

Employee Name: Employee Name

Start Date: Date

Department: Product Development and Component Development

Employee Status: Full-time Part-time Temporary Intern

FLSA Status: Exempt Non-Exempt

Job Summary

Design and development of new products and modifications to existing products. Activities may include product design and development, technical management, personnel management, methods / process development, design modeling, tooling design/fabrication, equipment design/fabrication, design verification and validation, and documentation.

Essential Functions

- Manage product development programs with minimal oversight.
- The role has overall responsibility for project planning, scheduling, and assigning work direction to team members. This individual will lead efforts for product design and testing assuring compliance with the company's QMS and applicable regulatory requirements, lead the execution of clinical builds and participate in manufacturing transfer to operations.
- Interface directly with customers to ensure their needs are being met.
- Communicate program progress and critical decisions to company management.
- Design and implement new products based on customer specifications.
- Develop product requirements and specifications based on customer needs and applicable guidelines (industrial and government guidelines and/ or standards).
- Specify and develop tests for product testing determining acceptability of designs to requirements.
- Perform data analysis (statistical and practical) and develop appropriate action plans based upon such analysis.
- Develop tooling and fixturing for product assembly and testing.
- Support pre-clinical testing.
- Serve as a technical resource to other departments as needed.
- Follow company policies and procedures.
- Identify opportunities for productivity and quality improvements.
- Support company finance, accounting, human resources, quality, regulatory, and clinical departments as necessary to ensure compliance with requirements.
- Follow company policies and procedures

- Functional Knowledge
- Experience leading design & development of mechanical aspects of IPG's and/or other active implantable required.
- Familiarity with key suppliers for common implantable pulse generator components such as cans and feedthroughs highly desired.

Education, Experience, Required Skills

- Bachelor's degree in an engineering field (equivalent work experience may be considered)
- Master's degree or higher recommended
- Ten years of medical device industry experience with strong strategic focus in the areas of Product and Process development would be ideal but not required.
- Experience with programs including SolidWorks and/or Mastercam
- MS Office Proficiency
- Strong problem-solving skills to identify, gather, and analyze information develop solutions and resolve problems in a timely manner
- Must have knowledge of machining and assembly practices, tools and fixturing (plastic and/or metal preferred)
- Proficiency in 3D CAD Software (preferably Solidworks). In addition to fixture design, must also be able to open, view and manipulate assemblies
- Demonstrated ability to implement change, in a way that positively impacts overall department and company performance
- Must be able to handle multiple projects simultaneously
- Must excel at working in a team environment with a high level of people/interpersonal skills and demonstrated ability to cross functionally drive results
- Must be willing to work in lab, machine shop, and clean room environments to support project work.
- Must have excellent time management skills.
- Excellent written and verbal communication skills
- Ability to handle and be trusted with confidential and/or sensitive information.
- Able to work in a fast-paced, constantly changing environment.
- Ability to be flexible and to handle multiple projects in an organized, timely manner.
- Able to problem-solve, work under pressure, and to effectively manage stress.
- Ability to work overtime if needed
- Ability to travel to support projects and customer requirements

Physical Requirements

- Prolonged periods of sitting at a desk and working on a computer.
- Must be able to lift up to 25 pounds at times.
- Must wear gown, gloves, and ear protection if applicable.

Authority and Responsibility

Accountable for their performance and will have authority as delegated to complete their tasks and objectives.

DISCLAIMER

The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not to be construed as an exhaustive list of all responsibilities, duties, and skills required of personnel so classified. All personnel may be required to perform duties outside of their normal responsibilities from time to time, as needed.

I have reviewed and determined that this job description accurately reflects the position.

Reviewed by: _____
Employee Date

Reviewed by: _____
Manager Date