Job Title:	**Quality Engineer**	Department:	Quality Assurance
Reports to:	Director of Quality	Division:	Ithaca, NY
Hours:	Full-time – 40 Hrs/week	Rev Date:	11-09-20

Primary Function

This is a role in Quality Assurance focusing on New Product Development, pre-market access, production controls and post-market surveillance. Additional duties and projects to be assigned based on business needs and strengths and interests of the candidate.

I. Core Duties and Responsibilities

- Responsible for design and development quality including adherence to procedures for design input, review, output, V&V and transfer as well as initial production.
- Monitor and ensure compliance with regulatory requirements (e.g. compliance with FDA, MDD/MDR, ISO13485:2016, etc.) and quality system requirements (Transonic Quality System). Advise, assist and lead the project team if any proposed course of actions could affect company or product compliance.
- Participate in the Material Review Board (Non-conforming material investigation and disposition), Corrective Action Board (Failure Analysis and CAPA), and Audit process (Internal and External Audits).
- Review and approve test and validation documents, receiving inspection requirements, sampling plans and Change Orders for product and process changes.
- Initiate change orders to correct drawings, specifications, and Quality System Procedures.
- Participate on Risk Management and Risk Analysis review for clinical and research products.
- Oversee and facilitate reportability decisions for incoming customer complaints.
- Initiate and facilitate continuous improvement projects for Quality Systems as well as support continuous improvement efforts from other departments as needed. NOTE: Typical continuous improvement projects include supplier quality, process/procedure/workflow improvement, and product compliance planning.
- Will be required to perform other work-related duties as requested, directed or assigned by management.

II. Working Relationships

- Work cross-functionally in the development and/or maintenance of products.
- Internal departments such as: Quality Assurance, Regulatory Affairs, Engineering, R&D, Planning and Manufacturing
- External sources, consultants, and agencies both foreign and domestic as required

III. Education and Experience

- A minimum of a BS in Engineering or related professional field is required
- A minimum of 3 years in a "decision-making" position within Quality Assurance is required
- Prior experience in a medical device or other highly regulated environment is preferred

- Experience in Regulatory Affairs is a plus
- Experience with electrical component inspection and assembly is a plus
- ASQ Certification (CQE, CQA, CMDA, CSSBB) is a plus

IV. Knowledge, Skills and Abilities

- Good organizational skills
- Good written, oral, interpersonal, group and telephone communication skills
- Ability to use Microsoft Office Suite including Microsoft Word, Excel, PowerPoint and Outlook.
- Knowledge of Statistical Process Control preferred
- Minitab experience is a plus
- Proficiency in:
  - Design controls
  - Design validation and verification
  - Process validation (IQ, OQ, PQ)
  - Statistical sampling methods
  - Standards compliance such as electrical safety, EMC, biocompatibility, usability

V. Supervisory Responsibilities

- No direct reports

VI. Physical Demands & Work Environment

- Position primarily requires sitting, standing talking and walking in an office environment and stooping, climbing, standing, walking and talking in a processing environment
- Nature of work requires depth perception, close and far vision, normal color distinction, potential for eyestrain and normal finger dexterity
- This position must adhere to safety requirements and may require periodic use of personal protective equipment.
- Office environment with occasional Manufacturing exposure
- Hours of work may exceed normal business hours with occasional evening meetings
- Periodic travel for company business will 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 change existing ones as management deems necessary to meet the ongoing needs of the company.