Job Description – Senior / Principal Quality Engineer

Reports To – Manager, Quality Engineering

Job Responsibilities

In this role, there will be a significant focus on production quality. This will include supporting in-process inspection, final inspection, final product release activities, will lead investigation and resolution of nonconformances, and own production risk documentation.

Ideal candidates will have direct experience with product line support in a medical device (preferably Class III) manufacturing environment, actively engaged with day-to-day production activities alongside Operations Engineers, Supervisors, and production personnel.

Direct experience with process and equipment qualification / validation, sterile barrier packaging, labeling, and ethylene oxide (EtO) sterilization processes is preferred.

General Description and Duties:

To perform this job successfully, an individual must be able to perform each essential job task satisfactorily. The tasks 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.

- **Production:** Develop and implement quality inspection procedures including sampling plans, for production level components, sub-assemblies and finished goods. May also be responsible for the development and implementation of inspection methodologies, fixtures, measurement systems and calibration of such.
- **Process Verification and Validation:** Provide input regarding appropriate statistical methods, test methodologies, test facilities and equipment. Coordinate testing and manage resulting documentation. This can include process validation, equipment installation/operational qualification, test method validation, etc.
- **Quality Systems:** May maintain and improve company quality systems in compliance with FDA, International Standards (ISO), Canadian, and other regulatory agencies. This function is responsible for supporting company quality compliance and to provide control of processes, materials, and product in compliance with the Axonics Quality System.
- **Documentation:** Create, review, and approve controlled documents on an electronic document control system (e.g. work instructions, quality specifications, engineering specifications, procedures and validation protocols and reports).
- **Compliance:** Ensures compliance with company quality policies and practices by participating in product and material reviews, assist in resolving problems related to the manufacture, test, validation, and documentation.
- **Product Release:** Review and approve lot history records and sterile load records to ensure product compliance with specifications and regulatory requirements. Provide support, guidance, education and training to personnel, ensure inspections, tests, and sterilization is performed in accordance with procedures.

Projects and Other Duties:

- Perform other duties as assigned

Position Qualifications

- Extensive experience and knowledge of regulatory requirements such as GMP's, ISO, etc.
- Knowledge of and ability to effectively use analytical tools and methods including statistics, DOE, and the use of computer software packages related to testing, data collection, calibration, etc.
- Strong understanding of medical device manufacturing processes, receiving inspection, in-process and finished device inspections, non-conforming material resolution, CAPA, and record keeping.
- Strong understanding of process validation, metrology, and inspection equipment.
- Strong communication skills (both written and verbal) required.
- Ability to work independently or in a team setting required.

Minimum Education:

- BS in Engineering or scientific discipline.

Minimum Experience:

- 3-15+ years of Quality experience within Medical Device or related industry. High risk and/or implantable medical device experience is highly preferred.
- Experience with an Enterprise Resource Planning systems, such as QAD, SAP, JD Edwards, etc. is preferred.