NOVACYT GROUP

INTERNAL VACANCY

Job title: QA/RA Specialist
Location: Camberley (Microgen)

Job Summary

Reporting directly to the Sr QA/RA Manager, the QA/RA Specialist shall ensure that the introduction of all new projects within the business meet the requirements of the Quality Management System and using data analysis improve the outgoing quality of the company.

The QA/RA Specialist shall act as the key contact for quality and compliance activities and will assist operations in all quality related aspects of manufacturing to ensure best practice is adopted.

Main duties and responsibilities

- Support the Sr QA/RA Manager in maintaining a QMS that meets the applicable regulatory and company requirements including ISO 13485/9001/EC certification.
- Assist in the creation of standard operating procedures and policy guidelines.
- Consulting company personnel in achieving and maintaining regulatory conformity as a prerequisite to worldwide market access of IVD products.
- Supporting the Sr QA/RA Manager with post-market regulatory compliance / surveillance activities for EU and international product approvals.
- Overseeing the customer complaints process and assisting with customer complaint investigations.
- Involvement in project teams in the development and introduction of new Products and/or Processes.
- Working with the teams to ensure they meet the requirements of the Quality Management System.
- Proactive approach to leading project groups using a structured problem-solving approach to improve the quality of the product/process.
- Monitoring the process and reporting on trends. Generating trend analysis reports and creating Key Performance Indicators for critical products and processes.
- Supporting the document control and document approval activities.
- Working with the quality team to maintain compliance with laws and regulations ensuring the Camberley and Bridport sites are in an “Audit Ready” state.
- Perform other duties as required or assigned by the Sr QA/RA Manager.

Qualifications and experience required

- Ideally educated with a bachelor’s degree or HNC in a relevant scientific discipline.
- A quality background within the IVD industry would an advantage.
- Auditing skills - Internal Auditor to ISO 13485/9001 is desirable.

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Qualifications and experience required contd.

- Highly motivated, self-starter, and responsible person. Proactive and self-directed. Have the initiative and drive to develop new concepts and carry ideas through.
- Excellent planning and organisational skills. Able to successfully manage multiple projects. Ability to manage and prioritise numerous and complex projects utilising effective time management skills.
- Computer literate and experienced in the use of Microsoft Office packages.
- Ability to read and understand technical material.
- An approachable style with good communication skills. Good communicator / enquiring, methodical and organized. Good oral and written communication skills.

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	