



## **We are looking for the best, and so should you!**

High Growth Company  
Opportunity to Learn and Grow  
Shape your Career  
See the Importance of Your Work

Millstone Medical Outsourcing, headquartered in Fall River, MA is looking for an energetic individual to join its Quality Team as Quality Engineer II. Millstone is a fast growing, fast paced medical service provider for the top Orthopedic companies in the industry. Millstone'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. We are FDA and ISO registered and employ a detailed internal quality system to ensure ISO compliance.

### **Responsibilities:**

The Quality Engineer II is primarily responsible for supporting engineering projects at Millstone. The Quality Engineer (QE) II will also:

- Lead and manage engineering and operations projects per agreed upon timelines that include equipment, software, product & process validations.
- Lead corrective action teams, sometime across multiple sites, as part of Millstone's CAPA system to investigate, determine root cause, develop and implement corrective actions.
- Lead change control efforts through Millstone's change control process as necessary
- Develop and provide oversight to gage R & R's and serve as primary point of contact for documentation associated with out of tolerance equipment.
- Identify and lead preventive action projects that reduce non-conformances and improve operational efficiencies
- Complete statistical analysis and provide metrics internally as well as to clients (management review, CQR, KPI, etc.) as required.
- Serve as the primary Quality contact for selected client groups, which includes review of validations, document changes, process changes, and client issued SCARs.
- Participate in internal and external audits as needed.
- The QE II will perform other duties as requested or required across all areas of the Company.



### **Required Knowledge and Skills:**

- Bachelor's degree in Engineering and 5-7 years of experience in an ISO 13485 and FDA environment is required.
- Excellent verbal and written communication skills
- Excellent interpersonal and customer service skills
- High attention to detail and the ability to work in a team environment are essential
- Ability to multitask and complete work independently is crucial.
- Excellent problem solving and decision-making skills are needed.

### **Additional Information:**

Millstone Medical Outsourcing offers a competitive salary, health, dental and vision benefits beginning on the first day of employment and 401K with company match. Other benefits include paid vacation, paid sick time, holiday pay and voluntary benefits in addition to an employee-centric work environment. To learn more about Millstone Medical Outsourcing's opportunities, visit us online at [www.millstonemedical.com](http://www.millstonemedical.com). If interested, please forward resume to [hr@millstonemedical.com](mailto:hr@millstonemedical.com).

*Millstone Medical Outsourcing provides equal employment opportunity to all applicants and employees. No person is to be discriminated against in any aspect of the employment relationship due to race, religion, color, sex, age, national origin, ancestry, disability, sexual orientation, gender identity, genetic information, citizenship status, marital status, pregnancy, veteran status or any other status protected by applicable federal, state, or local law.*