**Who we are looking for:**

Transonic, the originator of innovative volume flow measurement technologies, is looking for a dynamic, critical-thinking, self-directed initiator who can be a key contributor in the company’s regulatory affairs department for our medical devices, life-sciences, and OEM markets. We are looking for someone with an understanding of FDA, EU and other key country’s regulatory requirements to support our worldwide product registrations. We are hoping for someone who thrives in a fast-paced environment while still being detail-oriented and who is able to think along with multiple projects and priorities.

**Who we are and what we offer:**

Transonic is a small family company of around 130 staff with big goals. Our sales/service divisions in Europe and Asia provide us with worldwide reach. We develop and pioneer innovative technologies and solutions, often the first of their kind, which help ensure that:

* Our clinicians get the data they need to make critical decisions to improve their patient’s lives,
* Our researchers get the measurement solutions they need to perform better research,
* Our OEM clients can improve the functionality of their devices with our measurement capabilities inside.

Several of our research and clinical products have gained worldwide gold-standard status, largely through their innovative nature, the reproducibility and accuracy of our measurements, and our robust product designs. We support our customers with top-notch training and support materials that demonstrate a deep understanding of our technology, and we go above and beyond to teach our users best practices and to help them implement our measurements. We are a tight knit group with a lot of long-term staff who believe passionately in our solutions and technology and because we are small, there is a lot of room for career growth and development. Decisions are made quickly as a group, and we work hard to make the engineering department an enjoyable place to work where staff feel that they are valued and can contribute as a part of our team. We offer competitive pay & great benefits, such as company paid 401k contributions, full, company-paid medical insurance, paid holidays, vacation and other benefits.

**Primary Function**

This position will support worldwide regulatory registrations for our current and future medical devices as well as support process compliance in conjunction with our engineering department. All candidates should have a depth of experience in applicable FDA and foreign medical device regulations, including ISO 13485 and FDA 21 CFR 820 and the EU MDR.

**Duties and Responsibilities**

* Remain current on all applicable regulatory guidances that impact the company’s ability to legally market medical devices around the world.
* Remain current with all mandatory and recommended certifications, processes, and applicable standards as they relate to global regulatory compliance.
* Assist in the creation of regulatory documentation in conjunction with the Engineering team that can be used to support FDA, EU and other worldwide regulatory submissions.
* Support Transonic during internal audits with our notified bodies
* Support registration activities with our distribution channels through creation and provision of the applicable regulatory documents and filings
* Maintain documentation and certifications for all country-based registrations
* Create gap analysis and remediation plans for identified gaps when standards are updated and drive project teams to fulfill those remediation plans.
* Review Marketing Communications, Instructions for Use and other technical documentation to ensure they comply with regulatory claims standards
* Perform training on regulatory procedures and updates on guidances to company personnel.
* Facilitate the Risk Management Process in compliance to applicable external standards and corporate policies.
* Create and update Standard Operating Procedures as required to support emerging regulatory standards.
* Work with the Engineering team to develop usability test plans and human factors testing that meets the various EU and US standards.

**Working Relationships**

* The position works closely with many of Transonic’s key staff, such as the Regulatory & Quality Director, the Distributor Managers, Marketing Managers and Engineering Staff.

**Education and Experience**

* Bachelor’s degree in engineering, science, or technical discipline
* 3+ years of progressive experience in medical device engineering preferred
* 3+ years’ experience in medical device regulatory guidance interpretation and facilitation preferred
* Knowledge of ISO 13485, MDD 93/42/EEC and MDR 2017/745, domestic FDA and international regulatory requirements, especially the EU MDR, medical device registrations, design control activities for medical devices
* Experience with FDA and Notified Body inspections
* Experience with Class II (US)/Class I, Class II and Class III (Europe) medical devices
* Experience with Human factors/usability testing preferred

**Knowledge, Skills and Abilities**

* Ability to work independently without close supervision.
* Must have excellent organizational skills.
* Ability to handle multiple tasks simultaneously and ability to manage project timelines.
* Excellent communication skills, oral, written, and electronic
* Must be accurate in handling detailed information/data.
* Must have strong ethics and be diligent in follow up along multiple projects
* Proficient in the Microsoft Suite of products
* Ability to read and interpret complex engineering and mechanical drawings and documentation/
* Able to interpret FDA and foreign regulatory guidance as it relates to medical devices and medical devices containing software

**Supervisory Responsibilities**

* None

**Physical Demands & Work Environment**

* Work environment is an open office & cubicle setting.
* Position primarily requires sitting, standing, walking, stooping, reaching, and talking in an office environment.
* Must adhere to safety requirements.

Disclaimer: This Job Description is not intended to be all-inclusive and may be subject to change to include new responsibilities and tasks or change existing ones as management deems necessary to meet the ongoing needs of the company.