Job Description

JOB TITLE: SENIOR STERILE PACKAGING ENGINEER	
BUSINESS DIVISION: WISHBONE MEDICAL INC	**Status:** SALARY/EXEMPT
DEPARTMENT NAME: NEW PRODUCT DEVELOPMENT	**Type**: FULL-TIME
PREPARED BY: HUMAN RESOURCES	**DATE**: 1/27/2022
WORK LOCATION: CORP - WARSAW	**REPORTS TO: CHIEF TECHNOLOGY OFFICER**

SUMMARY:
The position of Senior Sterile Packaging Engineer is responsible for working with regulatory, development, and supply chain partners to create new sterile packaging designs and associated DHF (Design History File), from concept to design transfer, through post market surveillance of medical devices. This role also serves as subject matter expert for Red Star and Response Ortho with respect to sterile packaging and the sterilization process regarding validations and process control, and subject matter expert for WishBone sterile package design and development, ensuring sterile packaged product meets all requirements for sterilization, shelf life, transportation, and distribution. He/she is also responsible for determination and creation of novel sterile and non-sterile packaging designs, along with associated validation and verification activities, including drafting protocols, report, and technical justification rationales, procedures, instructions, and forms that affect cleaning, sterile packaging, clean room monitoring, sterilization, and biocompatibility according to Medical Device Standards for use by the Wishbone Medical and WishBone subsidiaries.

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

- Define, develop, lead, and implement sterile packaging designs across product lines in collaboration with the product development teams. New designs must meet product design requirements including packaging, labeling and sterilization
- Provide continuous engineering support for packaging and sterilization on existing products and line extensions
- Design packaging components and develop sterile packaging systems for new and existing medical device products
- Review and approve all packaging and labeling specifications and other technical documentation for assigned product lines
- Review all new products, packaging, sterilization, or process changes to mitigate any potential increased risk for sterility and packaging integrity for both WishBone and WishBone subsidiaries
- Define, develop, and lead sterile packaging related validations and testing needs, including sealing validation, design of experiments OQ and PQ, transit study and aging study, sterilization validations, and define process monitoring needs
- Ensure that process monitoring activities for all sterile packaging related process are carried out appropriately at the sterile packaging facilities
- Draft procedures, business processes, and work instructions, train technicians and develop test method validations related to sterile packaging at both WishBone and WishBone subsidiaries
- Draft technical protocols, reports, and appropriate justifications for sterile packaging
- Ensure that all sterilization and packaging related validations are current and complete with each sterile packaging facility
- Support design transfer activities and ensure all critical parameters are captured and controlled according to process risk and capability
- Support operations in optimizing sterile packaging related equipment and processes in our manufacturing facility. Provide engineering support to our manufacturing facility on packaging during production. Also consult for our contract manufacturing and their associated customers for other sterile pack designs

- Ensure that the sterile packaging activities and timelines of assigned product lines align with company priorities and product launch dates
- Investigate post market surveillance signals related to sterile packaging and participate in audits related to sterile packaging designs and processes
- This role may have direct report(s)

QUALIFICATION REQUIREMENTS:
- 3-7 years of experience in sterile packaging in medical device, pharmaceutical, or related industry; medical device is preferred
- Bachelor's degree in packaging, packaging engineering, or packaging science

OTHER SKILLS and ABILITIES:
- Proficient in Microsoft Office
- Self-motivation and project planning experience
- Knowledge in ISO 11607, ISO 11137, and all relevant sterile packaging ASTM standards and quality control
- Manufacturing, validation, and 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 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:** Sr. Sterile Packaging 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.