Job Title:	**RA/QA Engineer**	Department:	Regulatory Affairs
Reports to:	Director of RA	Division:	Ithaca, NY
Hours:	Full-time; 40 Hrs/week	Rev Date:	5/28/2024

Who we are looking for

Transonic, a leader in innovative volume flow measurement technologies, seeks a dynamic, critical-thinking, and self-directed initiator to join our Quality Assurance department. This role is crucial in ensuring the quality of our diverse product offerings for medical devices, life sciences, and OEM markets. The ideal candidate will possess a solid understanding of quality management principles, including ISO 13485 and MDSAP requirements, and will play a pivotal role in maintaining the company's compliance with these standards. We are searching for a team member who thrives in a fast-paced environment, is detail-oriented, can effectively prioritize projects, and is forward-thinking in identifying opportunities for improvement within our quality systems.

Who we are and what we offer

Transonic is a small family-owned company with approximately 110 staff members with big ambitions. We have global reach through our sales and service divisions in Europe and Asia. We pioneer and develop innovative technologies and solutions that help ensure:

- Clinicians receive critical data to make life-saving decisions.
- Researchers access accurate measurement solutions for better research outcomes.
- OEM clients enhance their devices' functionality with our advanced measurement capabilities.

We foster a collaborative and passionate work environment with a management team that values quick decision-making and staff contributions. We offer competitive pay and great benefits, including company-paid 401(k) contributions, fully company-paid medical insurance, paid holidays, vacation, and more.

Primary Function

As a Quality Engineer, you will focus on ensuring the quality and reliability of our ISO13485 QMS and our medical devices. The primary focus of this position is the control and follow-up of Transonic's CAPA process – the QE will lead the weekly CAPA meetings, ensure all follow-up is timely, follow up on CAPA responses due for audits, and engage in carrying out failure investigations, verification of effectiveness and implementation for those CAPAs directly assigned to them. Additional responsibilities may include other areas such as backup for the QE's who are assessing customer complaints, managing engineering change orders, or handling non-conforming material reports. The QA and RA teams are tight-knit, and each member learns other parts of QA/RA processes to back up their teammates in various areas. A broad skillset is thus gained by all team members, with each QE developing an area of expertise and leadership in one or two primary areas.

Job Title:	**Quality Engineer**	Division:	Ithaca, NY
Department:	Quality Assurance	Rev Date:	5/28/2024

I. Core Duties and Responsibilities

- Manage the Corrective Action Board functions, including leading the weekly CAB meeting, following up with CAPA leaders on process, extension requests, and various VAPA stages, and ensuring timely completion of CAPAs throughout the company.
- Performing solo CAPA management for relevant Quality CAPAs including Failure investigations, verification of effectiveness, implementation, and any needed training as a result of the CAPA activities.
- Engage in and support major and minor internal and external audits, enter findings in the QMS's Audit & CAPA modules, and ensure corrective actions are carried out in a timely manner and are in compliance with relevant ISO, FDA, and MDR requirements.
- Initiate engineering change orders to correct work instructions, Process and Procedures, and manage/reconcile issues with the document control system including the QMS and its related Work Instruction System.
- Initiate and facilitate continuous improvement projects for Quality Systems and support continuous improvement efforts from other departments as needed.
- Support the RA team with other work-related duties as requested, directed or assigned by management, such as international registration support, etc.

II. Working Relationships

- Collaborate with internal departments such as Quality Assurance, Regulatory Affairs, Engineering, Manufacturing Engineering, Planning, and Manufacturing.
- Interact with external sources, consultants, and outside agencies such as notified bodies, as required.

III. Education and Experience

- A minimum of a BS in Engineering or related professional field is required.
- 3+ years of experience in quality engineering is preferred.
- Prior experience in a medical device or other highly regulated environment is preferred.
- Experience with electrical component inspection and assembly is a plus.
- ASQ Certification (CQE, CQA, CMDA, CSSBB) is a plus.

IV. Knowledge, Skills, and Abilities

- In-depth knowledge of quality management systems (QMS) and regulatory requirements (ISO 13485, FDA, MDR, etc.) preferred.
- Strong understanding of statistical methods, root cause analysis, and corrective/preventative action methodologies (e.g., Six Sigma, Lean, fishbone/5 whys, etc.).

- Excellent communication and collaboration skills to work effectively with internal and external stakeholders.

V. Supervisory Responsibilities

- No direct reports

VI. Physical Demands & Work Environment

- Primarily involves sitting, standing, talking, and walking in an office environment, with occasional exposure to our Manufacturing environment.
- Requires depth perception, close and far vision, normal color distinction, potential for eyestrain, and normal finger dexterity.
- Must adhere to safety requirements and may periodically use personal protective equipment.
- Office environment with occasional exposure to Manufacturing.
- Hours may exceed normal business hours with occasional evening meetings.
- Periodic travel for company business may be required.

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