



Job Description

JOB TITLE: Principal Product Development Engineer	
BUSINESS DIVISION: WishBone Medical	Status: Full-time
DEPARTMENT NAME: Engineering & Design	Type: Exempt
PREPARED BY: Human Resources	DATE: 06/01/2020

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.

- Plan multiple projects simultaneously. Estimate, track, and complete projects on time
- 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 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.
- People Management
 - Lead groups of Development Engineers and Designers as required
 - Provide guidance to other team members
 - Train both team and broader organization members

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
- CAD experience with Siemens NX preferred.

QUALIFICATION REQUIREMENTS

Minimum BS degree in one of the following engineering disciplines (7-10 yrs experience): Mechanical Engineering, Biomedical Engineering, Bioengineering, or Biomedical Engineering Technology

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 frequently is required to stand; walk; and use hands to finger, handle, or feel objects, tools, or controls. The employee is occasionally required to reach with hands and arms. The employee must occasionally lift and/or move up to 20 pounds.

WORK ENVIRONMENT: Associate will normally work in an office environment but may also be subject to high noise levels from machines, and physical hazards from moving machine parts.

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

REVIEWED AND APPROVED BY:

<i>HUMAN RESOURCES MANAGEMENT</i>	<i>Associate</i>
NAME:	NAME:
TITLE:	TITLE:
REVIEW DATE:	REVIEW DATE:

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.