



Job Description

JOB TITLE: STERILE PACKAGING ENGINEER	
BUSINESS DIVISION: WISHBONE MEDICAL INC	Status: SALARY/EXEMPT
DEPT NAME: QUALITY & REGULATORY	Type: FULL-TIME
PREPARED BY: HUMAN RESOURCES	DATE: 1/25/2022
WORK LOCATION: CORP - WARSAW	REPORTS TO: SR STERILE PACKAGING ENGINEER

SUMMARY:

The position of Sterile Packaging Engineer is responsible for working 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, that each sterile packed kit meets all requirements for biocompatibility, and that the packaging withstands both shelf life and distribution testing. This position is responsible for creation of validation protocols, 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 its Customers.

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

- Review BOM's and DFEMA's for correlation of critical features in design for sterile packaging during design transfer
- Support design transfer activities, including development of control plans with suppliers, capturing all critical parameters and controlled according to process risk and capability
- Review all new products, packaging, or process changes to mitigate any potential increased risk for sterility and packaging integrity
- Ensure through audit that validations are current and complete with each sterile packaging facility. Confirm protocols are written to medical device standards and that the execution of the validations are complete without any open non-conformance
- Review all sterile packed product acceptance documentation and release of product by lot
- Monitor and manage biocompatibility with product development, suppliers, and sterile packaging facilities

QUALIFICATION REQUIREMENTS:

- 2+ years' experience in the medical device industry working in a sterile packaging environment or BS in Sterile Packaging Engineering

OTHER SKILLS and ABILITIES:

- Proficient in Microsoft Office
- Self-motivation and project planning experience
- Desired understanding of sterile packaging
- Quality control and 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:

<i>MANAGER</i>	<i>ASSOCIATE</i>
NAME:	NAME:
SIGNATURE:	SIGNATURE:
TITLE: Sr. Sterile Packaging Engineer	TITLE: 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.
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