Job Description

JOB TITLE: Sr. Regulatory Affairs Specialist	
BUSINESS DIVISION: Operations	**Status:** Full-time
DEPARTMENT NAME: Quality & Regulatory Affairs	**Type**: Salary
PREPARED BY: Human Resources	**DATE**: 5/4/2020

Summary
Sr. Regulatory Affairs Specialist is responsible for regulatory affairs and regulatory compliance items for WishBone Medical, Inc. per the direction of the VP of QA/RA. The primary focus is to support product development teams during product development from a regulatory perspective, write regulatory submissions, review marketing collaterals for consistency to approved intended uses, and perform tasks to ensure post market compliance. Regulatory affairs support may be required for additional geographies.

Principal Duties And Responsibilities
- Core team member for product development serving as Regulatory representative, ensuring project deliverables have been prepared accordance with medical device regulations and standards.
- Lead activities required for regulatory strategy development, including research of standards and US FDA guidance documents, and communication of the information pertaining to the appropriate regulatory pathway for new or modified products.
- Write US FDA regulatory submissions and associated forms/documents.
- Supporting post market activities: performing post-market surveillance activities, supporting submission of vigilance reports, and supporting recall/correction activities.
- Supervises entering product status into the GUDID database upon placement in market and mentoring of other Regulatory Affairs Associates.
- Support all QMS/Product audits from the FDA or authorized regulatory authorities.
- Writes package inserts. Reviews all labeling, including surgical techniques and physical package labeling.
- Reviews and evaluates promotion and advertising material for compliance with applicable regulations
- Miscellaneous responsibilities as assigned

Expected Areas Of Competence
- Strong interpersonal, organizational, problem-solving and analytical skills; strong attention to detail.
- Demonstrated strong writing and communication skills;
- Ability to manage competing priorities; versatility and willingness to work with changing priorities.
- Must work precisely according to procedures, rules and regulations, has a passion for continuous improvement and quality.
- Able to demonstrate the highest ethical standards, actively promotes trust, respect and integrity in all dealings both inside and outside the Company.
- Must have service-oriented approach, flexible and proactive towards changing needs.
- High level of proficiency in Microsoft Word, Outlook, Excel and PowerPoint is essential.

Experience Requirements
- Bachelor's Degree or equivalent is required, scientific field preferred
- 3-5 years of experience in Quality / Regulatory Affairs, including preparation of 510(k) submissions to the FDA.

- 2+ years of experience in medical device.
- A combination of education, experience, leadership, strategy and QA/RA influence may be considered.

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 accommodations 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
Teammate will normally work in an office environment but may occasionally be subject to noise levels from machines in a manufacturing environment.

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

REVIEWED AND APPROVED BY:

HUMAN RESOURCES MANAGEMENT	***Associate***
NAME:	**NAME:**
TITLE:	**TITLE:**
REVIEW DATE:	**REVIEW 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.