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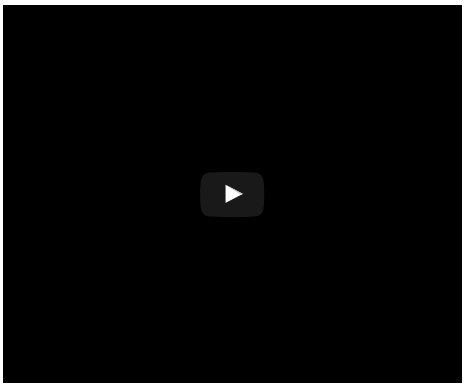
Senior Applications Chemist - Quality

Req. #	5817	**Company Name**	Waters Division
Category	Quality Assurance	**Location**	US-MA-Milford
Type	Regular Full-Time		

More information about this job:

Company Description:

For over 50 years, Waters Corporation has developed innovative analytical science solutions to support customer discoveries, operations, performance, and regulatory compliance. Specifically, the company designs, manufactures, sells, and services high performance liquid chromatography, ultra performance liquid chromatography, and mass spectrometry technology systems and support products primarily in the United States, Europe, Japan, and Asia. Our innovations enable significant advancements within the pharmaceutical, life science, biochemical, industrial, food safety, environmental, academic and government industries. Waters is a publicly traded corporation (NYSE:WAT) with more than 6,000 employees and is represented in over 100 countries around the world.



Waters Corporation is an Equal Opportunity Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, sexual orientation, gender identity, disability or protected veteran status.

Overview:

Summary of Position:

The Sr. Quality Applications Chemist, who works under the direction and supervision of the Sr. Operations Quality Engineer, leads the planning and execution of projects and activities for the facility to improve product and process quality, and analyzes laboratory results and quality data (complaints, process non-conformances, process capability, etc). The Sr. Quality Applications Chemist will also be a key resource in identifying and implementing best practices for laboratory procedures, process improvement, problem solving, and driving customer satisfaction.

This individual is responsible for supporting the Waters Instrument Quality Assurance Laboratory within the Milford plant by leading quality initiatives related to production process development, product testing, test method development, and Quality System Management. This includes responsibility for development and organization of the quality laboratory procedures and processes, leading investigations into product non-conformances, executing day-to-day LC/MS product release testing, leading Corrective Action and Preventive Action (CAPA) investigations, and driving improvement activities and projects related to product and process quality. The support to Milford Operations will include providing daily guidance on Good Manufacturing Practices (cGMPs) and effective risk management. This position is hands-on in a fast-paced environment which will interact with multiple functions (R&D, Engineering, Test Engineering, Reliability Engineering, Regulatory, and Purchasing) and sites (sister manufacturing sites and contract manufacturers) to resolve quality issues.

Responsibilities:

Duties:

- Develop standard operating procedures, quality protocols, qualification documents, and lab test methods for product

- Develop standard operating procedures, quality protocols, qualification documents, and lab test methods for product acceptance activities. Test method development will include cleaning validation and daily Quality Control testing.
- Execute day-to-day product acceptance and release testing within the Quality Assurance Laboratory on LC/MS or appropriate instrumentation.
- Develops, modifies, applies and maintains quality evaluation and control systems/protocols within the Quality Assurance Laboratory. Review records, procedures, work instructions, forms etc. to ensure that they are accurate, complete and compliant with the process and with the requirements of the quality management system / GMP.
- Collaborates with internal supplier/customers to ensure quality standards are in place.
- Ensures that corrective measures meet acceptable standards and that documentation is compliant with requirements.
- Investigates deviations and out-of-specification results.
- Drive failure investigations to ensure root causes are found and appropriate corrective actions are implemented to prevent repeat non-conformances.
- Determine adequacy of acceptance activities and make necessary improvements.
- Support change management activities to ensure process changes are managed and approved effectively.
- Perform quality review of validation documentation to ensure that it is accurate, complete and compliant with the requirements of the quality management system.

Qualifications:

Education:

- Bachelors Degree in Science (Biology, Physics, Chemistry, etc.), Chemical Engineering, or technical field with emphasis on statistical skills. Advanced degree preferred.

Experience:

- Minimum 6 years of experience in Quality Assurance or GxP related field
- Minimum 4 years of experience within a regulated Laboratory executing, reviewing, and approving acceptance activities,
- Minimum 4 years experience using Liquid Chromatography and/ or Mass Spectrometry techniques
- Demonstrated use of data analysis to make critical decisions and drive change
- Working experience with cleaning validation, test method development, or method validation
- FDA 21 CFR 820 or 211 - cGMP knowledge base in Biotechnology Industry (Biologics, Pharmaceuticals, or Medical Devices)
- Superior leadership, facilitation, interpersonal, and communication skills
- Demonstrated implementation of continuous improvement methodologies
- Exposure to equipment qualification, process, or software validation
- Ability to work independently across multiple organizations
- Good report writing and reviewing skills

Desired Qualifications:

- Experience using Waters Empower and Waters Mass Spectrometers
- Operational Excellence/Six Sigma/Lean training or certifications
- Project management certifications (Black Belt, Green Belt, Certified Associate in Project Management (CAPM), Project Management Professional (PMP), etc)
- Experience using SAP or Oracle
- Experience with particle counting techniques
- Experience with inorganic analysis techniques

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