## MANUFACTURING ENGINEER

JOB DESCRIPTION

## Position Summary

The Manufacturing Engineer plans, assembles and tests new and innovative products as a primary team member on the Operations team. Responsible for organizing and hands-on assembling highly complex medical device product involving electrical, mechanical and optical components and subsystems. The position also requires the team member to acquire operational working knowledge and know-how in process and manufacturing controls, intersystem dependency, manufacturing and assembly, software tool and equipment use, test and measurement, field services, documentation and reporting.

## Essential Duties and Responsibilities

The essential functions include, but are not limited to the following:

* Machine, build, assemble and test performance of engineering prototypes, iterations, and subsequently DVT & clinical builds to support clinical trials; wherever relevant, machine, build, assemble and verify performance of test fixtures to support manufacturing builds.
* Adhere to Clients Environmental Health and Safety and Quality guidelines as they relate to department clean room medical device manufacturing
* Work collaboratively with R&D and QA in developing, evaluating/testing, documenting, improving and implementing manufacturing processes/methods, tooling and fixtures; support transitioning investigational device through product development to manufacturing/production; support manufacturing and process optimization.
* Collect data and analyze process performance and capabilities for company products, including new products and products already in production; perform tolerance analysis for components, manufacturing materials, packaging, and supplies used for in-house processing.
* Lead effort to develop and maintains process Failure Modes and Effects Analyses (pFMEAs) for engineering processes; prepare user requirements, technical specifications, and design specifications; identify process requirements, advise and support operations management, and implement equipment and fixturing needed for process development and manufacturing efforts.
* Develop and maintain documentation for design control, product configurations, manufacturing procedures, lot history records, (e.g., bills-of-materials, Product Specifications, Assembly Instructions/MPI’s, FA’s, FG’s, DMR’s), and other Quality System requirements.
* Document all other observations and results in Company’s issued notebook.
* Lead and/or actively participate in product/process engineering problem solving; lead and/or actively participates in process/product improvement projects (in cooperation with R&D and QA).
* Assist procurement with supplier selection and interface with vendors.
* Recommend new technologies to improve system performance and reliability. Performs productivity and costing analyses (e.g., calculate direct labor, time studies & materials costs for new and existing products), providing solutions that improve efficiency and scalability for years to come.
* Identify opportunities and implement cost reduction plans for existing products.
* Support the transfer of product lines and the qualification-validation efforts.
* Perform other work-related duties as assigned

## Minimum Qualifications (Knowledge, Skills, and Abilities)

* Bachelor’s degree in Manufacturing Engineering, Biomedical Engineering, Electrical Engineering, Electromechanical Engineering or Aerospace Engineering
* Minimum of 5-10 years of related experience
* Experience with Solidworks, 3D printing, and hands-on mechanical and electrical engineering skills
* Prior experience in cardiovascular interventions and optical engineering experience a plus
* Self-motivated, independent and collaborative; the ability and willingness to work in a fast-paced environment while managing multiple priorities and meeting development schedule without close supervision.
* Knowledge of and compliance with applicable Quality System requirements such as QSRs, FDA, ISO, MDD and other applicable regulations.
* Experience and understanding Process Validations (IQ, OQ, PQ), Six Sigma, and Lean Manufacturing
* Advanced problem-solving, organizational, analytical and critical thinking skills, with strict attention to detail and the ability to identify technical gaps and taking action to address them
* Ability to translate complex and technical information to all levels of the organizations, communicate and recommend course of action after considering potential risks of alternatives
* Excellent documentation and communication skills and interpersonal relationship skills including negotiating and relationship management skills
* Acceptance to be overseen by managers and more senior team members, while also the ability and willingness to supervise others in resolving complex issues in specialized area based on existing solutions and procedures
* Ability to provide guidance for the successful completion of major projects and may function in a project leadership role

## Physical Demands and Work Environment

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this position. Reasonable accommodations may be made to enable individuals with disabilities to perform the functions. While performing the duties of this position, the employee is regularly required to talk or hear. The employee frequently is required to use hands or fingers, handle or feel objects, tools, or controls. The employee is occasionally required to stand; walk; sit; and reach with hands and arms. The employee must occasionally lift and/or move up to 50 pounds. Specific vision abilities required by this position include close vision, distance vision, and the ability to adjust focus. The noise level in the work environment is usually low to moderate.

## Note

This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Employees will be required to follow any other job-related instructions and to perform any other job-related duties requested by any person authorized to give instructions or assignments. All duties and responsibilities are essential functions and requirements and are subject to possible modification to reasonably accommodate individuals with disabilities. To perform this job successfully, the incumbents will possess the skills, aptitudes, and abilities to perform each duty proficiently. Some requirements may exclude individuals who pose a direct threat or significant risk to the health or safety of themselves or others. The requirements listed in this document are the minimum levels of knowledge, skills, or abilities. This document does not create an employment contract, implied or otherwise, other than an “at will” relationship.