

VACANCY

Job title: Principal Scientist (Validation)

Location: Southampton

Job Summary

Primerdesign is looking for an enthusiastic and talented Principal scientist for an opportunity to join an expanding R&D department within a fast-growing and friendly biotech business.

We are experts in real-time PCR, a molecular biology technique for detecting the presence of nucleic acids. We have customers in many different industries including academia, research, diagnostics, food industry and the veterinary industry selling to over 100 countries worldwide.

An exciting new venture for the company lies with developing CE IVD diagnostic assays and designing innovative molecular diagnostics solutions. Your primary role will be to lead a team heavily involved in these activities.

Main duties and responsibilities

- Leading research efforts to meet the objectives determined by the organization:
 - Planning work and managing deadlines
 - Mentoring other researchers
- Demonstrating excellent interpersonal skills, working in a collaborative manner
- Leveraging expertise in a diverse array of molecular biology techniques (e.g. isothermal PCR, lateral flow assays, next-gen sequencing)
- Assist, when required in the development and optimization of new molecular technologies
- Ensuring the team has the resources (e.g. equipment, staff, training etc.) to properly perform validation and clinical performance tasks
- Reporting findings to stakeholders such as research and development managers and company executives.
- Management of diagnostic assay development projects post pilot manufacture through the analytical and clinical validation process through to the delivery of the project
 - Working closely with QA/RA in ensuring that projects are run to relevant quality standards (including the CE-IVD and FDA standards) for medical devices and in-vitro diagnostic equipment
- Managing and organising work on product validation in accordance with regulatory directives
- Deliver technical reviews and certification scheme management in support of regulatory submissions

Other duties and responsibilities

- Contributing significantly to product development activities including the design, work schedules and risk identification
- Maintaining laboratory equipment in accordance with internal standards
- Providing technical support and advice to stakeholders and clients via phone and email, when necessary:
- Performing troubleshooting and evaluation of PCR data generated internally and by external labs; prepare reports and recommend corrective action
- Documenting results in technical reports and present data at team meetings

- Planning, organising and executing validation studies to support product development activities
- Collaborating with customers and partners on new products and applications
- Excellent verbal and written communication as well as good organisation skills are required

Qualifications and experience required

Essential

- A Bachelor's degree in a related field
- 5 years' experience in industry
- Previous PCR knowledge and hands-on experience
- Ability to plan experiments, problem solve and progress projects independently

Desirable

- PhD in a related field
- Experience of working within a quality system, particularly ISO 13485.
- Previous experience in scientific product development or creating complex study designs desired.
- Previous statistical data analysis experience would be beneficial
- Experience handling Hazard Group 2 organisms in a Category 2 Laboratory

Hours of Work	37.5 hours per week
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For further information or to apply for this vacancy please e-mail recruitment@novacyt.com
