Job Description

JOB TITLE: PRODUCT DEVELOPMENT MANAGER	
BUSINESS DIVISION: WISHBONE MEDICAL INC	**Status:** FULL-TIME
DEPARTMENT NAME: NEW PRODUCT DEVELOPMENT	**Type**: FULL-TIME
PREPARED BY: HUMAN RESOURCES	**DATE**: 1/25/2022
WORK LOCATION: CORP - WARSAW	**REPORTS TO:** DIRECTOR OF PRODUCT DEVELOPMENT

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

ESSENTIAL DUTIES AND RESPONSIBILITIES: *(includes the following but other duties may be assigned)*

- Manage and complete work duties arising from assigned projects related to product development
- Lead group of Product Development Engineers including training, mentoring, and career development
- Product Owner for new product development projects using Agile Scrum format. Create and manage project backlogs and user stories. Create and manage project release burndowns and proactively report project status to personnel for multiple projects simultaneously
- Oversee design and development of medical implants, single-use and reusable instruments, and/or packaging from concept through market introduction. Ensure that designs meet performance specifications, regulatory, and manufacturing requirements
- Work with surgeons, marketing, and sales to define and refine design inputs, generate design concepts and prototypes independently, perform meaningful and timely design evaluations, including tolerance analysis, FEA, simulated use testing, dry labs, and wet tissue labs, and oversee generation of documentation of clinical and surgical technique observations to create meaningful design solutions
- Generate innovative concepts for new medical device designs to satisfy clinical requirements. Lead and participate in concept generation activities, including brainstorming sessions
- Ensure that DHFs are accurate, complete, and well-organized
- Conduct and review risk analysis activities and complete related forms, including risk plans, DFMEA, risk/benefit assessments, risk reports, and others, as needed
- Perform and review tolerance analysis of components and assemblies to ensure proper fit and function
- Conduct and/or monitor product verification and validation testing to demonstrate product safety and efficacy
- 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
- Approve Document Change Orders (DCOs) and/or Engineering Change Orders (ECOs) and obtain approvals from others, as required
- Participate in Material Review Board activities and make decisions regarding product and material discrepancies and initiate appropriate action to prevent subsequent problems or discrepancies

QUALIFICATION REQUIREMENTS:

- Minimum BS degree in Mechanical Engineering, Biomedical Engineering, Bioengineering, or Biomedical Engineering Technology, or related field
- 7-10 years' experience in one of these disciplines
- Excellent oral and written communication skills
- Ability to lead cross-functional teams in more than one project at a time
- Ability to mentor and train other product development engineers
- GD&T and CAD experience with Siemens NX preferred
- Ability to meet deadlines; dependable, and self-directed
- Capable of working in fast-paced team environment

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 accommodation 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 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:

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.

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. WHEN OVERTIME IS SCHEDULED, IT IS MANDATORY.

REVIEWED AND ACCEPTED BY:

MANAGER	***ASSOCIATE***
NAME:	**NAME:**
SIGNATURE:	**SIGNATURE:**
TITLE: Director, Product Development	**TITLE:** Product Development Manager
DATE:	**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.