ChoiceSpine
Job Description

Job Title: **Product Development Engineer**

Department: R&D
Location: Knoxville, TN (not remote)
Reports To: Engineering Manager
Shift: First
FLSA Status: Exempt

SUMMARY

Under routine guidance, primarily responsible for the design and development of new spinal products/product families and/or the enhancement of existing products. Involved in creating designs, modeling and drafting, utilizing a 3D CAD system. Other responsibilities include assisting in the development process with Marketing, Purchasing, Manufacturing, Quality, and Regulatory to help complete delegated tasks from project conceptualization through full market launch.

PRIMARY RESPONSIBILITIES

- Research, develop, and design spinal implants & instruments in accordance with FDA and ISO requirements. New Product Development as well as maintenance of existing legacy systems.
- Support identification and timely execution of product development process and project deliverables including concept design, testing, design finalization, verification/validation activities, transfer, and launch support.
- Execute development activities of complex line extensions and special instrument modifications in an abbreviated schedule with assistance of Senior Engineering Staff
- Create designs using CAD (SolidWorks) intended for both subtractive and additive manufacturing methods. Generate 3D part files, 3D assembly files, & 2D technical drawings.
- Write protocols, execute, analyze test data, and generate reports to verify or validate that designs meet functional and performance specifications, including interactions with outside testing facilities.
- Generates and manages the Change Order process for initial release & revision of device related changes, including potential impacts on current design inputs, risk, and relevant controlled documents in the system Design History File.
- Competent interface with ALL customers (Surgeons, Distributors, FDA, Manufacturers, Consultants, Etc.) to discuss design inputs, functional instruction, and current challenges for new product development as well as legacy systems.
- Collaborate with senior engineering and cross functional departments to identify and ensure project team and senior management are aware of upcoming milestones and risks/issues.
- Utilize in-house rapid prototyping and interface with suppliers to provide support during the manufacturing process.
- Review and approve product Inspection Standards, overlays, and gauges in collaboration with the Quality department.
- Comfortably provide technical assistance to other areas of the organization including, but not limited to Sales, Marketing, Quality, Regulatory, Purchasing, Sales Support and Executive Management.
- Conduct static and fatigue stress analysis on developed designs using FEA including interpretation of results.
- Collaborate & offer background, knowledge, & expertise with other Group staff.
- Follow organizational & group guidelines, procedures, protocols.
- Assist senior engineering staff and patent counsel to prepare invention records and assist in the patent submission process.
- Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities, and activities may change at any time with or without notice.

EDUCATION and EXPERIENCE

- BS in Mechanical Engineering or Biomedical Engineering or equivalent
- 3-6 years of experience preferred.
- Product development experience preferred.
- Spinal or Orthopedic Implant design experience preferred.

QUALIFICATIONS

- Proficiency with CAD software required (SolidWorks preferred).
- Working knowledge & experience with product development cycle and phased/gate approach of small projects.
- Familiarity of general manufacturing processes and common materials used to produce medical implants and instruments. Familiarity with Additive Manufacturing preferred.
- Experience with GD&T, stack-up analysis, and mechanical testing preferred
- Exposure and familiarity of relevant ASTM, ISO, FDA standards, regulations, guidelines.
- 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).
- Ability to read, write, and interpret technical documents such as engineering drawings, regulations, company policies and procedures.
- Competent in basic science and engineering principles including physics, algebra, statistics, the ability to understand and solve technical problems, collect and analyze data, draw valid conclusions and communicate findings.
- Familiarity with Project Management planning preferred (MS Project, Smartsheet, etc.)
- Experience in the identification and investigation of issues, proposals of appropriate solutions, and implementation aid to resolve the problem.

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.