



Diagnostic Device Regulatory Specialist: 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: **Regulatory Specialist**

GENERAL SUMMARY:

Under the general supervision of the President, the Regulatory Specialist is responsible for all activities involving MMQCI's compliance, submissions and registrations according to applicable *in vitro* diagnostic regulations, including but not limited to, FDA 21 CFR 820, ISO 13485, and EU IVDR 2017/746. The Regulatory Specialist works closely with MMQCI's Quality Assurance Specialist and MMQCI staff to maintain and grow MMQCI's Quality System based on 21CFR820 and ISO 13485. The successful candidate has strong *in vitro* laboratory diagnostic industry background and is experienced interacting with FDA, Notified Bodies, EU Competent Authorities and other international regulatory authorities. It is expected that the Regulatory Specialist will rapidly be able to function independently with minimal supervision. 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. Establishes and maintains MMQCI's ISO 13485 certification and prepares input into Technical Files for CE marking of MMQCI products and maintains international product registrations.
2. Prepares and submits FDA pre-submissions, de novo requests, and 510(k) submissions for MMQCI's Class II products and maintains appropriate FDA registrations.
3. Interprets statutes, regulations, policies and guidances for MMQCI staff teams, communicating how these impact product development and Design Control, manufacturing, and/or marketing.
4. Remains current on regulatory issues/trends affecting MMQCI products, assessing and communicating their impact to QA/RA colleagues and product development/support teams.
5. Participates in, and may conduct, internal, customer, FDA, and ISO audits.
6. 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).
7. Provides training or presentations to cross-functional groups on a variety of regulatory topics.
8. Writes SOPs and trains key personnel as needed.
9. Suggests significant opportunities for improvement (cost, cycle time, quality, etc). Analyzes feasibility and participates in developing, executing, or monitoring implementation plan.

10. 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. B.S. degree or higher degree in Life Sciences. RAPS Certification preferred.
2. Minimum 5 years of quality assurance and regulatory affairs experience in a cGMP and ISO regulated medical or *in vitro* diagnostic device facility.
3. Demonstrated success in preparing, filing and completing regulatory submissions/dossiers (e.g., 510(k), Technical Files).
4. Working knowledge of 21 CFR 820 - Quality System Regulation, and ISO 13485 regulation is required.
5. Must be able to think critically which includes analytical abilities such as interpret regulations and/or standards, apply them to product changes and determine resulting course of action.
6. Detail oriented with excellent organizational skills.
7. Experience in laboratory medicine is highly preferred.
8. Good communication skills, written and oral, with excellent computer skills including Excel.
9. Ability to multi-task in a fast-paced dynamic environment with changing priorities.
10. Strong work ethic.
11. Willingness to learn and pitch in as part of team
12. 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

A cover letter is required. Please Email resume and cover letter to: HR@mmqci.com

Contact Information:

Human Resources

Maine Molecular Quality Controls, Inc.

23 Mill Brook Road

Saco, Maine 04072

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 are in a brand new, state-of-the-art facility located in Saco right next to the Eastern Trail. Come join us!