

TITLE: Manufacturing Process Engineer

DEPARTMENT: Operations

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BURLINGTON, MA**

ConforMIS, Inc. is a privately held medical device company based in Burlington, Massachusetts. It was founded in 2004 to provide dramatic advancements in patient care by utilizing imaging technology to create personalized, patient-specific implants and instrumentation.

Job Summary:

This position is responsible for the selection, development, qualification, and scale-up of both internal manufacturing processes and suppliers. Process objectives are the high quality, high volume production of patient-tailored implants and associated instruments.

Essential Duties and Responsibilities:

- Verification and validation of processes and products using statistical analysis
- Assure compliance with the requirements set forth by US FDA QSR and ISO regulations on both internal processes and supplier products.
- Support and continuous improvement of current manufacturing processes
- Support R&D team by participating in design reviews, providing manufacturing input into design discussions, and review of design documentation.
- Work with suppliers to develop cost effective manufacturing processes that meet established company and industry guidelines.
- Find, develop, and qualify new suppliers
- Documentation of manufacturing processes and inspection criteria within the company's documentation procedures.
- Evaluate and recommend capital equipment to best suit needs of company's selected fabrication processes.
- Participate on project teams as liaison to operations and suppliers.
- Other duties as assigned

Qualifications:

- 5-10 years of experience in manufacturing process support and development for casting and/or machining operations.
- Medical Device/GMP experience preferred
- Bachelor's Degree in Engineering.

Skills, Abilities, Competencies Required:

- Understanding of ISO 13485 and QSR regulations
- Knowledge of statistical analysis (Green Belt preferred)
- CNC machining and/or grinding processes preferred
- Investment casting experience preferred
- Injection molding experience preferred
- Strong verbal and written communication skills
- Ability to work in a team environment and execute job responsibilities with minimal direct supervision and have high attention to detail

ConforMIS is an Equal Opportunity Employer

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