MMQCI
MAINE MOLECULAR QUALITY CONTROLS, INC.

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

Product Development Scientist II – MOLECULAR DIAGNOSTICS

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 also provides custom products to IVD manufacturers for test development, internal QC and kit controls. 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, rapidly growing company that offers a relaxed but challenging work environment with opportunities to gain experience using the latest molecular biology tools.

Do you like to experiment with DNA and RNA?? Are you familiar with the chemistry of nucleic acid?? We are seeking an experienced scientist to assist with the design, development and validation of novel quality control products for molecular diagnostic tests.

Title: R & D Scientist II

Primary Duties and Responsibilities

- Work on the bench as a key team member to design, develop, validate and manufacture new quality control products for molecular diagnostic tests according to current Good Manufacturing Practice (cGMP).
- Provide innovative ideas useful in the design and development of de novo reference materials.
- Maintain a current knowledge base pertaining to MMQCI's industry, e.g. gene discovery, medical decision points, new clinical test methodology, new technologies useful to manufacture, etc.
- Design optimal sequences for control products through use of public data bases.
- Engineer complex DNA constructs to be used as targets in control products by using molecular techniques such restriction enzyme digest, ligation, sequencing and cloning with a variety of vectors and cells.
- Bring products from design to validation under Design Control according to FDA 21CFR820 regulations and prepare appropriate reports.
- Develop and maintain documentation of product development and validation according to MMQCI's Quality System. Documentation must be adequate for FDA 510K submission and Quality Audits.
- Establish, validate, perform and interpret a variety of molecular clinical assays including detailed sequence analysis using multiple alignment and variant reporter software for NGS and other applications
- Work with pathogens and/or mammalian cells in a BSL2 environment.

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Required Qualifications

Education

B.A or B.S. in biology, molecular biology or chemistry or relevant experience and a minimum of 2 years in relevant discipline or MS with 1-2 years relevant experience, or PhD with minimal experience. Significant knowledge in general molecular biology techniques including cloning, sequencing and amplification is required.

Experience

- Extensive hands-on cloning experience using a variety of cloning techniques is required.
- Experience with general molecular techniques such as restriction enzyme digest, ligation, sequencing, RT-PCR, qPCR and NGS is required.
- Skilled in the use of current sequence databases is required.
- Experience in development of molecular assays is required.
- Experience in product development for the *in vitro* diagnostic industry and familiarity with cGMP regulations is preferred.
- Knowledgeable in quality control practices for molecular test methods, regulatory requirements and how MMQCI's products are used in the clinical laboratory is strongly preferred.
- Experience with BSL2 protocols and safety requirements is preferred.

Skills and Abilities

- Strong problem-solving skills and interest in troubleshooting
- Well-organized
- Ability to work independently
- Ability to multitask and manage multiple priorities
- Excellent communications skills, oral and written
- Flexible; accustomed to fast-changing priorities of a small company
- Works efficiently and quickly but with attention to detail
- Strong teamwork and interpersonal skills
- Strong work ethic
- Innovative

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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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. In order to accommodate our rapid growth, we are currently expanding our state-of-the-art facility which is conveniently located in Saco, right next to the Eastern Trail, open for walking, jogging, and biking. Look for the building with the shiny DNA helix on the outside and come join us!

BENEFITS:

- Medical insurance
- Dental insurance
- 401(k)
- Profit sharing plan
- Vacation
- Holidays
- Sick leave

How to apply: by Email HR@mmqci.com
No Phone inquiries accepted
A cover letter is required.

Contact Information:

Human Resources
Maine Molecular Quality Controls, Inc.
23 Mill Brook Road
Mill Brook Business Park
Saco, Maine 04072