Job Description

JOB TITLE: MANAGER, QUALITY ASSURANCE AND REGULATORY AFFAIRS	
BUSINESS DIVISION: WISHBONE MEDICAL INC	**Status:** SALARY / EXEMPT
DEPARTMENT NAME: NEW PRODUCT DEVELOPMENT	**Type**: FULL-TIME
PREPARED BY: HUMAN RESOURCES	**DATE**: 8/11/2021
WORK LOCATION: CORP - WARSAW	**REPORTS TO:** EVP, PROD DEV, QUALITY, & REGULATORY

SUMMARY:

The Manager of Quality Assurance & Regulatory Affairs is responsible for managing quality assurance and regulatory support for Wishbone Medical. The primary focus is to ensure that the Quality Management System (QMS), Design Quality Assurance, and Regulatory Affairs Controls are compliant to current and future USFDA, ISO and MDR Standards and Regulation for Medical Devices, including sterile packaging. Quality and regulatory affairs support may be required for additional geographies. This position is also responsible for monitoring and continually improving current QMS, Design Quality, and Regulatory Affairs systems for the effectiveness of execution and compliance.

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

- Ensure the QMS, design quality, and regulatory affairs requirements are effectively established and maintained in accordance with medical device regulations and international standards
- Monitor conformance of the device with the QMS prior to release, ensuring regulatory documentation is prepared and maintained, post-market surveillance obligations are met, requirements for submission of vigilance reports are complied with, and compliance of devices used for clinical investigation are documented
- Direct post-market engineering assignments and activities, and develop strategies for health risk assessments
- Communicate with Regulatory/Governmental agencies, including responding to requests from foreign governments and/or distributors to prepare and submit documentation for marketing approval, as well as provide routine regulatory information to affiliates
- Develop systems, on-board and train employees, and manage processes for quality and regulatory requirements including, but not limited to, design quality assurance, corrective and preventative actions (CAPA), quality audits, post market surveillance and vigilance, and recalls and removals
- Interpret and apply FDA regulations to business practices and provide regulatory input, advice, and guidance to the organization. May author and publish electronic submissions
- Manage Design Quality and Regulatory Affairs project teams
- Keep all areas of WishBone Medical informed of regulatory requirements and emerging issues which may affect the registration approval of products. Assess impact of engineering changes on current regulatory filings
- Participate in all announced and un-announced QMS/product audits from the FDA or authorized regulatory authorities. May direct the planning and execution of all internal and external audits
- Review, evaluate, and approve promotion and advertising material for compliance with applicable regulations
- Responsibility for oversight and prioritization of departmental tasks and projects
- Miscellaneous responsibilities, as assigned

QUALIFICATION REQUIREMENTS:

- Bachelor's degree, or equivalent, required
- 6-8 years' experience in Quality and/or Regulatory Affairs
- 3+ years' experience in medical device
- 1+ year in a management role with direct reports, required
- A combination of education, experience, leadership, strategy, and QA/RA influence may be considered

OTHER SKILLS and ABILITIES:

- Strong interpersonal, organizational, problem-solving, and analytical skills
- Strong attention to detail
- Demonstrated strong writing and communication skills, ability to communicate effectively at multiple levels, including with regulatory agencies, superiors, peers, and direct reports
- Ability to manage competing priorities and projects of various sizes, constitutions, and management of personnel
- Versatility, flexibility, and willingness to work with changing priorities
- Advanced knowledge of overall business environment, the orthopedic industry, and the marketplace, with 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, actively promote trust, respect, and integrity in all dealings, both inside and outside the Company
- Mastery of relevant regulations and ability to stay abreast of regulations pertinent to medical devices, biologics, drugs, and combination products, as applicable
- Experience in post-market activities, including complaints, MDR, and CAPAs
- Must have service-oriented approach, and be flexible and proactive towards changing needs; ability to handle increasing levels of responsibility
- High level of proficiency in Microsoft Word, Outlook, Excel, and PowerPoint, required
- Advanced knowledge of FDA regulations, including labeling regulations, and regulations outside of the US/EU, 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: EVP, Prod Dev, QA/RA	**TITLE:** Manager, QA/RA
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.