



## SENIOR VALIDATION ENGINEER

### 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 Engineering Department as a Senior Validation Engineer. 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:**

- Document and execute equipment and process validations (IQ, OQ, PQ) on various types of manufacturing equipment and end-of-line processes
- Creation of manufacturing work instructions
- Interface with customers on technical issues, project timeline, and validation support
- Actively participate on cross functional teams
- Provide support for operations and communicate with Program Managers
- Provide training of operations personnel
- Institute and apply best engineering practices to processes to facilitate high quality output and efficient throughput
- Ensure effective use of designs, material, equipment, and personnel throughout operations
- Negotiate and administer facility engineering services, materials, and equipment contracts as appropriate
- Participate in the development and implementation of facility engineering technology and automation solutions to increase ecological sustainability and operational efficiency
- Possess strong communication and interpersonal skills to build relationships with employees across the organization, including key client groups, peers, senior management, and subordinates
- Ensure process validation program is robust, compliant, and current
- Develop and maintain re-validation program with risk-based approach

- Facilitate and/or support validation training, project management activities as required, and support change management

#### **KNOWLEDGE & SKILLS:**

- Bachelor's degree with 5 years Validation Engineering experience. Less experience may be considered with a Master's degree
- Experience in managing and executing projects
- Strong interpersonal and organizational skills
- Possess excellent leadership and project management skills
- Must be capable of multi-tasking and performing assignments that have loosely defined objectives
- Ability to effectively communicate verbally and in writing
- Must be able to plan, coordinate, perform, and supervise contract staff with minimal oversight
- Ability to apply fundamental engineering principals to resolve issues relating to processing equipment and product launches
- Ability to apply working knowledge of applicable regulatory standards (FDA, ISO, OSHA, EPA, CFR, etc.) and good understanding in GMP requirements and validation processes
- Statistical Data Analysis experience highly preferred
- Must be able to prioritize critical versus non-critical issues and communicate to management
- Ability to establish credibility and trust amongst all levels of the organization
- Act at high integrity and influence decisions impacting the performance of the site
- Ability to work under tight timelines and be able to motivate others to deliver expected results

**\*\* PLEASE NOTE: THIS POSITION IS NOT ELIGIBLE FOR VISA SPONSORSHIP &/OR RELOCATION ASSISTANCE\*\***

#### **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 and all of its current employment opportunities, please visit us online at [www.millstonemedical.com](http://www.millstonemedical.com). If you are qualified and would like to apply to this position, please send your 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.*