

# ChoiceSpine

## Job Description

**Job Title:** Senior Product Development Engineer

**Department:** R&D  
**Location:** Knoxville, TN (not remote)  
**Reports To:** Director of Engineering

**Shift:** First  
**FLSA Status:** Exempt

### SUMMARY

Under minimal supervision, 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 manage the project deliverables from 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.
- Lead identification and timely execution of complete product development process and project deliverables including concept design, testing, design finalization, verification/validation activities, transfer, and launch support.
- Execute development activities of multiple line extensions and special instrument modifications in an abbreviated schedule simultaneously.
- 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.
- Generates and manages the Change Order process for initial and updated revisions of appropriate Quality Management System documents and processes.
- Identify and collaborate on improvement of company and group policies, capacities, and direction.
- Primary 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.
- Communicate effectively across cross functional teams 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.
- Competently provide technical assistance to other areas of the organization including, but not limited to Sales, Marketing, Quality, Regulatory, Purchasing, Sales Support and Executive Management.
- Routinely 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.
- Work with clients 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
- 5+ years of experience required.
- Product development experience required.
- Spinal or Orthopedic Implant design experience preferred.

## **QUALIFICATIONS**

- Experience and Proficiency with CAD software required (SolidWorks preferred).
- Full working knowledge & experience with product development cycle and phased/gate approach of small to medium projects.
- Knowledge of general manufacturing processes, and familiarity with common materials and practices to produce medical implants and instruments. Experience with Additive Manufacturing preferred.
- Experience with GD&T, stack-up analysis, and mechanical testing.
- Experience and knowledge relevant ASTM, ISO, FDA standards, regulations, guidelines.
- Successful 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).
- Capable of presenting and sharing information with management, surgeons, and/or field personnel when requested (PowerPoint skills preferred).
- Proficiency in 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.
- Experience with Project Management planning preferred (MS Project, Smartsheet, etc.)
- Competency in the identification and investigation of issues, determination of appropriate solution, and implementation 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.