

ChoiceSpine

Job Description

Job Title: Senior Product Development Engineer

Department: R&D
Location: Knoxville, TN
Reports To: Senior Manager of R&D
Shift: First
FLSA Status: Exempt
Prepared By: Jayden Garfield
Prepared Date: 21 Nov 2019
Approved By:
Approved Date:

SUMMARY

Under minimal supervision, primarily responsible for the design and development of new products/product families and/or the enhancement of existing products. Involved in creating designs, modeling and drafting, leading and managing development projects. Other responsibilities include assisting in the development processes for Manufacturing, Quality, Regulatory and Planning for projects from conceptualization through full market launch.

PRIMARY RESPONSIBILITIES

- Research, develop, and design spinal implants & instruments. New Product Development as well as maintenance of existing legacy systems.
- Independently lead and timely execution of complete project deliverables.
- Ensure continual improvement in quality, delivering higher value services.
- Lead the entire product development process including concept design, supplier selection, testing, design finalization, verification/validation activities, transfer, and launch support.
- Managing partnerships with vendors and other entities as needed.
- Communicating effectively across all project disciplines and cross functional teams to ensure project team and senior management are aware of upcoming milestones and risks/issues.
- Perform detailed design work and creation of drawings using SolidWorks.
- Conduct static and fatigue stress analysis on developed designs using FEA.
- Manage documentation requirements for system Design History Files.
- When requested, provide assistance and technical expertise to other areas of the organization including, but not limited to Sales, Marketing, Quality, Regulatory, Purchasing, Customer Service and senior management.
- Collaborate & offer background, knowledge, & expertise with other Group staff.
- Follow organizational & group guidelines, procedures, protocols.

QUALIFICATIONS

- CAD experience required (SolidWorks preferred).
- Familiarity with product development cycle and phased/gate approach.
- Knowledge of general manufacturing processes, and familiar with common materials and practices to produce medical devices.
- Experience with GD&T, stack-up analysis, and mechanical testing.
- Exposure and knowledge of ASTM, ISO, FDA standards, regulations, and guidelines.
- Be comfortable with autonomy of responsibility in addition to a team environment.
- Be adept and flexible to manage multiple tasks at once while keeping to the set schedule of each task.
- Capable of presenting and sharing information with management, surgeons, and/or field personnel when requested (PowerPoint skills preferred).
- Project Management planning experience preferred (MS Project, Smartsheet, etc.)
- Spinal Implant and Instrumentation design experience required.

EDUCATION and EXPERIENCE

BS in Mechanical Engineering or Biomedical Engineering, and at least 5 years of medical device experience required.

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 sit and talk or hear. The employee is occasionally required to stand, walk, use hands to finger, handle, or feel and reach with hands and arms. The employee must occasionally lift and/or move up to 25 pounds.

WORK ENVIRONMENT

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.

Working environment is typical of an office environment. The noise level in the work environment is usually moderate.