Job Title:	**Manufacturing Process Engineer**	Dept:	G&A / EndoGear
Reports to:	President EndoGear	Division:	Transonic EndoGear, Davis, CA
Hours:	Full-time – 40 Hrs/week	Rev Date:	10-5-2020

Introduction and Primary Function

Transonic EndoGear is a small innovative early-phase biomedical company (chronic implantable telemetry products) based in Davis, California.

We are currently seeking a Manufacturing Process Engineer.

The candidate for this position will require a broad spectrum of knowledge as he/she will wear many hats while being involved in different aspects of manufacturing and process development support and related administrative tasks. Responsibilities include guiding a small manufacturing and assembly team and creating/sustaining its workflow. The successful candidate will have a great opportunity to help develop and grow with the Company.

I. Duties and Responsibilities

- Organize, schedule, direct and control daily activities of manufacturing and process functions including all areas of production; final quality control testing and shipping deliverables.
- Establish and implement improved standards for Manufacturing Process Instructions to increase product quality and minimize nonconformities.
- Organize and plan work orders and daily manufacturing activities of production staff by communicating job expectations, planning, monitoring and appraising job results
- Provide medical grade material selection and design guidance on mechanical aspects of implantable telemetry devices undergoing development and testing.
- Mechanical CAD design and prototype fabrication both for manufacturing, testing and production.
- Identify and lead testing efforts on material design improvements to existing products.
- Initiate Purchase Orders and internal Work Orders to support planned production activities.
- Write and update manufacturing work instructions; create testing protocols. Continuous improvement of production, to minimize non-value-added activities and reduce cost of quality. Document non-conformances and process changes into the Quality System.
- Ensure the documentation and records are completed, reviewed and stored in accordance with GMP's, internal work instructions, and quality requirements.
- Assist in support and validation and verification activities for all new products and processes
- Interface with Transonic Ithaca (TSI) on issues of NCMR's, CAPA's, investigations, inventory control, finance, administration and purchasing
- Inventory management using Macola. Plan and monitor raw material and finished goods inventory to support global market demands. Month-end inventory reporting to TSI.
- Monitor safety stock, create, assign and follow up on production orders. Perform analysis of backlog items and take action as needed.
- Plan and coordinate maintenance, repair, and calibration of all production related gauges and equipment. Maintain records of these activities. Coordinates external resources as required.
- Assist in production as needed, final testing and final visual inspection.

- Coordinate shipment of sales orders with TSI Customer Service to ensure delivery to schedule. Pull, verify, and pack final product for shipment in accordance with customer requests and company policies and procedures.
- Coordinate shipments of goods authorized for customer return with TSI Customer Service and / or TSI Quality Assurance.
- Quality Assurance control for manufacturing, adherence to Safety standards and recordkeeping such as SDS files.
- Support all other areas as needed; Engineering, Testing, Shipping, etc.
- Perform other work-related duties as requested, directed or assigned by management.

II. Working Relationships

- Communicate with TSI and all levels and functional areas within internal organization;
- Interface with Research Team as product moves from prototyping to regular production;
- External vendors.

III. Education and Experience

- Bachelor's Degree in Biomedical Engineering with mechanical engineering emphasis. Master's degree preferred.
- Minimum of 3 years working in small-assembly manufacturing setting.

IV. Knowledge, Skills and Abilities

- Experience with 3D printing processes and ability to use 3D drawing software to create objects used in manufacturing, testing and production.
- Good knowledge of medical materials used in long term implantations both in humans and animals.
- Requires broad knowledge of purchasing, forecasting, distribution, inventory control, and manufacturing process controls.
- Prior experience in a highly regulated environment such as the Pharmaceutical, Medical Device or Aerospace industries is desirable.
- Strong organizational skills and the ability to multi-task.
- Ability to define problems, collect data, establish facts, deal with abstract & concrete variables, and then to draw valid conclusions. Must react with a strong sense of urgency
- Good oral and written communication skills with R&D scientists, engineers, and suppliers is required.
- Expertise in Microsoft Word and Excel and prior experience in the use of an MRP/ERP system is required.

V. Supervisory Responsibilities

- Small Manufacturing Staff

VI. Physical Demands & Work Environment

- Corrected normal vision and standard color vision are required
- Good manual dexterity
- Ability to lift up to 25 pounds
- Sitting, standing, walking, talking, stooping in an office and production environments; adhering to safety standards with proper use of PPE as recommended or required
- Office and Manufacturing environments
- Occasional exposure to elements such as odor, noise, dust, heat, cold and/or chemicals

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.