



Healing today. Curing tomorrow.

Job Title : Mechanical Engineer / Senior Mechanical Engineer
Department : Research & Development
Reports To : VP - Research & Development
FLSA Status : Exempt

Position Summary:

The Mechanical Engineer / Senior Mechanical Engineer will be responsible for developing and delivering Class III medical products that meet customer needs and regulatory requirements, while achieving the business goals of the company. The Mechanical Engineer / Senior Mechanical Engineer will act as the lead mechanical R&D engineer and provide technical direction in the development and design of medical devices in an FDA regulated environment.

Essential Duties and Responsibilities:

- Defines and establishes technical requirements for new products based on customer and marketing input and regulatory requirements.
- Uses CAD software and other tools to develop product concepts and deliver complete design packages to meet product and regulatory requirements.
- Conducts formal design reviews, writes test protocols, performs testing and generates engineering reports to demonstrate and verify that the product design meets the product requirements.
- Interacts with external development partners, test agencies and contract manufacturers to meet project goals and schedules.
- Follows internal policies and procedures to complete work assignments and comply with FDA/QSR design controls for the development of durable medical devices and disposables.
- Applies his/her extensive and diversified knowledge of engineering principles and practices in broad areas of assignments and related fields. Serves as the technical expert for the organization in the application of advanced theories, concepts, principles, and processes for an assigned area of responsibility.
- Researches and investigates new technology, components, materials and processes that can be applied to future generation products.
- Develops and documents new intellectual property for the company that will help maintain a strong market presence in various therapy areas.
- Develops and validates testing fixtures to support production.
- Leads assigned engineering projects and tasks. Should technically supervise, coordinate and review the work of a small staff of engineers and/or technicians, estimates manpower needs and schedules and assigns work to meet completion date.
- Responsible for the evaluation, purchase or design of equipment that meets health, safety and environmental standards set by the company.
- Responsible for ensuring personal and company compliance with all Federal, State, local and company regulations, policies and procedures for Health, Safety and Environmental compliance.
- Other duties may be assigned.

Education and Experience:

- BS in Mechanical Engineering or closely related discipline. A graduate degree in the field of Engineering would be an asset.
- 6 or more years in the design and development of high technology products with at least 3 years experience developing FDA Class II or III medical devices.
- Experience with the complete product development lifecycle of complex electromechanical equipment. Must prove that have worked and successfully finished at least two new product development projects that went through complete product development cycle i.e. Concept to Market.
- Project management experience is desired and must have the ability to manage several projects concurrently.
- Experience with the design, development and validation of medical disposables and packaging.
- Must have a thorough understanding of the wide array of materials and manufacturing processes commonly used in the construction of medical electronic products, precision mechanisms and enclosures. Experience should include hands-on development of components constructed of injection molded plastics, precision sheet metal, metal castings, machined parts, motors and drives, electronic modules, power supplies and cables.
- Knowledge of ASME Y14.5 and other established drawing standards is a must. Proficient with using MCAD applications to develop complex product designs. SolidWorks strongly preferred.
- Must have a clear understanding of theoretical and practical fundamentals in science and mechanical engineering, as well as experimental engineering techniques.
- Must have ability to write clear and thorough development documentation per medical industry/FDA requirements.
- Hands-on experience in the lab with constructing and debugging prototypes. Experience with using measurement equipment, operating LabVIEW and DAQ systems is desirable.
- Must have the ability to perform engineering analysis of design and complex assemblies for tolerances and manufacturability. Exposure to device manufacturing environment is a plus.
- Experience using Finite Element Analysis (FEA) and CFD analysis tools to reduce time to market and develop safe and reliable products.
- Should have knowledge of statistics as applied in engineering work.
- Excellent verbal / written communication and presentation skills
- Knowledge of the human anatomy is a plus.
- Significant experience with developing products to meet the regulatory requirements of the FDA, UL, CE, FCC, IEC, AAMI, ISO and other regulatory authorities. Must be able to demonstrate a thorough understanding of the FDA/QSR design control process for medical devices.

Physical Requirements:

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. While performing the duties of this job, the employee occasionally works near moving mechanical parts and is occasionally exposed to risk of electrical shock. The employee may be required to work in a clean-room environment and is required to wear special garments in such situations. The employee is occasionally required to use hands to finger, handle, or feel objects, tools, or controls and reach with hands and arms. Specific vision abilities required by this job include close vision. The employee should be able to travel up to 20% of her/his time.

The noise level in the work environment is usually moderate.