23 Mill Brook Road
Saco, Maine 04072
Fax: 207-885-1079
www.mmqci.com

Manager of Manufacturing Operations

EMPLOYER: Maine Molecular Quality Controls, Inc. (MMQCI), located in Saco, Maine, designs, develops, manufactures, and sells unique quality control products used by hospital laboratories and manufacturers to monitor the accuracy of tests for genetic, oncologic, and infectious diseases. MMQCI has patented 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 and offer a relaxed but challenging work environment.

POSITION TITLE: **Manager of Manufacturing Operations: Molecular Diagnostic Products**

GENERAL SUMMARY:

The successful candidate will be an experienced manager who enjoys performing a variety of tasks at a fast pace. The Manager of Manufacturing Operations is responsible for all processes contributing to the manufacture of MMQCI's products, including cGMP manufacture, production, quality control testing and written documentation. The Manager will oversee MMQCI staff performing manufacturing and testing of products, and will be responsible for assigning work orders and scheduling processes from manufacture through kitting of finished goods. The Manager will assist with the transfer of new products from R&D, and the improvement of existing products. The Manager of Manufacturing Operations reports directly to the President.

PRINCIPAL DUTIES AND RESPONSIBILITIES:

- Responsible for the manufacture of all MMQCI products in a clean room environment, according to cGMP, 21CFR Part 820.
- Oversees all QC release testing of MMQCI products.
- Oversees production activities, including labeling, filling and kitting of product.
- Oversees the preparation of reagents used for manufacturing purposes and is responsible for labware cleaning and sterilization.
- Provides data, interprets results and writes reports as required for investigations of product issues and resolution of problems initiated through non-conformances, corrective action, customer complaints, and/or audit findings.
- Responsible for the cleanliness of manufacturing area and provision of required resources.
- Responsible for continual process improvement of Manufacturing.
- Authors and updates manufacturing SOPs as needed for maintenance of MMQCI's Quality System.
- Trains staff as required and creates Training & Development Plans for the manufacturing team.
- Ensures that all manufacturing SOPs, policies, and processes are adhered to by MMQCI staff according to cGMP.

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- Collaborates and communicates frequently with MMQCI Quality Assurance team and other staff to ensure manufacture of products of the highest quality by adherence to MMQCI's Quality System.
- Oversees purchasing and inventory of laboratory supplies.
- Assists as needed with equipment validation, calibration and maintenance, as well as environmental testing.
- Assists with validation of test procedures used for manufacture and QC testing.
- Stays current in literature relevant to molecular techniques and quality control practices of clinical laboratories in order to improve product and processes.
- Assist Customer Support team as needed.
- Contributes to general laboratory support functions.

MINIMUM KNOWLEDGE, SKILLS AND ABILITIES REQUIRED:

1. B.A. or B.S. in Biology/ Life Sciences, and a minimum of 7 years of relevant experience. Management experience is required. IVD manufacturing experience is required.

2. Familiarity with molecular biology techniques including cloning, sequencing, PCR, and electrophoresis is required.

3. Familiarity with working with DNA and RNA IVD products is required.

4. Highly organized with proven management and prioritization skills.

5. Strong problem solving skills.

6. Ability to work independently and with minimal supervision.

7. Ability to handle pressure of meeting tight deadlines.

8. Excellent communication skills, written and oral, and computer skills, particularly Excel.

9. Proven ability to manage people effectively, fairly, and diplomatically.

10. Thorough knowledge of cGMP regulations is required.

11. Must be a nonsmoker due to product contamination prevention requirements.

12. Must be able to stand for several hours and lift approximately 30 lbs.

The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills of personnel so classified.

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BENEFITS:

- Medical insurance
- Dental insurance
- Vacation
- Holidays
- Sick leave
- 401(k)
- Profit Sharing Plan

How to apply: by Email/ No Phone inquiries accepted
Email:HR@mmqci.com

A cover letter is required Please!

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!