

## Manufacturing Engineer (Marietta GA)

### Summary:

This posting is for a full-time Manufacturing Engineer position for Maruho Medical ([www.maruho-medical.com](http://www.maruho-medical.com)), an orthopedic medical device company with manufacturing operations in Marietta, GA.

The Manufacturing Engineer's primarily responsible is to manage product lines to include pilot and commercial manufacturing. This will include the management of the project (Transfer to manufacturing) to effectively transfer newly developed medical instruments from limited launch to full manufacturing, maintaining timelines and ensuring compliance with quality management systems and industry standards.

### Primary Duties & Responsibilities:

- Develop and maintain project timelines and communicate project status to the leadership team.
- Serve as the main point of contact with internal/external customers to ensure the project milestones are met in a timely manner and the projects stays on track.
- Work directly with the R&D team to gain the skills and knowledge for the assembly/manufacturing of the devices.
- Hands on manufacturing of the devices to establish lines and ensure that production demands are satisfied.
- Train manufacturing personnel to ensure that devices are manufactured according to specification.
- Set up individual project departments to establish a smooth process flow that includes the placement of capital equipment, inventory, associated equipment and Departmental SOP's.
- Writing, reviewing, and final sign off of production batch records, departmental SOPs and quality related documents.
- Work directly with procurement to ensure that raw materials and supplies are maintained at an acceptable level to ensure uninterrupted supply.
- Ensure that proper procedures are followed and required documentation is maintained per the quality standards.
- Ensure that the department and/or crew operations and maintains a clean, safe working environment while adhering to cGMP standards.
- Work with the R&D department to implement product enhancement changes for the devices.

### Education & Experience:

- Bachelor's Degree (Mechanical or Biomedical Engineering preferred)
- 5+ years of experience in medical device industry preferred
- Proficiency with CAD systems required (Solidworks preferred)

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888.404.3980 | [www.maruho-medical.com](http://www.maruho-medical.com)

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- Knowledge of plastics injection molding and metals manufacturing processes (laser welding, machining, etc.), and comfortable with mill, lathe and other shop tools.
- Understanding and application of 21 CFR 820, ISO 13485, and ISO 14971 standards
- Advanced problem-solving skills, strong attention detail, and excellent organizational and written/oral communication skills
- Self-starter with strong sense of urgency to meet timelines, and the ability to function well with ambiguity

### Benefits:

- Health insurance
- Paid time off
- Dental insurance
- 401(k)
- Vision insurance
- Life insurance
- 401(k) matching
- Flexible spending account