Job Title:	**QA Engineer**	Department:	Quality
Reports to:	Director of QA	Division:	Ithaca, NY
Hours:	Full-time; 40 Hrs./week	Rev Date:	5/15/2026

Primary Function

The Quality Engineer will support the quality, reliability, and compliance of Transonic's ISO 13485 Quality Management System and medical device products. The primary focus of this role will be complaint handling, failure analysis monitoring, standards and regulation monitoring, ECO scoping, and support of key Quality Assurance processes.

This position will ensure complaints are properly tracked, reviewed, followed up on, and closed in a timely manner while supporting applicable domestic and international regulatory requirements. The Quality Engineer will work cross-functionally with Quality Assurance, Regulatory Affairs, Engineering, Manufacturing Engineering, Repair, Planning, Manufacturing, and other internal teams to support complaint investigations, failure analysis activities, audit readiness, ECO scoping, and continuous improvement.

This role will also provide backup support for deviation processes, minor audits, Management Review data preparation, and other Quality System responsibilities as assigned. The Quality Assurance and Regulatory Affairs teams work closely together, and this position is expected to learn multiple QA processes to provide backup coverage and support team flexibility.

I. Core Duties and Responsibilities

Complaint Handling and Failure Analysis:

- Manage and support the complaint handling process, including complaint intake, tracking, follow-up, documentation review, and timely closure.
- Coordinate with Regulatory Affairs to support complaint reportability assessments and ensure required regulatory timelines are met.
- Lead or support periodic cross-functional complaint meetings to review new complaints, open complaint activities, overdue actions, failure analysis status, and closure progress.
- Monitor failure analysis activities related to complaints and follow up with responsible departments such as Repair, Manufacturing Engineering, Engineering, Manufacturing, and Quality Assurance.
- Ensure complaint records are complete, accurate, and documented in accordance with applicable Quality System and regulatory requirements.

Engineering Change Order Scoping and Deviation Process Support:

- Lead Engineering Change Order scoping activities across the company, including scheduling cross-functional ECO scoping meetings, reviewing proposed changes with impacted departments, ensuring the full scope and impact of changes are assessed, and confirming that required documentation, implementation tasks, and follow-up actions are identified before ECO release.

- Provide backup support for other ECO activities, including technical review support, follow-up documentation, implementation task tracking, and closure support as needed.
- Provide backup support for the deviation process, including deviation documentation, routing, review follow-up, impact assessment support, and tracking of assigned actions through closure.
- Assist with ensuring deviations are properly documented, reviewed, and closed in accordance with Quality System requirements.

Standards and Regulatory Monitoring:

- Support standards and regulation monitoring, including review of applicable ISO, FDA, MDR, MDSAP, and other regulatory or Quality System requirements.
- Communicate relevant standards or regulatory updates to appropriate Quality, Regulatory, Engineering, Manufacturing, and leadership teams as needed.
- Help assess the potential impact of updated standards or regulatory expectations on Quality System processes, procedures, documentation, or product-related activities.

Additional Quality System Support:

- Participate in internal and external audits, including audit preparation, audit support, documentation review, audit response support, and follow-up on audit findings.
- Support minor internal audits, including audit planning, execution support, documentation of audit results, observations, opportunities for improvement, and corrective action follow-up.
- Prepare, compile, and present quarterly Management Review data to the Senior Leadership Team, including Quality metrics, complaint trends, FAR status, ECO status, and deviation status.
- Review quality data for trends, gaps, and potential areas of concern, and communicate findings to Quality leadership.
- Assist with continuous improvement activities, including identifying process gaps, supporting corrective actions, improving documentation, and helping strengthen Quality System effectiveness.
- Support the QA team with other work-related duties as requested, directed, or assigned by management.

II. Working Relationships

- Collaborate with internal departments including Quality Assurance, Regulatory Affairs, Engineering, Manufacturing Engineering, Repair, Planning, Manufacturing, Document Control, Customer Service, and Operations.
- Interact with external sources, consultants, laboratories, distributors, auditors, notified bodies, or regulatory agencies as required.
- Work closely with cross-functional process owners to support complaint investigations, failure analysis, ECO scoping, deviations, audits, Management Review inputs, Quality metrics, and Quality System improvements.

III. Education and Experience

- Bachelor's degree in Engineering, Quality, Life Sciences, or a related technical field required.
- 3+ years of experience in quality engineering, quality assurance, complaint handling, or regulated manufacturing preferred.
- Prior experience in a regulated environment, preferably medical device, ISO 13485, FDA, MDR, MDSAP, or similar regulated industry, is preferred.

IV. Knowledge, Skills, and Abilities

- In-depth knowledge of quality management systems (QMS).
- Excellent communication and collaboration skills to work effectively with internal and external stakeholders.
- Strong attention to detail and ability to maintain accurate and audit-ready quality records.
- Ability to follow up on open actions and drive timely closure of assigned activities.
- Ability to work with cross-functional teams and explain quality requirements clearly.
- Strong problem-solving skills, including root cause analysis and failure investigation support.
- Ability to review data, identify trends, prepare summary reports, and present information to leadership.
- Willingness to learn multiple Quality Assurance processes and provide backup support to team members.

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.

Job Title:	**Quality Engineer**	Division:	Ithaca, NY
Department:	Quality Assurance	Rev Date:	5/15/2026