Job Description – Quality Engineer

Reports To – Director, Quality Engineering

Job Responsibilities

To ensure compliance with the Axonics Quality System, ISO standards, FDA and Health Canada requirements, and City, County, State, Fire Marshall and Federal safety regulations. Maintenance and improvement of policies and procedures focused on delivering product and services that are in compliance with company Quality Systems and regulatory requirements.

General Description and Duties:

To perform this job successfully, an individual must be able to perform each essential task satisfactorily. The tasks listed below are representative of the knowledge, skill, and/or ability required to perform this job effectively.

- **Quality Systems:** 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.
- **Management:** Responsible for departmental supervision, training, and ongoing support of staff. Required to effectively communicate project goals and establish staff responsibilities and project tasks. Provide technical guidance and training (mentorship) to less senior staff members to contribute to their ongoing development within the company.
- **Product Development:** Is a key member of the product development team representing the Quality function. Steer and support the design control aspects of product quality, program management, and quality planning from product design through manufacturing.
- **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.
- **Production:** May 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.
- **Auditing:** Conduct internal and external (e.g. supplier) GMP and ISO compliance audits. Reports results and recommendations for changes as required. Confirms acceptable follow up action on audits.
- **Documentation:** Create, review, and approve controlled documents on an electronic document control system (e.g. Quality Manual, work instructions, quality specifications, engineering specifications, lot history and device master records, procedures and validation protocols and reports).
- **Training:** Coordinates and/or provides training to staff in GMP/ISO, Quality Systems, and Safety awareness. Provides ongoing development and maintenance of training materials and records.
- **Compliance:** Ensures compliance with company quality policies and practices by participating in product and material reviews, assist in "troubleshooting" problems related to the manufacture, test, validation and documentation. Responsible for MRB, corrective

action, process control, complaints, document control, calibration & preventive maintenance programs and product/process/equipment validation activities.
- **Regulatory:** Facilitate compliance with management strategy and regulatory agencies.
- **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.
- **After Sales Product Monitoring:** Coordinate attention to customer complaints, corrective actions, Medical Device Reports (MDR'S) and product recalls. As required research and investigate product failures and the reasons for such.
- **Logs & Recordkeeping:** Ensure compliance of quality related logs and records, including but not limited to CAPA, NCMR, ASL/APSL, equip0ment CAL/PM, and Training.
- **Safety:** Develop, implement and maintain required safety programs for flammable, hazardous and bio-hazardous material handling, storage and disposal in compliance with City, County, State, Fire Marshall and Federal safety regulations.

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 us 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 internal and supplier auditing, process validation, metrology, and inspection equipment.
- Thorough knowledge of applicable City, County, State, Fire Marshall and Federal safety regulations.
- Excellent communication skills (both written and verbal) required.
- Ability to work independently or in team setting required.
- Must be able to travel extensively (approximately 10-20% of time).

Minimum Education:

- MS/BS in Engineering or scientific discipline or equivalent experience

Minimum Experience:

- Minimum 3+ years Quality role in Medical Device or related industry.

Work Environment & Physical Demands of the Job:

- The noise level in the work environment is usually quiet. While performing the duties of this job, the employee is regularly required to remain in a stationary position at least 50% of the time; operate computers and other office equipment; and communicate and exchange information. The employee is occasionally required to reach with hands and arms and to move within and between the buildings. A computer terminal is used to access, input, and

retrieve data. The employee must occasionally lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision.

- The job requires travel by air, train, and car travel, sometimes for long distances and extended periods of time.

Additional Important Information:

- Axonics may make reasonable accommodations to enable individuals with disabilities to perform the functions of this job, unless doing so would result in an undue hardship on Axonics.
- This job description is subject to change and management reserves the right to assign or remove duties and responsibilities of this job at any time.