



QUALITY ENGINEER I

We Deserve the Best – And So Do You!

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

Millstone Medical Outsourcing is looking for an energetic individual to join its Quality Department as a Quality Engineer I. 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:

- Responsible for providing Prevention, Appraisal, and Failure tasks associated with ongoing process operations including:
 - Contract/Purchase Order (PO) review
 - Drawing/specification review
 - Inspection requirements planning
 - Gage & inspection tool design
 - Metrology & calibration
 - Validation & verification
 - Inspection monitoring
 - Process surveillance
 - Internal audit
 - Data analysis
 - Corrective & preventive action investigation & reporting
 - Material review
 - Complaint investigation and improvement studies
- Assist in the creation and maintenance of system procedures & work instructions as well as prepare Inspection Reports for use in operations
- Works seamlessly with customers and calibrate with workmanship expectations
- May also serve as Tissue Bank Director for regulatory purposes
- Consistently above average when it comes to productivity/efficiencies, sets the pace for others
- All other duties as assigned

KNOWLEDGE & SKILLS:

- Bachelor's Degree with at least 2 years of Quality Engineering experience
- Advanced inspection and mechanical aptitude
- Excellent verbal and written English communication skills
- High attention to detail and the ability to work in a team environment are essential
- Understanding of GD&T
- Knowledge and execution of issues related to FDA/GMP compliance
- CAD/CAM, Solidworks/Unigraphics or similar experience
- Ability to use standard measuring instruments, gauges, read and understand basic prints/drawings
- Advanced Math skills in algebra, trigonometry, & basic statistics concepts
- Capability to develop/design fixtures
- Advanced ability to create Microsoft Excel, PowerPoint & Word documents with expert ability to incorporate functions & write macros. Microsoft Office certification a plus.
- Excellent interpersonal and customer service skills
- Easily able to recognize & communicate potential issues
- Ability to follow and review department procedures for correctness and write/re-write procedures when necessary
- Excellent interpersonal and customer service skills
- Works well with internal customers from various levels of the organization
- Capacity to train others, including "training the trainer"
- Works independently and easily resolves minor daily issues/problems
- ASQ CQE certification highly preferred
- Six Sigma training a plus

PHYSICAL REQUIREMENTS:

Standing, stooping, light lifting (25 lbs. or less), manual dexterity, ability to read fine print, 20/20 vision or corrected 20/20 vision

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. If interested in this position, please send your resume to 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.

All employment offers are contingent upon successful completion of our pre-employment drug screening and background/criminal check, consistent with applicable laws.