Quality Assurance/Regulatory Specialist II: 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 II

GENERAL SUMMARY:

The Quality Assurance/Regulatory Affairs (QA/RA) Specialist II is responsible for all activities involving quality assurance and compliance with applicable regulatory requirements; conducts audits and reviews/analyzes data and documentation. Under the supervision of the Manager of QA/RA, the QA/RA Specialist II is responsible for implementation, management, and maintenance of policies, procedures, and systems that ensure quality compliance to MMQCI's Quality System, based on federal Quality System Regulation 21CFR820. The successful candidate has a strong *in vitro* laboratory diagnostic industry background and is experienced in using and maintaining a Quality System according to 21CFR820. It is expected that the QA/RA Specialist II 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. Reviews and approves all 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). Works closely with Manufacturing to investigate MRNs and establish CAPAs addressing root cause.
2. Reviews and approves validations of new equipment and processes.
3. Assists or performs internal audits and supplier audits.
4. Supports FDA and customer audits.
5. Assembles Device Master Records for new products.
6. Oversees training documentation of all MMQCI employees.
7. Maintains MMQCI's ISO 13485 certification and prepares input into Technical Files for CE marking of MMQCI products and maintains international product registrations.
8. Prepares and submits FDA pre-submissions, de novo requests, and 510(k) submissions for MMQCI's Class II products and maintains appropriate FDA registrations.
9. Interprets statutes, regulations, policies and guidance for MMQCI staff teams, communicating how these impact product development and Design Control, manufacturing, and/or marketing.
10. Remains current on regulatory issues/trends affecting MMQCI products, assessing and communicating their impact to QA/RA colleagues and product development/support teams.

11. Participates in, and may conduct, internal, customer, FDA, and ISO audits.
12. Works closely with QA/ RA and other MMQCI staff to review and approve product labeling changes, promotional literature and marketing materials, rework of non-conforming product, CAPA closures and Medical Device Reports (MDR).
13. Provides training or presentations to cross-functional groups on a variety of regulatory topics.
14. Writes SOPs and trains key personnel as needed.
15. Perform other duties as assigned, including but not limited to, help monitor, maintain, and improve the quality system and serve as the person responsible for post-market surveillance, reporting and recalls.

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. Excellent proof-reading skills are required.
3. Knowledge of current GMP regulations for medical devices is required.
4. Very detail oriented.
5. Knowledge of ISO 13485 is preferred.
6. Experience in laboratory medicine is highly preferred.
7. Good communication skills, written and oral, with excellent computer skills including Excel.
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're in a state-of-the-art facility + located in Saco, right next to the Eastern Trail. Come join us!