



We Deserve 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 is looking for an energetic individual to join its Engineering Department as Associate Validation 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 hands-on Associate Validation Manager will manage and lead the operations validation team to ensure we meet current regulations (process, environmental and cleaning qualifications) and work cross functionally in a team-based environment to find resolutions to validation issues and ensure proper qualification documentation is completed. In this lead role you will be the operations validation SME for the site!

Responsibilities Include:

- 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 timelines, and validation support
- Actively participate on cross functional teams to determine the root cause and corrective actions for problems associated with investigations
- Provide support for operations and communicate with Program Managers
- Lead, coach and mentor staff
- Utilize leadership and communication skills to communicate cross functionally, and within all levels of the company, including senior management in an effective manner including strong presentation skills
- Utilize knowledge of the principals of process and cleaning validation, current industry approaches, GMP and FDA validation guidelines to advance goals forward



Skills Required:

- Bachelor's degree in Engineering required
- 5 - 10 years validation experience
- Strong technical writing to develop client process validations
- Excellent communication skills
- Excellent attention to detail, analytical and problem-solving skills
- Experience with IQ, OQ and PQ protocols
- Knowledge of GMPs
- Experience developing staff regarding teamwork, validation techniques and procedures to ensure GMP compliance.

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. If interested, please forward 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.