



Quality Assurance/Regulatory Affairs Specialist I: Molecular Diagnostic Products

Employer: Maine Molecular Quality Controls, Inc. (MMQCI) designs, develops, manufactures, and markets unique quality control products used by hospital laboratories to monitor the accuracy of tests for inherited disease, pharmacogenetics, oncology, and infectious diseases. MMQCI has developed technologies to stabilize DNA and RNA for use as quality controls and continues to pursue the discovery of novel techniques useful for the development of new quality control products. We are a small, growing company that offers a relaxed but challenging work environment.

POSITION TITLE: Quality Assurance/Regulatory Affairs Specialist I

GENERAL SUMMARY:

The Quality Assurance/Regulatory Affairs Specialist I is responsible for activities involving quality assurance and compliance with applicable regulatory requirements. Under the supervision of the Manager of QA/RA, the QA/RA Specialist I is responsible for the maintenance of policies, and management of procedures, that ensure quality compliance to MMQCI's Quality System, based on federal Quality System Regulation 21CFR820. The successful candidate is experienced in using and maintaining a Quality System according to 21CFR820. It is expected that the QA/RA Specialist I will rapidly develop sufficient expertise to function independently. Maine Molecular is looking for the person with the energy and experience to step into this vital position in a growing company and grow along with us.

PRINCIPAL DUTIES AND RESPONSIBILITIES:

1. Maintains MMQCI Quality System documentation to ensure compliance with established procedures and regulatory compliance requirements, including, but not limited to, Standard Operating Procedures (SOPs), Master Batch Records, Change Orders, Material Review Notices (MRNs) and Corrective and Preventive Actions (CAPAs).
2. Works closely with Manufacturing to support and document MRNs and CAPAs.
3. Assists or performs internal audits and supplier audits.
4. Supports FDA and customer audits.
5. Assists in the assembly Device Master Records for new products.
6. Maintains training documentation of all MMQCI employees.

MINIMUM KNOWLEDGE, SKILLS AND ABILITIES REQUIRED:

1. Education Requirements: Bachelor of Science degree in Life Sciences and at least 5 years of employment in a cGMP regulated facility and at least 2 years of experience in Quality Assurance.
2. Good communication skills, written and oral, with excellent computer skills including Excel.
3. Excellent proof-reading skills are required.
4. Very detail oriented.
5. Knowledge of current GMP regulations is required.
6. Knowledge of ISO 13485 is preferred.

7. Experience in laboratory medicine is highly preferred.
8. Ability to multi-task in a dynamic environment with changing priorities.
9. Strong work ethic.
10. Ability to meet challenging timelines, in spite of obstacles.
11. Willingness to learn and pitch in as part of team
12. Ability to communicate clearly and constructively to correct non-conforming behaviors and practices.
13. Must be a nonsmoker due to product contamination prevention requirements.

BENEFITS:

- Medical insurance
- Dental insurance
- 401(k)
- Profit sharing plan
- Vacation
- Holidays
- Sick leave

How to apply: by Email/ No Phone inquiries accepted

Email: HR@mmqci.com

A cover letter is required.

Contact Information:

Human Resources

Maine Molecular Quality Controls, Inc.

23 Mill Brook Road

Saco, Maine 04072

Email: HR@mmqci.com

LOCATION: MMQCI is conveniently located in beautiful southern coastal Maine, minutes from the Maine Turnpike, Portland International Jetport, and less than 2 hours from Boston. Close by are fabulous Portland restaurants, sandy beaches, and a plentiful supply of Maine lobsters! Many terrific outdoor activities are easily accessible including hiking, biking, kayaking, fishing, skiing and snowshoeing. We have a beautiful, state-of-the-art facility located in Saco, right next to the Eastern Trail. Come join us!