SENO
MEDICAL INSTRUMENTS INC.

Job title	*Manufacturing Engineer*
Reports to	*Director of Service and Manufacturing*

Job purpose

The Manufacturing Engineer will be responsible for the design transfer process and daily management of the contract manufacturers of our medical devices and key components. The Manufacturing Engineer is the knowledgeable source of the manufacturing details and drives new product introduction and manufacturing changes.

Duties and responsibilities

- Ensure compliance with ISO-13485, GMP, EU and FDA regulations.
- DMR and DHR creation and review, participation in non-conformance investigations, root cause analysis and CAPAs.
- Ability to write and review SOPs, non-conformance reports, protocols and reports as necessary.
- Author and execute protocols as needed for IQ/OQ/PQs.
- Act as a team role model and change agent. Positively lead and mentor less experienced team members.
- Monitor work of contract manufacturers; alter schedules to meet unforeseen conditions; control flow of work to ensure maximum use of available capacity and effective use of labor, tools and equipment.
- Provide prompt problem solving for key issues, from root cause identification, containment, problem resolution, and ensuring repeat issues are avoided.
- Identify opportunities and initiate new processes to enhance operations, reduce costs and support production goals.
- Develop, implement and maintain metrics designed to continuously monitor all aspects of the production process.
- Stay informed concerning new manufacturing technologies and equipment in order to manufacture and reduce cost through efficiencies.
- Review processing schedules and production orders to make decisions concerning inventory and production requirements.
- Write manufacturing work instructions.
- Drive implementation of the design transfer of new products and desired manufacturing changes.

Qualifications

- Bachelor's degree in Manufacturing, Mechanical, or Electrical Engineering or equivalent.

- A minimum of 8 years of manufacturing experience; Medical device experience preferred.
- Experience managing compliance associated with quality and regulatory.
- Strong knowledge of lean, six sigma, kaizen, and continuous improvement initiatives.
- Experience with new product introduction and process/equipment changes, preferably in an FDA regulated environment (IQ/OQ/PQ/PPQ).
- Project management experience of complex new product introduction or process/equipment changes
- Knowledge of manufacturing operational systems, best practices, processes, and technology.
- Ability to communicate ideas and information clearly, effectively, and frequently (oral and written).
- Highly proficient in Microsoft Office.

Working conditions

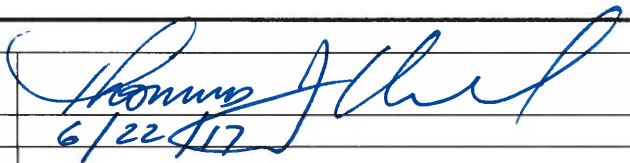
- Approximately 25% travel required.

Physical requirements

N/A

Direct reports

N/A

Approved by:	
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