NOVACYT GROUP

INTERNAL VACANCY

Job title : Programme Manager
Location: Primerdesign, Southampton
Closing date : 16 March 2018

Job Summary

Primerdesign has an exciting opportunity in their Research and Development department, working as a Programme 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.

The Programme Manager will be responsible for building, controlling and managing a portfolio of Medical Device CE marking schemes focused around the company's area of expertise. Additionally, they will be organising, reviewing and evaluating medical device technical documentation, advising and mentoring colleagues and undertaking Medical Device QMS assessments. 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.

Main duties and responsibilities

- Provide specialist regulatory, operational and strategic support to commercial and research managers within the company, and support 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.

Qualifications and experience required

The ideal candidate 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
- Proven experience in project or programme management

Other requirements

- 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 Wendy Karban, Group HR Manager, wendy.karban@novacyt.co.uk

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