Job Title:	**Director of QA**	**Department:**	**Quality Assurance**
Reports to:	**CEO/President**	**Division:**	**Ithaca, NY**
Hours:	**Full-time - 40 Hrs/Wk**	**Rev Date:**	**15, April, 2025**

Who We Are:

Transonic is a small, family-owned company with around 90 dedicated team members at our Ithaca headquarters. We develop innovative flow measurement systems used in surgeries, hemodialysis, research, and other medical applications to improve patient outcomes worldwide. Working at Transonic means contributing to meaningful work that truly impacts lives. We are a high-mix, low-volume manufacturer, supporting niche markets across a wide spectrum of clinical and research applications including surgical and tubing-based blood flow measurements, life science research, and OEM components as part of our "Transonic Inside" offerings.

We foster a collaborative work environment and believe every role contributes to our success. Our staff are committed and diligent, knowing the importance of each product they create or support. We offer competitive pay and exceptional benefits, including fully company-paid medical insurance with low copays, paid holidays and vacation, and company-funded 401(k) contributions. Additional low-cost options for dental, vision, and life insurance are also available. The schedule is fully in-person, as is necessary to support the QA team and the manufacturing staff.

Who We're Looking For:

We are seeking a proactive, hands-on Director of QA to lead our quality team and support a broad portfolio of regulated medical devices, research products, and OEM components. This role is integral to the success of our operations and requires a leader who is both strategic and deeply engaged in day-to-day activities. The ideal candidate is a collaborative problem-solver, committed to continuous improvement, operational excellence, and cross-functional teamwork.

We have a team of 6 dedicated Quality Engineers, each of whom leads specific QA functions (e.g., CAPA management, Complaints & Audits, ECO & SDS, Incoming Inspection & Device Calibrations, NCMR & Supplier Management), while backing up their teammates, and are looking for a QA Director to lead the team in prioritization, training and cross-training activities, Management Review activities, and improving our quality efforts.

This position involves regular coordination with other internal departments, including Regulatory Affairs, Purchasing, Customer Service, Finance, and Manufacturing, as well as communication with external stakeholders across global markets, such as our international Divisions & Distributors, US sales team, external notified bodies, and suppliers. Strong interpersonal, organizational, and analytical skills are essential to ensure alignment across our teams and maintain high-quality processes and procedures.

We're looking for an energetic, self-motivated individual with a genuine interest in learning about our products, customer applications, and the detailed manufacturing processes that support them. As a small, close-knit company, our managers take a hands-on approach—actively engaging with their teams, supporting operations, and leading by example. The ability to multitask, prioritize across shifting needs, and contribute to company-wide initiatives is key.

This role will also be instrumental in identifying process improvement initiatives and ensuring robust cross-training across all roles in the QA team. We're excited to find a team member who brings a solution-oriented mindset and a passion for continuous improvement to help us grow and succeed together.

Primary Function

This position is responsible for the overall leadership of the Quality Team and ensuring that Transonic's Quality Management System is managed in accordance with the various external regulations and standards that drive us (e.g. ISO 13485 Quality Management System, Medical Device Single Audit Program (MDSAP), EU MDR 2017/745 Regulation, and other applicable country regulations). The position is key to ensuring that a quality-based mindset is propagated throughout our organization. The Quality Team handles administration of our QMS, which includes ECO management, CAPAs and Failure Investigations, NCMRs, Failure Analysis and Supplier Management, Complaints & Reportability/Vigilance activities, Incoming Metrics and Inspection, Material Safety and SDS, Calibration & Maintenance of Devices, Quality Metric monitoring & reporting, Management Review, Declarations of Conformity sign-off, and Internal/External Audits. The Director of QA needs to be willing to learn the processes and procedures of these roles so that they can provide appropriate leadership, guidance, prioritization, and backup, as well as lead the cross-functional training efforts.

I. Duties and Responsibilities

- Drive continuous improvement in quality and compliance through quality metrics (e.g., customer complaints, product deviations, rework, scrap, warranty failures, and supplier quality metrics).
- Directly manage, monitor, and mentor the Quality staff in each of the Quality Processes previously noted to ensure their performance is effective, and support product development activities with guidance and methods that result in improved product quality, compliance, and speed to market.
- Ensure compliance of Quality Management System with all relevant Food and Drug Administration (FDA) and other international regulations, ISO 13485 and other appropriate standards, and internal corporate procedures and policies.
- Coordinate Management Reviews with the Regulatory team regarding quality data trends and quality system compliance with applicable regulations and standards.
- Provide leadership during external audits with notified bodies, regulatory agencies, and OEM clients to ensure findings/observations are properly documented and corrective actions are efficiently and effectively taken.
- Act as Transonic's Management Representative with the responsibilities and authorities laid out within our quality manual and the applicable standards and guidance documents.
- Responsible for tracking and providing necessary updates to notified bodies on changes to products and the quality system, as well as reportable complaint notifications in conjunction with the Regulatory Affairs team.

- Responsible for quality reviews of sterile products and yearly sterilization supplier requalification
- Responsible for final sign-off of Engineering Change Orders, Deviations, Complaints, Failure Investigations/Failure Analysis, Post-Market Surveillance Plans & Reports, Clinical Evaluation Plans & Reports, Supplier Quality Plans/Agreements

II. Working Relationships

- Leads the internal QE team while supporting productive cross-functional interaction with other internal department leads and staff, such as Regulatory Affairs, Customer Service, Engineering, Manufacturing, Manufacturing Engineering, Marketing, Finance, Repair & Service, and Sales.
- Interface with FDA, EU NB, Health Canada, South Korea's KFDA, and other pertinent Health Authorities worldwide during notifications, audits, etc.
- Interact externally with customers, suppliers, and external agencies (e.g., Intertek, etc.)

III. Education and Experience

- BS in Engineering or related field.
- 5-10 years of experience in medical devices, preferably Class IIa/III (EU), Class II (FDA)
- Experience in managing a Quality team, preferably in medical device.
- Experience successfully managing cross-functional projects.
- Experience in audits, both internal and external.
- Experience with:
  - Using quality methods to drive continuous improvement in product quality
  - Driving quality initiatives that improve product quality, customer satisfaction, and QA/RA compliance.
  - Statistical Process Controls (SPC)
- Experience with:
  - ISO 13485
  - EU MDR Requirements
  - FDA's 21 CFR and GMP Requirements

IV. Knowledge, Skills, and Abilities

- Excellent organizational and management skills.
- Excellent written, oral, interpersonal, and group communication skills.
- Ability to use Microsoft Office 365 Suite, including Word, Excel, PowerPoint, Teams, and Outlook.

V. Supervisory Responsibilities

- Direct reports include:
  - Quality Assurance Engineer(s)
  - Quality Technicians
  - Incoming Inspection & Calibration Maintenance Staff

VI. Physical Demands

- Position primarily requires sitting, standing, and walking in office areas and the manufacturing area.

VII. Work Environment

- Position requires working in a normal office and manufacturing floor environment.
- Occasional exposure to elements such as odor, noise, dust, heat, cold, or chemicals.
- The position may require periodic use of personal protective equipment.
- Travel is unusual but may be required periodically

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.