



JOB DESCRIPTION

Title: Principal Mechanical Engineer
Department: Research & Development
Reports to: Vice President, Research & Development
FLSA Status: Exempt
Effective Date: March 11, 2011
Revised Date:

Summary

Responsible for technical development and design of NeoMend medical devices, with a primary focus on surgical sealant delivery systems design.

Essential Duties and Responsibilities

- Directly responsible for development and design of innovative delivery system platforms to support market needs across an array of hydrogel products, including but not limited to:
 - Planning and administration of delivery system design efforts through all phases of product development (concept to full commercialization);
 - Prototype product design, development and testing;
 - Pre-clinical and clinical product evaluations;
 - Commercial and industrial design integration; and
 - Design Verification & Validation protocol development, testing and report writing.
- Leads designated multi-functional product development teams.
- Conducts design reviews and performs failure mode and effects analysis.
- Participates as Principal Mechanical Engineer in designated development teams.
- Interfaces with Manufacturing in the development of production assembly processes to support commercialization of design concepts.
- Establishes requirements necessary to maintain FDA, ISO and CDMR compliance.
- Performs special projects and other duties as assigned.

Education, Experience, & Skills

- Bachelor of Science degree in Mechanical or Biomedical Engineering (B.S.M.E.).
- Minimum of ten (10) years experience in Medical Device Design in New Product Development.
- Expertise in developing New Technology (*Revolutionary* development, not *Evolutionary* development), from product conception through to commercialization, bringing a brand-new platform to market for the company.
- Extensive experience with all aspects of the product development cycle including developing concepts, feasibility studies, project planning, prototype design, documentation, DOE, testing, analysis and reporting.
- Proven track record of success in developing innovative, technologically advanced devices.
- Proficient in Solidworks; expertise in Matlab and/or Labview a plus.
- Experience developing experimental studies, DOE, and analysis of experimental results.
- Experience with injection molded parts design.
- Experience with ISO / FDA Quality System Requirements and guidelines.



Education, Experience, & Skills (continued)

- First-hand knowledge of materials and fabrication techniques.
- Experience with small scale fluidics, fluid dynamics and/or Computational Fluid Dynamics (CFD) software (such as STAR-CCM+) and analysis background is a plus.
- Experience with FEA a plus.
- Experience with small gas-assist pressure-delivery devices, preferably for hand-held medical devices and/or medical adhesive delivery systems is preferred.
- General knowledge of MS Office, PowerPoint, Excel.
- Strong organizational and communication skills.

Abilities/Attributes

- Highly analytical and hands-on.
- Detail-oriented.
- Ability to assume complete responsibility (take complete ownership).
- Results-oriented, good at setting priorities and staying focused.
- Hard-working, driven, self-starter, self-motivated, a 'can-do' / 'whatever it takes' attitude.
- A team player with a positive attitude.
- Strategic focus towards solution of problems.

Physical Demands

The physical demands described here are representative of those that must be met by an employee to successfully perform 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 is regularly required to stand, walk, and sit for extended periods of time. Occasionally the employee will be required to lift or move at least 25 pounds. Approximately 10% travel.

Employee signature _____

Date _____

Print Name _____

Approved by Nicole Emergen

Date 09/12/2011