NOVACYT GROUP

INTERNAL VACANCY

Job title: Diagnostic Assay Development Manager
Location: Southampton - Primerdesign
Closing date: 26th October 2018

Job Summary

We currently have an exciting opportunity in our Research and Development department, working as a Diagnostic Assay Development Manager within the regulatory certification schedule.
Primerdesign is focused on the design, manufacture, validation and supply of real-time PCR kits and reagents. This includes rigorous CE and ISO13485 certification.
Due to the impressive growth ambitions of Primerdesign, the research and development team has doubled in size over the past 3 years. We are passionate about what we do and our people striving to deliver world class results. Our strategic growth within operations has led to vacancies for Technical Specialists within the R+D team.

This is an excellent opportunity to join an ambitious molecular technology company and be involved in the evaluation of cutting-edge innovation and state of the art technologies.

This opportunity offers both diversity and variety, building, controlling and managing a portfolio of Medical Device CE marking schemes focused around the company's area of expertise. Additionally, organising, reviewing and evaluating medical device technical documentation you could also be undertaking Medical Device QMS assessments or advising and mentoring colleagues in your areas of competence. Strong inter-personal communication and project management skills are at the heart of this role as you work daily with the R+D team planning and executing validation work according to regulatory directives.

To be a success in this role you will apply the significant knowledge and extensive 'hands on' experience gained in research, design and development of medical devices, including the application of the principles of design control, risk management and performance or clinical evaluation.

You will also have demonstrated strong inter-personal and communication skills, as well as a track record in project or programme management.

Main duties and responsibilities

- Provide specialist regulatory, operational and strategic support to commercial and research managers within the company, and the business in the delivery of CE medical device marking schemes
- Deliver technical reviews and certification scheme management in support of CE marking
- Build, control and manage a portfolio of Medical Device CE marking schemes focused around the company's area of expertise and in line with the company's ISO13485 quality management system
- Provide Medical Device expertise leadership and mentoring in areas of competence to company medical device personnel
- Provide in-house and external training for device/assay combination products.

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Qualifications and experience required

The ideal candidate to fill this role will have the following qualifications, skills and experience:

- BSc, MSC or PhD degree in Life Sciences
- Thorough knowledge of the design and development of products including the principles of design control, risk management and performance or clinical validation
- Experience in one or more of the following disciplines: devices which incorporate medical applications, process validation, regulatory documentation, analytical methods, technology transfer
- Understand the concepts and intent of Product Certification and service orientation
- Knowledge of business processes and the application of quality management standards
- Conceptual and analytical thinking, efficiency and results orientation
- A team player good at relationship building internally and externally

Hours of Work	37.5 hours per week
For further information or to apply for this vacancy please e-mail Kay Campbell, HR kay.campbell@novacyt.com	