



Job Description

JOB TITLE: PROJECT MANAGER	
BUSINESS DIVISION: WISHBONE MEDICAL INC	Status: FULL-TIME
DEPARTMENT NAME: NEW PRODUCT DEVELOPMENT	Type: FULL-TIME
PREPARED BY: HUMAN RESOURCES	DATE: 8/18/2021
WORK LOCATION: CORP - WARSAW	REPORTS TO: DIRECTOR, PRODUCT DEVELOPMENT

SUMMARY: The position of Project 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)*

- Plan multiple projects simultaneously and estimate, track, and complete projects on time
- Design and develop single-use and reusable medical instruments, implants, and/or packaging, from concept through market introduction, ensuring 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 and proactively report project status to personnel
- Develop CAD models and drawings of single-use and reusable medical instruments, implants, and/or packaging, including 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, and dry and wet tissue labs, and oversee generation of documentation of clinical and surgical technique observations to create meaningful design solutions
- Maintain Design History Files (DHF) per company procedures, ensuring 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, 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
- Provide technical guidance to other team members

QUALIFICATION REQUIREMENTS:

- Experience in CAD with Siemens NX
- 5-7 years' experience in a related field
- Minimum of a BS degree in Mechanical Engineering, Biomedical Engineering, Bioengineering, or Biomedical Engineering Technology

OTHER SKILLS and ABILITIES:

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

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 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: The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodation 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:

<i>MANAGER</i>	<i>ASSOCIATE</i>
NAME:	NAME:
SIGNATURE:	SIGNATURE:
TITLE: Director, Product Development	TITLE: Senior Product Development Engineer
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.

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