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 Manager of Manufacturing Operations reports directly to the President and will play a key role in leading by example to continue the positive, get-it-done, everyone-pitch-in culture of the MMQCI manufacturing team. The successful candidate will be an experienced manager who enjoys diving in to perform a variety of tasks at a fast pace and taking on a hands-on role, as expected of all MMQCI managers. The Manager of Manufacturing Operations is responsible for all processes contributing to the precise manufacture of MMQCI’s high quality products, including cGMP manufacture, production, quality control testing and written documentation. The Manager will be responsible for assigning work orders and scheduling processes from manufacture through kitting of finished goods for on-time delivery. The Manager will assist with the transfer of new products from R&D, and the improvement of existing products and processes.

PRINCIPAL DUTIES AND RESPONSIBILITIES:

- Responsible for the manufacture of all MMQCI products in a clean room environment, according to cGMP, 21CFR Part 820.
- Mentors, trains and maintains Training & Development Plans for 15 direct reports.
- All QC release testing of MMQCI products.
- Production activities: labeling, filling and kitting of product.
- Proper preparation of labware and reagents used for manufacturing.
- Provides data, interprets results and writes reports as required for batch release, investigations of product issues and resolution of problems initiated through non-conformances, corrective action, customer complaints, and/or audit findings.
- The cleanliness of manufacturing area and provision of required resources.
- Continual process improvement of Manufacturing, QC and Production, proposing well-thought out improvements, manual and automated, based on deep knowledge of nucleic acid chemistry, related equipment, and risk-based decision making.
- Authors and updates manufacturing SOPs as needed for maintenance and continuous improvement of MMQCI’s Quality System.
- Ensures all manufacturing SOPs, policies, and processes are adhered to by MMQCI staff according to cGMP and MMQCI’s Quality System.
• Collaborates and communicates frequently with MMQCI Quality Assurance team and other MMQCI staff.
• 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.
• Assists Customer Support team with customer inquiries as needed.
• Contributes to general laboratory support functions.

MINIMUM KNOWLEDGE, SKILLS AND ABILITIES REQUIRED:
1. B.A. or B.S. in Biology/ Life Sciences
2. Minimum of 7 years of relevant IVD manufacturing laboratory experience.
3. Minimum of 5 years of management experience.
4. Experience and interest in molecular biology techniques used in IVD manufacturing including cloning, sequencing, PCR, and electrophoresis.
5. Hands-on experience working with DNA and RNA IVD products.
6. Thorough understanding of molecular diagnostic assays currently used in hospital labs for patient care and by MMQCI to generate data for QC release of MMQCI’s products.
7. Highly organized with proven management and prioritization skills.
8. Strong problem solving skills.
9. Strong data analysis and troubleshooting skills.
10. Ability to handle pressure of meeting tight deadlines.
11. Excellent communication, written and oral, and computer skills, particularly Excel.
12. Proven ability to manage and lead people effectively, fairly, and diplomatically.
13. Thorough knowledge of cGMP regulations.
14. Must be a nonsmoker due to product contamination prevention requirements.
15. 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.

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