

Validation Technician

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: Validation Technician

GENERAL SUMMARY:

The successful candidate will enjoy performing a variety of tasks at a fast pace. Validation Technician is part of the Technical Operations team that supports the Company in various ways by installing, qualifying and maintaining equipment used to manufacture, store and test product and validating new processes and procedures. The Validation Technician performs environmental testing to ensure products are manufactured in a clean / uncontaminated environment. A successful candidate is comfortable in a clean room laboratory environment where gowning and aseptic technique are required. He or she enjoys being well-organized, performing detailed tasks according to established written Quality System procedures. It is expected that the Validation Technician will rapidly develop sufficient expertise to function independently with minimal supervision.

PRINCIPAL DUTIES AND RESPONSIBILITIES:

- Installs and qualifies equipment (IQ/OQ/PQ) for manufacturing and QC testing of product. Assists in writing validation protocols and reports, and creates written maintenance procedures.
- Calibrates and maintains equipment following written procedures. Coordinates with other department schedules to eliminate downtime of equipment and loss of production time.
- Performs environmental testing of manufacturing and QC areas. Testing includes particle testing (air sampling and contact plates) as well as contamination testing via swipes.
- May perform some QC assays related to environmental testing. Will assist with data entry into spreadsheets, graphing results, and trending / interpreting data.
- Coordinates with outside vendors for equipment repair. May perform some basic repair of equipment.
- Assists with validation of product test procedures, including new QC assays, modifications to QC assays, and stability studies, working closely with a cross-functional team of QC and R&D.



- Assists with validation of new manufacturing processes, components, and process improvements while working closely with manufacturing, QC, and R&D.
- Documents all work with 100% accuracy in a timely manner by recording lot numbers, dates, etc. on documents as required by MMQCI's Quality System in accordance with current Good Manufacturing Practice (cGMP).
- Carefully and consistently follows all MMQCI's protocols to protect product integrity, including repetitive cleaning of benches, donning of gloves, booties, lab coats, facemasks, hairnets and other Personal Protective Equipment as appropriate.
- May be required to assist manufacturing with other tasks as needed, for example, testing of received-in raw supplies from an outside vendor.

MINIMUM KNOWLEDGE, SKILLS AND ABILITIES REQUIRED:

- 1. B.S. in Biology / Life Sciences is required.
- 2. Work experience in a laboratory setting is preferred.
- 3. Familiarity with molecular biology (working with DNA / RNA) is highly desired.
- 4. Ability to perform procedures quickly but with stringent accuracy and attention to detail.
- 5. Good communication skills, written and oral, and at a minimum, basic computer skills, including Excel.
- 6. Experience in a GMP or ISO quality system environment is preferred.
- 7. Must be a nonsmoker due to product contamination prevention requirements.
- 8. 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 have a beautiful, state-of-the-art facility located in Saco, right next to the Eastern Trail. Come join us!