



Manager of Manufacturing Engineering and Advanced Manufacturing Engineering

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:

We seek a highly motivated, hands-on engineering manager to manage our Manufacturing Engineering group. 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. ME is responsible for our critical cleanroom utilities including HVAC for ISO class 7 and 8 cleanrooms as well as purified water systems. ME is responsible PM and maintenance of equipment post-validation after it is placed into production.

The Manager of Manufacturing Engineering is responsible for managing a team of manufacturing and process engineers responsible for planning and executing the manufacturing process development for new product introduction, continuous improvement and product or process issue. She/he will oversee the team while driving completion of design of experiments, process qualification, scrap and COGS reduction initiatives, issue root cause analysis, process changes and risk analysis. The Manager of Manufacturing Engineering owns developing the strategy and monitoring the success of equipment selection and implementation, initiatives in process and yield improvements, and driving cost reduction activities.

Key Responsibilities:

- Provide guidance and direction to a group of existing engineers and build out the team as required to support the objectives and needs of Millstone Medical Outsourcing.
- The incumbent will be responsible developing the processes and requirements to implement new product lines and/or manufacturing capacity and then leading the team to execute these projects.
- Lead projects to evaluate engineering solutions and make recommendations to senior management. Manage vendor selection process and vendor performance.



- The incumbent will also be responsible for providing design for manufacturing (DfM) feedback to our project engineers, validation engineers and customers to realize superior design efficiency and cost management.
- Works with customers and upstream suppliers to understand assembly and finished good manufacturing processes and acts as technical expert to ensure repeatable and reproducible quality/reliability during the life of the product(s).
- Interfaces with quality and project engineering to support investigation of product/component/material issues or supply constraints and assists with troubleshooting.
- Spearheads Six Sigma (Problem Solving and Process Improvement) and Lean initiatives to develop project opportunities to gain rates of improvement from manufacturing lines. Utilizes Design of Experiments to optimize manufacturing processes.

Skills and Experience Required:

- 10+ years of progressive experience with medical device manufacturing
- 3+ years in an engineering management role
- Bachelor's Degree in Engineering (Mechanical or Electrical preferred). Advanced degree preferred.
- Ability to work in a fast-paced environment with multiple priorities
- Exemplary verbal and written communication skills
- Demonstrated success introducing new products and new processes into a production environment
- Excellent project management skills.
- experience designing and costing mechanical equipment, fixturing, tooling and facilities
- Good understanding of statistical methods, six sigma methodologies, design of experiments and lean.
- Strong ability to manage and prioritize multiple projects while maintaining accuracy and meeting deadlines; able to balance short-term, urgent needs with long-term strategic initiatives.
- The ideal candidate will have previous experience in a few of the following areas: Process Validation, Medical Packaging, Reliability Engineering (CRE), Design for Manufacturing (DfM), Lean Manufacturing, Process Control Concepts, Design of Experiments (DOE), and design/process Failure Mode and Effects Analysis (FMEA).
- Proficient in common office computer software.

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.