Job Description

JOB TITLE: DESIGN QUALITY ENGINEER	
BUSINESS DIVISION: WISHBONE MEDICAL INC	**STATUS:** FULL-TIME
DEPARTMENT NAME: PRODUCT DEVELOPMENT	**TYPE**: EXEMPT
PREPARED BY: HUMAN RESOURCES	**DATE**: 5/20/2021
WORK LOCATION: CORP-WARSAW	**REPORTS TO:** EVP, PROD DEV, QUALITY & REGULATORY

SUMMARY: The position is responsible for developing, establishing, and maintaining risk management files for all new product development of orthopedic implants, instruments, and packaging. The Design Quality Engineer also participates in CAPA activities, quality initiatives, as well as post-market engineering activities. WishBone Medical is a small start-up and this position will provide an opportunity to make a difference for the company long-term.

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

- Facilitate risk management activities throughout all design phases
- Work with product development and design engineering in the completion of product verification and validation activities
- Work with product development, design, and supplier quality in definition of CTQs
- Apply sound, systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues
- Support development of US FDA submission requirements
- Support all Company initiatives as identified by management and in support of Quality Management Systems (QMS), Environmental Management Systems (EMS), and other regulatory requirements. May serve as coordinator in quality initiatives
- Support Quality Improvement projects for the site, including formal quality efforts such as CAPA, NCMR, and audit responses
- May assist with complaint analysis and trending in support of post-market surveillance
- Supports post market / sustaining engineering efforts on commercialized product
- Support Health Risk Assessments (HRAs) to ensure risk assessment and root cause analysis are consistent across products and systems
- Complies with US Food and Drug Administration (FDA) regulations, other regulatory requirements, Company policies, operating procedures, processes, and task assignments
- Maintains positive and cooperative communications and collaboration with all levels of employees, customers, contractors, and vendors
- Performs other related duties and responsibilities, as assigned

QUALIFICATION REQUIREMENTS

- BS in Engineering (preferred), science or technical field
- 2-5 years' work experience in the medical device industry, preferred
- Experience with FDA requirements 21 CFR 820, knowledge of regulations such as GLP, GMP, ISO 13485 and ISO 14971, as well as other international regulatory requirements, preferred
- Experience in related areas, such as R&D or Manufacturing, may also be applicable if experience includes work responsibilities listed above

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 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.

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

REVIEWED AND APPROVED BY:

MANAGER	***ASSOCIATE***
NAME:	**NAME:**
SIGNATURE:	**SIGNATURE:**
TITLE: EVP, Prod Dev, Quality & Regulatory	**TITLE:** Design Quality 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.