

ChoiceSpine

Job Description

Job Title: Product Development Engineer

Department: R&D

Location: Knoxville, TN

Reports To: Director of Product Development

Shift: First

FLSA Status: Exempt

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Prepared Date: 12 Feb 2021

Approved By: Steve Ainsworth

Approved Date: 16 Feb 2021

SUMMARY

ChoiceSpine is seeking a Product Development Engineer that will be responsible for the design and development of new spinal medical device products/product families and/or the enhancement of existing products. The Product Development Engineer will be involved in creating designs, 3D models, and drawings utilizing SolidWorks. Other responsibilities include assisting in the development process with cross functional teams including Marketing, Purchasing, Manufacturing, Quality, and Regulatory to help manage their project from conceptualization through full market launch.

PRIMARY RESPONSIBILITIES

- Research and develop spinal implants and instruments in accordance with FDA and ISO requirements.
- Create designs using CAD (SolidWorks) intended for both subtractive and additive manufacturing methods.
- Create 3D part files and 2D technical drawings using SolidWorks and Adobe Acrobat.
- Write protocols, execute, analyze test data, and generate reports to verify or validate that designs meet functional and performance specifications.
- Interact and coordinate with senior engineering and cross functional departments to establish project plans, product requirements, and other documentation activities in accordance with design control and risk management procedures.
- Provide assistance to the Sales, Marketing, and Sales Support departments as needed.
- Utilize in-house rapid prototyping and interface with suppliers to provide support during the manufacturing process.
- Follow organizational and group guidelines, procedures, protocols.

EDUCATION and EXPERIENCE

- BS in Mechanical Engineering, Biomedical Engineering, or related technical discipline
- 4-6 years of experience in a technical field required.
- Product development experience required.
- Spinal or Orthopedic Implant design experience preferred.

QUALIFICATIONS

- Proficiency with CAD software required (SolidWorks preferred) and Microsoft Office suite
- Familiarity with product development cycle and phased approach.
- Knowledge of general manufacturing processes, and familiar with common materials and practices to produce medical devices.
- Ability to read, write, and interpret technical documents such as engineering drawings, regulations, company policies and procedures.
- Proficiency and knowledge in basic science and engineering principles including physics, algebra, geometric dimensioning and tolerancing, basic statistics, tolerance analysis and the ability to understand and solve technical problems, collect and analyze data, draw valid conclusions and communicate findings.
- 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

PHYSICAL DEMANDS

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 handle or feel; and reach with hands and arms. The employee must occasionally lift and/or move up to 25 pounds.

WORK ENVIRONMENT

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

The physical demands and 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.