Job Description – Senior Quality Engineer, Failure Analysis

Reports To – Manager, Quality Engineering

Job Responsibilities

This position is responsible for medical device complaint investigations and write-ups as part of the Complaint Handling, Medical Device Reporting and Vigilance Reporting process and is performed in accordance with applicable regulations and Axonics Quality System requirements. This position will ensure timely, accurate, and complete failure investigations, root cause analyses, risk analyses, CAPA activities, and other complaint- related tasks are performed and documented for product field failures. This will include trend analysis of complaint data and other assigned tasks.

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.

- Collaborate with Engineers, suppliers, Clinical Specialists, and Operations personnel to facilitate a deep understanding of device functionality and failures and to perform in depth root cause analysis.
- Acquire, analyze, and interpret information from data logs and various applications as well as perform physical deconstruction of devices as part of Root Cause Analysis.
- Utilize laboratory equipment, such as: probes, X-ray systems, optical digital microscopes, electrical test software, and other test equipment.
- Design and execute experiments and test methods to test theories to refine failure modes and determine root cause.
- Write analysis reports, detailing clear and accurate analysis findings.
- Provide progress updates for various cross-functional meetings.
- Work within cross-functional internal and external teams to investigate device field complaints and provide solutions to resolve complaints in a timely manner.
- Follow instructions from Quality Management and keep them updated with complaint status. Strong at verbal and written communication.
- Perform failure analysis of mechanical and electromechanical medical devices using various types of test equipment, fixtures, and software tools.
- Use applicable quality tools (Root cause analyses), ensure timely, accurate, and complete failure investigations of product complaints leading to the root cause and corrective/preventive action and ensure that all activities are documented in the complaint management system.
- Organize/lead cross-functional teams to analyze complaint trend data and drive updates to applicable risk management documentation as needed.

Projects and Other Duties:

- Perform other duties as assigned

Position Qualifications

- Demonstrated knowledge and ability to use statistical methods such as trend analysis, pareto, and other charting techniques.
- 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.
- Ability to work independently or in a team setting is required.

Minimum Education:

- Bachelor's degree in mechanical engineering, electrical engineering, computer science, or related field is required.
- Advanced degree and/or certifications (ASQ, CQE, Six-Sigma) preferred.

Minimum Experience:

- A minimum of 5 years' experience in the medical device industry.
- A minimum of 2 years' experience in a failure analysis role.
- Electrical engineering knowledge is required.
- Experience with a complaint handling tool such as Sparta TrackWise Digital (Salesforce) is preferred but not required.