Job Description

JOB TITLE: Sterile Packaging Engineer	
BUSINESS DIVISION: Operations	**Status:** 40 hours
DEPARTMENT NAME: Quality	**SHIFT**: 1st
PREPARED BY: Human Resources	**DATE**: 10/14/2020

SUMMARY: Sterile Packaging Engineer works with regulatory, development and supply chain partners from DHF (Design History File) development to design transfer of DMR (Device Master Record) and then through manufacturing, sterile packaging, sterilization and to shelf DHR (Device History Record). The primary focus is to ensure sterile packaging and the sterilization process are fully validated and that each sterile packaged product meets all requirements for sterilization, shelf life, transportation and distribution.

This position is responsible for determination and creation of novel sterile and nonsterile 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.

The position shall report directly to Supply Chain Management and Quality and communicate team results with Senior Management and internal partners.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- 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.
- Design packaging components and develops sterile packaging systems for new and existing medical device products.
- Review and approves all packaging/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.
- 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 work instructions, train technicians and develop test method validations to perform sterile packaging related tests when necessary.
- 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 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 involves consulting 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.
- Other duties as assigned

QUALIFICATION REQUIREMENTS: 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.

EDUCATION and EXPERIENCE REQUIREMENTS:

- Three to five experience in sterile packaging in medical device, pharmaceutical, or related industry
- Bachelor's degree in packaging, packaging engineering or packaging science

OTHER SKILLS and ABILITIES:

- Proficient in Microsoft Office
- Self-Motivation
- Project Planning Experience

DESIRED UNDERSTANDING:

- Knowledge in ISO 11607, ISO 11137, and all relevant sterile packaging ASTM standards.
- Quality Control
- Manufacturing
- 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 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 15 pounds. Specific vision abilities required by this job include close vision and distance vision.

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.
The noise level in the work environment is usually quiet to moderate.

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.