



Quality Assurance/Regulatory Affairs Associate

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, 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 Associate

GENERAL SUMMARY:

The Quality Assurance/Regulatory Affairs (QA/RA) Associate 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 Associate is responsible for assisting the team with the maintenance of MMQCI's Quality System policies and procedures that ensure quality compliance to U.S and international regulations. A successful candidate is capable of providing support to our QA/RA specialists and internal customers with day-to-day tasks as well as short and long term projects. Task include, but are not limited to, record review, filing, document archiving, and document control activities. MMQCI is looking for a person that will rapidly develop sufficient expertise to function independently with minimal supervision. This position also offers performance related growth opportunities within our QA/RA team, and potentially in other areas of the company.

PRINCIPAL DUTIES AND RESPONSIBILITIES:

1. Supports QA/RA with the maintenance of 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 (CO), Material Review Notices (MRNs) and Corrective and Preventive Actions (CAPAs), and training. Maintenance of documentation includes record retention activities.
2. Assists with internal and supplier audits.
3. Supports regulatory and customer audits.
4. Assists in the assembly Device Master Records for new products.
5. Maintains training documentation of all MMQCI employees.

MINIMUM KNOWLEDGE, SKILLS AND ABILITIES REQUIRED:

1. High School diploma is required. Associate Degree preferred.
2. At least 1 year working in an office setting is required.
3. Proficiency with Microsoft Office software (Excel, Word, Outlook) is required.
4. Very detail oriented.
5. Excellent proof-reading skills are required. This will include, but not be limited to, the inspection of documents (small print and symbols) for correctness without external magnification.

6. Ability to manage multiple priorities with little supervision.
7. Flexible; accustomed to fast-changing priorities of a small company.
8. Good communication skills, written and oral, with excellent computer skills.
9. Knowledge of current cGMP regulations is considered a “bonus” skill
10. Knowledge of ISO 13485 and FDA 21CFR 820 is preferred.
11. Ability to multi-task in a dynamic environment.
12. Strong work ethic.
13. Willingness to learn and pitch in as part of team.
14. Ability to lift boxes weighing up to 50lbs from standing or squatting position using a step stools or small ladder.
15. 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!