controls, and applies proper documentation practices.

## General Description and Duties:

*To perform this job successfully, an individual must be able to perform each essential task satisfactorily. The tasks listed below are representative of the knowledge, skill, and/or ability required to perform this job effectively.*

- **Technical Competence:** Works as part of a project team and may own a segment of the project, with complexity varying according to the engineering level. Conduct research, design, and development of new processes and products/procedures enhancements. Contribute to statistical analysis methods, test methodologies, process, and equipment design. Furthermore, the senior-level may lead or manage technical projects and influence technical decision-making. Individuals in these roles are expected to efficiently handle problems, demonstrate creativity in solutions, and independently apply specialized knowledge to solve technical challenges, often under complex constraints.
- **Document Development:** Assists in the development of documents in accordance with industry standards, regulatory requirements, and product specifications. The senior-level is anticipated to manage document matrix, lead document development with support from different stakeholders.
- **Testing and Validations:** Performs testing, analyzes data, and writes technical documents in accordance with good documentation practices and regulatory requirements.
- **Cross-functional Collaboration:** Works closely with internal teams (engineering, operations, quality, and marketing) and external partners (vendors, consultants, and regulatory bodies) to prepare, support, and conduct R&D activities as required. The senior-level is expected to provide technical training to junior engineers and technicians as needed.
- **Quality System and Regulatory Acceptance:** Possesses an understanding of the Quality Management System (QMS), adheres to and applies QMS principles and standards to daily engineering tasks. Delivers engineering testing and documentation in line with regulatory requirements for the approval of products by U.S. and international regulatory agencies. Engages in and contributes to the risk assessment process.
- **Safety:** Performs job functions in a safe and effective manner.

## Position Qualifications

- Ability to develop prototype parts and products on the lab workbench or in software simulation environment (e.g., SolidWorks, CST, Ansys).
- Ability to search, review, and analyze public information, including journal articles and patents, to assess state of the art and current solutions.
- Ability and patience to analyze, debug, and optimize the assigned project/product modules.
- Ability to use Windows Office tools for recording/presenting data. Advanced data processing or programming skills using MATLAB, Python, or other similar languages are preferred.
- Excellent communication skills, both written and verbal.
- Ability to travel both domestically and internationally.
- Ability to work independently with minimal supervision while maintaining accountability. Quick learner with strong adaptability to evolving project requirements. Self-motivated, proactive, and capable of delivering results within set deadlines.
- Passion and desire to work for a market-changing medical device manufacturer.

## Minimum Education:

- Bachelor's Degree in electrical, biomedical, mechanical, or relevant engineering field.
- Master's degree or PhD is preferred.

## Minimum Experience:

- 0-5 years of experience in related engineering/manufacturing of Class II or III medical device is preferred, based on the engineering level. Equivalent experience in other regulated environments is acceptable.
- Prior medical device R&D experience is preferred, but not required.