Job Description – Quality Engineer, Complaints

Reports To – Director, Quality Engineering; or 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.

- 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 in verbal and written communication.
- Perform failure analysis of mechanical and electromechanical medical devices using various types of test equipment, fixtures, and software tools.
- Using 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.
- Work with product line Quality Engineers to complete post market risk assessments and drive periodic updates to Risk Management Reports and potentially other documents.
- Develop, update, and maintain Job Aids and Work Instructions to facilitate and standardize investigation activities.

Projects and Other Duties:

- Perform other duties as assigned

Position Qualifications

- 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.
- Excellent communication skills (both written and verbal) required.
- Ability to work independently or in a team setting required.

Minimum Education:

- BS in Engineering or scientific discipline or equivalent experience.

Minimum Experience:

- 3-5 years in a Quality role in the Medical Device or related industry. High risk and/or implantable medical device experience is preferred.
- Software and Electrical knowledge.
- Previous device investigation experience.
- Experience with a complaint handling tool such as Sparta TrackWise Digital (Salesforce) is preferred but not required.