Job Title: Manager, Quality
FLSA: Salaried Exempt
Department: Quality
Reports to: Director, Quality Engineering

Job Responsibilities:

To ensure compliance with the Axonics's Quality System, ISO standards, FDA requirements and City, County, State, Fire Marshall, and Federal safety regulations. Development and implementation of policies and procedures focused on delivering product and services that comply 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 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.

- **Quality Systems:** Implement, maintain, and continually improve company quality systems in compliance with FDA, International Standards (ISO) and other regulatory agencies. This function is also responsible for steering and supporting company 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. May participate in budgeting process and maintains budget to expected expenditures.

- **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.

- **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:** Establish and implement a supplier qualification/certification process, conduct internal and external (e.g. vendor) cGMP and ISO compliance audits. Reports results and recommendations for changes as required. Confirms acceptable follow up action on audits.

- **Documentation:** Creates reviews and approves controlled documents (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 cGMP/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 (MDRs) 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, NCR, ASL, 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:

- 4+ years in medical device or related industry, high risk electronic devices, including manufacturing in and out of clean rooms, and new product development a big plus.
- 5+ years in Quality Management of several Engineers and Technicians with progressive responsibilities.
- Experience in commercial ramp up of a product and how to design/implement procedures that allow for some flexibility in this process.
- The ability to take complete ownership of an initiative and drive it to completion.
- Strong with NCMR, CAPA, device complaint investigations and risk assessments.
- Strong with GDP, GMP, change controls, and communication of these best practices to the extended team.
- Extensive knowledge about ISO and FDA CFR regulations with audit defense experience (front room or back room).
- ETO sterilization process experience, clean room controls, micro-biological testing and familiarity with packaging for ETO processed devices a plus.
- Supplier quality/audit experience a plus.
- Previous experience in bringing a company into regulatory compliance and approval both domestically and internationally.
- Extensive experience and knowledge of regulatory requirements such as cGMP'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.
- Excellent communications 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).

Special Knowledge, Skills and Abilities:

- Process and task oriented, organized, quick thinker with ability to coordinate multiple activities at once.

- High energy level, hands-on approach, comfortable performing multifaceted projects in conjunction with day-to-day activities.
- Superior interpersonal abilities. Ability to get along with diverse personalities, tactful, mature, flexible.

Minimum Education:

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