

Job title

Product Development Engineer

Edit

Company

WishBone Medical, Inc

Edit

Job location

100 Capital Drive
Warsaw, IN 46580

Edit

Visible on job post: No
Remote work allowed: No

Advertising location

Warsaw, IN 46580

Job Type

Full-time

Edit

Job description

Job Description

Edit

JOB TITLE: Product Development Engineer

BUSINESS DIVISION: WishBone Medical **Status:** Full-time

DEPARTMENT NAME: Engineering & Design **Type:** Exempt

PREPARED BY: Human Resources **DATE:** 05/20/21

• **SUMMARY:** The position is responsible for design and development of medical instruments (single-use and reusable), implants, and/or packaging from concept through market introduction, and ensuring that designs meet performance specifications, regulatory and manufacturing requirements.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following. Other duties may be assigned.

- Design and develop medical instruments (single-use and reusable), implants, and/or packaging from concept through market introduction. Ensure that designs meet performance specifications, regulatory and manufacturing requirements.
- Generate innovative concepts for new medical device designs to satisfy clinical requirements. Lead and participate in concept generation activities, including brainstorming sessions.
- Manage product development projects and ensure that tasks are completed within the planned time.
- Track projects to project plans. Proactively report project status to personnel.

- Develop CAD models and drawings of medical instruments (single-use and reusable), implants, and/or packaging. Includes component, subassembly, and top-level drawings.
- Work with surgeons, marketing and sales to define and refine design inputs, generate design concepts and prototypes independently, perform meaningful and timely design evaluations (such as tolerance analysis, FEA, simulated use testing, dry labs and wet tissue labs etc.), and oversee generation of documentation of clinical and surgical technique observations to create meaningful design solutions.
- Maintain Design History Files (DHF) per company procedures. Ensure that DHFs are accurate, complete and well organized.
- Conduct risk analysis activities and complete related forms – including Risk Plans, DFMEA,
- Risk/Benefit Assessments, Risk Reports, and others as needed – for products under development and post-production as required.
- Perform and document tolerance analysis of components and assemblies to ensure proper fit and function.
- Develop prototype devices for testing, and for evaluation during verification and validation phases. Work with internal and/or external resources to produce prototype device components.
- Conduct and/or monitor product verification and validation testing to demonstrate product safety and efficacy. Determine which testing is required to satisfy product requirements, to investigate potential failure modes, and to otherwise address the project design inputs.
- Develop protocols, plan testing, and perform or monitor testing. Utilize statistical methods

Job Description – Product Development Engineer as required to plan testing and to analyze test results. Write test reports which draw conclusions from the results.

- Ensure that all work satisfies the requirements of the company's Quality Manual, with particular emphasis on Design Control.
- Conduct Design Reviews as specified in project plans, and in accordance with company procedure.
- Prepare documentation release packages, including detail drawings, bills of material, and/or procedures. Approve Document Change Orders (DCOs) and/or Engineering
- Change Orders (ECOs) and obtain approvals from others as required.
- Participate in Material Review Board activities. Make decisions regarding product and material discrepancies and initiate appropriate action to prevent subsequent problems or discrepancies.

MARGINAL/LESS ESSENTIAL JOB FUNCTIONS

- Flexibility in dealing with more than one project at a time;
- Ability to meet deadlines; dependable and self-directed;
- Capable of working in fast-paced team environment;
- Excellent oral and written communication skills
- Experience with Siemens NX preferred.

QUALIFICATION REQUIREMENTS

Minimum BS degree in one of the following engineering disciplines (3-5 yrs experience): Mechanical Engineering, Biomedical Engineering, Bio-engineering, or Biomedical Engineering Technology.

Experience developing external fixation devices.

Ideally should have software experience.

3 years medical device experience.

Travel requirements: Up to 5% long-distance travel (i.e. by plane).

The above description is intended to describe the general content, identify the essential functions of, and requirements for the performance of this job. It is not to be construed as an exhaustive statement of duties, responsibilities or requirements.

Applicant Qualifications

[Edit](#)

You have requested that Indeed ask candidates the following questions:

- Please list 2-3 dates and time ranges that you could do an interview.

Language

English

Edit

Expected Hiring Date

2 to 4 weeks

Edit

Hires Needed

1

Edit

Schedule

8 hour shift, Monday to Friday

Edit

Application settings

Apply method: **Email**
Send updates to: **marywetzels@wishbonemedical.com**
Employer Assist: **14 days**

Edit

Do you want applicants to submit a resume? **Yes**
Do you want to let applicants start the conversation? **Yes**

Selected Assessment Types

Work motivation, Project timeline management

Edit

Job Budget

[Sponsor this job for more candidates](#)

By clicking "Confirm", you agree to candidates appearing in your dashboard based on the preferences you've selected above. You also agree to our [Indeed Terms of Service](#).

Cancel

View Preview

Confirm