**Job Title:** Senior Quality Engineer, IPG
**FLSA:** Salaried Exempt
**Department**: Quality
**Reports To:** Director, Quality Engineering or Manager, Quality

**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 comply with company Quality Systems and regulatory requirements. The primary area of focus is the electronics manufacturing support for IPG (implantable Pulse Generator).

**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:** 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 (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, NCMR, ASL/APSL, equipment 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.
- Hands-on experience with electronic medical device manufacturing in clean rooms, including electrical components and plastic molding.
- Experience with laser welding processes and with failure investigations and/or root cause analysis.
- Experience working with new product development as well as sustaining engineering of commercialized product.
- Experience with design transfers, equipment validation, process validation.
- Knowledge of NCMRs, CAPAs, device complaint investigations and risk assessments.
- 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.
- 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:**

- 6+ years Quality role in Medical Device or related industry, high risk electronic devices a plus.