

SENIOR SCIENTIST – LATERAL FLOW and ELISA

Optimum Imaging Diagnostics - Scarborough, ME

SUMMARY:

OIDx has an immediate opening for a Senior Scientist who will be responsible for duties involved in the development and manufacturing of medical point-of-care diagnostic products. The Senior Scientist will assist in troubleshooting problems with current processes and products, brainstorm and develop ideas for new products, and implement new product ideas and technologies. As part of a fast-paced start-up, this person will have a variety of responsibilities ranging from product development and troubleshooting to manufacturing in a regulated environment. Experience in lateral flow immunoassays, ELISA, and techniques such as HPLC, SDS-PAGE, FPLC highly desired for this position. This position is integral to the success of OIDx and requires independent thinking to plan, prioritize and organize the diverse workload.

RESPONSIBILITIES:

- Development and manufacturing of lateral flow immunoassays and ELISAs for various infectious diseases.
- Maintains detailed documentation throughout all phases of research and development and plays key role in design transfer to manufacturing.
- Work within a Quality System incorporating ISO and FDA regulations for all aspects of product development and manufacturing.
- Operate variety of equipment such as liquid handling systems for production of lateral flow and ELISA devices.
- Perform experiments in the laboratory for development and optimization of products.
- Accurately record experimental data and results in laboratory notebooks. Compile and analyze test data for study reports.
- Uses expertise in lateral flow technology to design and implement new methodologies, materials, processes and products.
- Designs and conducts studies in various phases of product lifecycle.
- Integrate Product Development into OIDx priority project workflow.
- Adapt new technologies to OIDx products and manufacturing processes.
- Demonstration of successful transfer to manufacturing from R&D phases, including early stage feasibility analysis
- Competent and familiar with Lateral flow immunoassays, ELISA, assay development, protein conjugation, management experience, polymer sciences.
- Demonstrates expertise and strong leadership in lateral flow product development.
- Participate in validation and verification procedures pertinent to development and manufacturing of immunoassay tests and reagents, understanding conceptions of LOB, LOD, LOQ
- Research and develop ideas for new products technologies by keeping up-to-date with in vitro diagnostic (IVD) technologies.

EDUCATION & EXPERIENCE REQUIREMENTS:

- Master's Degree or PhD in a scientific discipline is preferred with a minimum of 6+ years' of experience in a research and development environment or an equivalent combination of education and experience in diagnostics
- Prior experience with immunoassays with specific focus in the Lateral Flow Assay and ELISA format
- Significant experience in conjugation, antibody production, membrane blocking, conjugate pad pre-treatment, assay optimization, reagent formulation and buffer composition
- Significant experience with analytical test methodologies
- Prior experience with point of care readers
- Experience with BIODOT equipment would be preferable
- Working knowledge of federal and other regulations governing medical device assembly and design, e.g. cGMP, QSR, ISO.
- Demonstrated experience managing and directing priorities and deliverables of a team of individuals.
- Experience and expertise necessary to ensure timely progression of assay development through OIdX's product pipeline
- Proficiency with statistical data processing, experience with JMP, mini-Tab, Excel or other statistical software.
- Ability and experience to plan and perform DOE (design of experiments).
- Ability to make data driven conclusions.
- Six sigma training or certificates
- Expertise in colloidal chemistry, protein chemistry, surface chemistry and microfluidic devices.

KNOWLEDGE/SKILLS & ABILITIES:

- Analytical- the individual gathers and monitors complex or diverse information skillfully.
- Oral & written communication- the individual speaks and writes clearly and persuasively.
- Planning/organizing- ability to prioritize and plans work activities for self and direct reports; uses time efficiently and develops realistic action plans.
- Problem solving- the individual identifies and resolves problems in a timely manner.
- Professional- the individual presents him/herself professionally at all time with an eye toward customer service and teamwork.
- Leadership- leads team, sets direction, mitigates risks, resolves issues to meet business needs.

OTHER DUTIES AND RESPONSIBILITIES

- As assigned to support company goals

Job Type:
Full-time

EDUCATION

Master's Degree required

Work authorization:
United States (Required)

Benefits offered:

- Paid time off and Health insurance

HOW TO APPLY:

- Please include in your cover letter that you found this job posting through biomaine.org. Apply through Indeed : https://www.indeedjobs.com/optimum-imaging-diagnostics-f249917/_hl/en_US?cpref=JXWAtnzf3XW5aRnY2g_zos_1WAXHb5RL-XIsrKEM7os