Development Scientist, Product Development
Predicine Inc., Hayward, California
Job ID: 000032

Predicine Inc. is a Silicon Valley-based biotech startup company focusing on precision diagnostics and medicine in cancer and other serious illnesses. We aim to provide innovative non-invasive diagnostic tests to enable precision medicine. Please take this opportunity to learn about Predicine, where we believe that people are our most important asset and are dedicated to creating a great place to work. At Predicine, we value a culture of creativity, integrity, responsibility, productivity, and teamwork. We invite people who share the same values to join us.

The position

We seek a highly motivated and talented individual focus on the development and validation of LDT assays. In this position, which is part hands-on and part at the desk, the Scientist will conduct assay development studies in support of regulatory submissions. The successful candidate is expected to effectively develop and execute on innovative projects, publish exciting research in high quality scientific or technical journals, present at professional meetings and promote collaborative efforts to push precision translational sciences forward. This individual is expected to be, or develop into, externally recognized expert in precision diagnostics and medicine.

As a Development Scientist, Product Development, you are expected to:

- Design, execute and analyze experiments to characterize the performance of products according to CLIA, CAP requirements and/or IVD FDA Design Control process
- Generate test protocols, review and analyze results, and generate V&V reports per CLIA, CAP, FDA and ISO regulations
- Characterize assay performance specifications
- Develop and Validate reagent QC test methods and performance specifications
- Participate in reagent stability test
- Record experimental methods and results accurately and consistently. Summarize experimental results in tabular and graphic formats
- Present findings or comprehensive project status reviews at internal seminars/meetings and Apply advanced technical writing skills to produce reports and documents. Prepare summaries, internal reports, presentations, manuscripts, etc

- Transfer of assay reagent and QC design to facilitate production lab operation and GMP manufacturing
- Support Manufacturing and Operations
- Assume responsibility for timely completion of projects, ensuring activities that are consistent with project critical path and responding appropriately to changing priorities
- Ensure technical activities under delegated supervision that are conducted within internal and external guidelines and regulations
- Perform other duties and assumes additional departmental responsibilities as required

Who you are

In adding new members to our team, we look for people who are also inspired by our mission and who would fit in well with the collaborative, rigorous and entrepreneurial spirit of the company culture. Because we know that people are critical to our success in bringing novel diagnostics and medicines to patients, we are dedicated to creating a great place to work and to providing our people with programs, services and benefits that would allow them to bring the best to the business and to their personal and professional growth.

- Ph.D. degree in Molecular Biology or a related field with 1+ years, OR
- MS degree with 5+ years, or BS degree with 8+ years of industrial experience with clinical and/or analytical studies designed for FDA regulatory submissions
- Solid conceptual framework and hands-on experience in molecular biology methodology development, including DNA and RNA purification, PCR, qPCR and/or NGS
- Knowledge on product development and verification, validation and manufacture processes, under QSR in support of CLIA and CAP submissions
- Hands-on experience in molecular diagnostic product design and development, product stability studies, verification and validation studies, and/or establishing product, process, and material QC specifications
- Proficient technical writing skills and excellent documentation skills for experimental work and data analysis
- Working knowledge of statistical analysis
- Experience with JMP software is a plus
- Experience with documentation system under Quality System is preferred

This is an exciting opportunity to participate in, and to enable, our vision of transforming healthcare through development of innovative technologies. If you are looking for opportunities to accelerate your growth and the growth of a company, and to make a positive and immediate impact on the society, please submit cover letter and resume to: hr “at” predicine “dot” com.

Predicine is an Equal Opportunity Employer.