Job Description

JOB TITLE: QUALITY ENGINEERING TECH	
BUSINESS DIVISION: WISHBONE MEDICAL INC	**Status:** SALARY / EXEMPT
DEPARTMENT NAME: QUALITY & REGULATORY	**Type**: FULL-TIME
PREPARED BY: HUMAN RESOURCES	**DATE**: 7/27/2021
WORK LOCATION: CORP - WARSAW	**REPORTS TO:** EVP, SUPPLY CHAIN AND QUALITY

SUMMARY: The Quality Engineering Tech is responsible for working with supply chain partners with emphasis on the Quality Management System documentation and product documentation for supplier management, design transfer, and product quality. The primary focus is to ensure the Quality Management System, design transfer documentation, device history record, approved supplier list, and quality metrics are maintained, per procedure, and ensure supporting documentation is complete and accurate, per current standard and regulation for medical device.

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

- Develop, review, and maintain approved supplier list, supplier contracts, supplier CAPA's, supplier performance reports, supplier audits, non-conforming product reports, quality system procedures, work instructions, and forms
- Assist in design transfer activities and documentation, from development to contract manufacturing, and ensure completion of control plans, PFMEAs, validations, MSA, routings, and inspection criteria according to product drawings and specifications
- Support Product Development and Design Quality in design for manufacturing and measurement

QUALIFICATION REQUIREMENTS:

- Associate degree in Engineering Technology, preferred
- 1+ year experience in medical device industry, working in Supply Chain or Quality, preferred

OTHER SKILLS AND ABILITIES:

To perform this job successfully, an individual must demonstrate an exceptionally high proficiency in creative problem solving and communication. The individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Knowledge and experience working with ISO 14971, 13485, 10993 and 21CFR Part 820 regulations
- Analyze and interpret engineering drawing specifications per ANSI 14.5 and established drafting standards
- Project planning experience

DESIRED UNDERSTANDING:

- Quality control
- Validation
- Statistics

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 accommodations 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, Supply Chain and Quality	**TITLE:** Quality Engineering Tech
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.