Job Title: Regulatory Affairs Specialist - International
FLSA: Salaried Exempt
Department: Regulatory
Reports To: Director of Regulatory Affairs/ Chief Operating Officer

Job Scope and Quality Impact:

This position is responsible for providing guidance on regulatory requirements as well as assisting in regulatory related projects and tasks ensuring compliance with EU, HC, TGA, UKCA 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., registration documents, 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 EU, HC, TGA, UKCA and other international 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 EU, HC, TGA and internal 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.