NOVACYT GROUP

VACANCY

Job title: Programme Manager
Location: Primerdesign (Southampton)

Job Summary

- Building, controlling and managing a portfolio of Medical Device CE marking schemes around the company's area of expertise and in line with the company's ISO13485 quality management system
- Organizing, reviewing and evaluating medical device technical documentation in support of CE marking
- Executing validation work according regulatory directives

Main duties and responsibilities

- Management of CE-IVD projects from the proposal stage 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 executing work on product validation in accordance with regulatory directives
- Coordinate and manage product development interactions across multi-discipline company teams with the appropriate level of expertise
- Lead meetings for all project stages, communicating ideas and promoting accountability throughout all stages of the product development cycle
- Generating timelines, resource demands and development risk profiles for new and current projects
- Deliver technical reviews and certification scheme management in support of CE marking
- 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.
- Produce content for sales and marketing teams including webinars, presentations, delivery of customer Q&A sessions.

Qualifications and experience required

Essential

- MSc/PhD in Life sciences or related field (e.g. Biochemistry, Pharmacology etc.)
- Previous PCR knowledge and hands-on experience is a must.
- 2 + years of relevant work experience is required, industry preferred
- The ability to work well within a team and have strong written and verbal communication skills is critical
- Excellent communication skills, organisation skills and outstanding attention to detail are required for this role

Desirable

- MSc/PhD in Life sciences or related field (e.g. Biochemistry, Pharmacology etc.)
- 5 + years of relevant work experience is required, industry preferred
- Understanding of assay design, experience working in disease research or with next generation sequencing data and customer facing experience would all be highly advantageous
- Experience of working within a quality system is highly advantageous, particularly ISO 13485
- Previous experience in scientific product development
- Previous statistical data analysis experience would be beneficial

Please ensure that you notify your current manager that you are applying for an Internal position.

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