Axonics
Modulation Technologies

Job Description – Quality Control Inspector

Manager – Quality Manager

Job Responsibilities

This position is responsible for testing, contributing to the development and manufacturability of specific product(s) in accordance with the company's Quality System and customer requirements. This position will facilitate meeting Operations requests, serving at times as the interface between Engineering, Manufacturing, vendors and/or suppliers. This position complies with Quality system by engaging in appropriate levels GMP/ISO test methodologies, adherence to Quality System Design Controls, and applies proper documentation skills.

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: Works as part of the Operations and Quality Department, troubleshoots and analyzes problems to identify, evaluate, propose, and implement corrective actions while documenting the process and verifying the results. Ensures that product documentation is in accordance with Quality System requirements.
- Product Enhancements: Contributes to product enhancement.
- Product Inspection: Receives, inspects, tests, and properly documents incoming components, assemblies, and finished good. Collaborates with Engineering and Quality to resolve non-conformances. Maintains proper material labeling and dispositioning in inventory. Properly maintains and completes operational records, reports, and other required documents. Tests and manages resulting documentation when needed.
- Manufacturability: Contributes to product enhancements aimed to improve yields and manufacturability.
- Production: Supports the implementation of quality inspection procedures. Contributes to the development and implementation of inspection fixtures, measurement systems and calibration of such.
- Documentation: Reviews assigned controlled documents (e.g. work instruction, quality specifications, engineering specifications, procedures and validation protocols).
- Training: Trains Assemblers and Technicians in the project group as needed.
- Safety: Performs job functions in a safe and effective manner. Helps promote employee adherence to safe procedures and practices throughout the company.
- Logs & Recordkeeping: Maintains compliance of quality related logs and records, including but not limited to, Receiving Log, CAPA, CMR, ASL, CAL/PM, and Training.

Projects and Other Duties:

- Performs other duties as assigned by supervisor

Position Qualifications

- Knowledge of and exposure to product testing and data collection.
- Experience in a fast paced, multitasking environment with the ability to organize and prioritize multiple tasks and meet deadlines.

Minimum Education:

- Associate's Degree, Technical Certificate, or equivalent work experience in medical device industry or similar products.

Minimum Experience:

- 3 years of experience in medical devices, operations, or quality.
- Experience working under regulated quality systems such as cGMP's, ISO, and the MDD is a plus
- Familiarity with Design Control procedures and requirements is a plus.
- Experience with Class II or II devices is a plus.