JOB DESCRIPTION

JOB TITLE: DIRECTOR OF QUALITY ASSURANCE	
BUSINESS DIVISION: WISHBONE MEDICAL INC	**STATUS:** SALARY/EXEMPT
DEPARTMENT NAME: QUALITY & REGULATORY	**TYPE**: FULL-TIME
PREPARED BY: HUMAN RESOURCES	**DATE**: 1/11/2022
WORK LOCATION: CORP - WARSAW	**REPORTS TO:** CHIEF TECHNOLOGY OFFICER

SUMMARY:

The Director of Quality Assurance is responsible for managing all facets of quality assurance, including ownership of the Quality Management System for Wishbone Medical. The primary focus is to ensure that the Quality Management System (QMS) and all aspects of quality assurance are compliant to current and future U.S. FDA, ISO, and MDR Standards and Regulation for Medical Devices, including sterile packaging for WishBone products. As WishBone Medical is a virtual manufacturer, this position also provides guidance for quality activities at the Red Star Contract Manufacturing and Response Ortho subsidiaries.

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

- Ensures the QMS and design quality requirements are effectively established and maintained in accordance with medical device regulations and international standards
- Responsible for business processes that ensure conformance of the device with the QMS prior to release and for post-market surveillance
- Responsible for management of the Design Quality Engineers as well as oversight and prioritization of departmental tasks and projects
- Develops systems, implements, and trains employees on quality and regulatory requirements including, but not limited to, corrective and preventative actions (CAPA), quality audits, post market surveillance and vigilance, and recalls and removals
- Manages systems for design, development, verification, validation, distribution, storage, tracking, post-market surveillance, and retrieval of information pertinent to the design quality processes
- Supports product development teams to help meet their objectives
- Oversees quality metrics and quality initiatives, including responsibility for quarterly and annual internal reporting
- Leads and manages post-market surveillance, including device investigations for complaints and field actions
- Develops and facilitates a strategy for a single global quality system and maintains a quality-focused culture
- Manages and ensures compliance to training requirements
- Point of contact and lead for all announced and un-announced QMS and product audits from the FDA or authorized regulatory authorities
- Directs the planning and execution of all internal and external audits
- Develops and maintains the quality department budget
- Reviews and approves document changes for Quality Assurance, as required

QUALIFICATION REQUIEMENTS:

- Bachelor's degree, or equivalent, is required
- 7-10 years of experience in Quality Assurance or Design Quality Engineering
- A minimum of 3 years' experience in medical device
- A minimum of 3 years' experience in a management role with direct reports is required
- A combination of education, experience, leadership, strategy, and QA/RA influence may be considered
- Experience in design quality engineering, measurement system analysis, and design verification and validation testing is preferred
- Working knowledge of Design Controls Process and Quality System Regulations for Medical Devices

OTHER SKILLS and ABILITIES:

- Strong interpersonal, organizational, problem-solving, and analytical skills with a strong attention to detail
- Demonstrated strong writing and communication skills and ability to communicate effectively at multiple levels, including with regulatory agencies, superiors, peers, and direct reports
- Ability to manage competing priorities and ability to manage projects of various sizes and constitutions
- Management of personnel
- Versatility, flexibility, and willingness to work with changing priorities
- Advanced knowledge of overall business environment, the orthopedic industry and the marketplace, and strong product knowledge
- Must work precisely according to procedures, rules, and regulations, and has a passion for continuous improvement and quality
- Able to demonstrate the highest ethical standards and actively promotes trust, respect, and integrity in all dealings both inside and outside the Company
- Ability to function well as a member of the team and team leader, as well as build relationships between QA and other areas of the organization
- Must have service-oriented approach and be flexible and proactive towards changing needs plus the ability to handle increasing levels of responsibility
- Must be exceptionally team focused and actively contributes to a positive and innovative work environment with the ability to build and lead a strong QA team and lead and influence others
- Ability to identify and assess business risks to develop Quality strategy
- High level of proficiency in Microsoft Word, Outlook, Excel, and PowerPoint is essential
- Ability to negotiate with regulatory agencies, management, and other groups, as necessary
- Advanced knowledge of FDA and E.U. regulations, including labeling regulations, and regulations outside of the U.S. and E.U., as applicable

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.

REVIEWED AND ACCEPTED BY:

MANAGER	***ASSOCIATE***
NAME:	**NAME:**
SIGNATURE:	**SIGNATURE:**
TITLE: Chief Technology Officer	**TITLE:** Director of Quality Assurance
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.