



Manufacturing Engineer (AME)

Millstone Medical Outsourcing, headquartered in Fall River, MA is a fast-growing company in need of motivated individuals to assist in the expansion of its Fall River, MA facility. Millstone Medical Outsourcing's business focus is sterile and non-sterile packaging of medical devices. Millstone also engages in other activities, such as mechanical inspection and assembly, which are designed to meet the outsourcing requirements of medical device manufacturers seeking to reduce costs while maintaining high levels of quality, accuracy and timeliness. Millstone Medical Outsourcing is FDA and ISO registered and employs a detailed internal quality system to ensure ISO compliance.

Position Overview:

The AME is responsible for developing and implementing the processes, equipment, and tooling used to execute on critical cleaning and sterile packaging of orthopedic medical devices. AME is responsible for process improvements as all documentation necessary for a smooth transition through any pilot phase into full production. The AME is responsible for developing and adhering to all manufacturing financial commitments in the new program business case including product cost estimates and manufacturing process CAPEX & OPEX budgets. Responsible for planning, project management and leadership of all manufacturing activities in support of new product development including the management of extended manufacturing team resources. Collaborate with design engineers to ensure product designs are cost effective, robust and manufacturable with high levels of quality.

Key Responsibilities:

- Develop and implement economical, repeatable manufacturing processes for new and existing products.
- Responsible for product quality, including resolving quality problems, validating processes, developing and implementing process controls and inspection procedures using PFMEA and other risk management methodologies.
- Responsible for work instructions, job instructions, labor standards and routings, and line balancing to meet required production rates.
- Responsible for ensuring manufacturing processes are compliant with all applicable regulations and Millstone quality system requirements.
- Drive continuous improvement and lean manufacturing methodologies into production.
- Ensure manufacturing processes are compliant with all applicable safety standards and policies.
- Develops workable project plans and timelines to meet goals.
- Assist in the development of effective operator instructions. Assist with related training of operators
- Act as an integral member of project teams tasked with resolving technical issues or continuous improvement projects.
- Collaborate with manufacturing to identify and troubleshoot process issues.



- Collaborate with program development on new product launches, the transfer of products to manufacturing, and ensure a high degree of process capability.
- Responsible for all necessary documentation and approvals.
- Partner with various departments to investigate the root causes of process problems and implement problem specific corrective actions.
- Be responsible for the development of fixtures and procedures to be used for product quality and process capabilities.
- Able to work independently with minimum supervision.

Skills and Experience Required:

- Candidates will have a B.S. in Engineering and a minimum of 5 years of experience in medical device processing/manufacturing engineering/product development.
- Ability to work in a fast-paced environment with multiple priorities
- Exemplary verbal and written communication skills
- Lean certified, black belt in six sigma and minitab proficiency is highly preferred

Contact:

Interested candidates should send resumes to hr@millstonemedical.com or apply in person at 580 Commerce Drive, Fall River, MA 02720

For Additional Information:

Millstone Medical Outsourcing offers a competitive salary, health, dental and vision benefits, 401(k) with company match and a warm, friendly working environment. To learn more about Millstone Medical Outsourcing's opportunities, visit us online at www.millstonemedical.com.