



## VALIDATION ENGINEER MANAGER

### 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 Validation Engineer Manager. 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

***\*\*This position is a hands-on leadership role with potential direct reports. \*\****

***\*\*\*Please note that this position is not a remote/contract position. The employee that fills this position will be full-time, working out of the Fall River, MA facility. \*\*\****

#### **JOB SUMMARY:**

The Validation Engineer Manager will act as a hands-on leader to the engineering team to ensure that all tasks associated with validation activities are completed successfully.

#### **RESPONSIBILITIES:**

- Serve as a principle technical expert regarding validation activities associated with equipment and processes
- Perform process analysis, improvements, along with equipment and process validations (IQ, OQ, PQ) on various types of manufacturing equipment and end-of-line processes
- Generate clear and concise work instructions, test methods, and visual standards
- Have a firm understanding of validation strategy (IQ, OQ, PQ), support protocols and reports
- Serve as Subject Matter Expert (SME) during internally and external regulatory audits
- Interface and negotiate with customers on technical issues, project timelines, and validation support
- Establish and streamline process validation procedures to improve program launch process
- Actively lead and participate on cross functional teams

- Provide technical support for operations involving day to day troubleshooting 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 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 and compliant
- 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
- Contribute to the effectiveness of the quality system by activity participating in NCR's, complaints, CAPA's, and root cause investigations.
- Provide mentorship and be able to manage junior engineers
- Act as document approver

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

- Bachelor of Science in Mechanical Engineering/Chemical Engineering/Bioengineering with 5-8 years 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
- 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



**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 its current employment opportunities, please visit us online at [www.millstonemedical.com](http://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, 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.*