



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 Team. 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.

Working collaboratively within the Quality team, the QA Associate will be responsible for coordinating activities related to the Non-Conforming Material process, including physical movement of material in and out of holding areas as well as the related inventory transactions and e-QMS records.

Responsibilities

- Initiating NCMR Forms when non-conforming or suspect product is identified at incoming inspection, manufacturing and the warehouse.
- Physically moving components, materials, and finished goods into MRB areas.
- Proper labeling of MRB material that is stored in designated MRB areas.
- Performing Oracle inventory move transactions of material in and out of MRB locations
- Assisting with containment activities to ensure all nonconforming or suspect material is found and place in a MRB location.
- Documenting NCMR investigation results on NCMR forms and tracking open NCMRs via spread sheet.
- Performing inventory cycle counts of NCMR materials located in the MRB locations.
- Assist with the implementation of rework, UAI, scrap and RTV dispositions.
- Verifying through objective evidence MRB dispositions (rework, return to vender, use as is, or scrap) have been properly completed per the NCMR Work Instructions.



Qualifications/Requirements

- High school diploma/GED plus 2-3 years of experience in a manufacturing environment, [Any experience in a regulated manufacturing environment (FDA CFR 21 820 and ISO 13485) is preferred, cGMP and GDP concepts.]
- Ability to communicate effectively in English (both written and oral). Writing skills are required in order to document product information and problem statement descriptions as well material containment actions.
- Proficient experience with software applications applicable to the job (MS Office, Excel Spreadsheets, ERP systems, e-QMS software)
- Demonstrate expertise to effectively communicate within a variety of levels in the organization and with clients.
- Demonstrate the proper handling, storage and control of components and finished good materials in a warehouse, manufacturing and clean room environment
- Ability to lift boxes and/or materials up to 25 pounds

Preferred Qualifications

- Experience with Oracle or similar Inventory Management databases
- Comprehension of regulatory requirements such as FDA CFR 21 820, 210, 211 or ISO 13485
- Technical / Associate Degree
- Lean Manufacturing / Six Sigma trained
- Attention to detail with ability to multi-task & handle tasks with competing priorities effectively

For 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.

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, protected veteran status or any other status protected by applicable federal, state, or local law.