Job Description – Regulatory Affairs Specialist

Reports To – Director of Regulatory Affairs/ Chief Operating Officer

Job Responsibilities

This position is responsible for providing guidance on regulatory requirements as well as assisting in regulatory related projects and tasks ensuring compliance with FDA regulations, ISO standards, and other regulatory agencies.

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.

- Provides guidance on regulatory requirements necessary for strategic and contingency planning, including developing regulatory strategic plans to teams for solutions.
- Represents regulatory affairs on product development and commercialization teams.
- Ensures compliance with standards and execution of corrective actions and is the liaison with domestic and international customers and vendors.
- Prepares and oversees documentation packages for submission to global regulatory agencies. Tracks timelines and documents milestone achievements for inclusion in regulatory submissions. Interacts with regulatory agencies as part of submission review and on-site audit support (e.g. IDEs, PMAs, annual reports, 510(k)s, STEDs, and CE marking design dossiers and technical files).
- Assists with customer complaints/CAPA system.
- Develops risk assessment review process for all marketed devices and implementation of changes to risk management process as needed.
- Monitors proposed and current US and EU regulations and guidance and advises on the impact of such regulations.
- Reviews documents for regulatory claims, promotional material, labeling content, product and process changes, and product documentation.
- Collaborates and takes direction from RA management.

Projects and Other Duties:

- Perform other duties as assigned.

Position Qualifications

- Strong working knowledge of US and EU regulations that affect Class III medical devices.
- Experience working on cross functional projects.
- Fluent English with strong written and verbal communication skills.
- Excellent analytical thinking and problem-solving skills.

Minimum Education:

- Bachelor's degree in a related field, a scientific degree is preferred.

Minimum Experience:

- 3 years of experience in a regulatory role or related area.

Work Environment & Physical Demands of the Job:

- The noise level in the work environment is usually quiet. While performing the duties of this job, the employee is regularly required to remain in a stationary position at least 50% of the time; operate computers and other office equipment; and communicate and exchange information. The employee is occasionally required to reach with hands and arms and to move within and between the buildings. A computer terminal is used to access, input, and retrieve data. The employee must occasionally lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision.
- The job requires travel by air, train, and car travel, sometimes for long distances and extended periods of time.

Additional Important Information:

- Axonics may make reasonable accommodations to enable individuals with disabilities to perform the functions of this job, unless doing so would result in an undue hardship on Axonics.
- This job description is subject to change and management reserves the right to assign or remove duties and responsibilities of this job at any time.