NOVACYT GROUP

VACANCY

Job title : RA Associate
Location: Camberley (Microgen)

Job Summary

Responsibility for the supporting the update and maintenance of the company's technical documentation for its range of IVD products in accordance with 98/79/EC and other regulatory requirements

Responsibility for supporting the Regulatory Affairs team in making global product registration

Main duties and responsibilities

- Update and maintain the company's technical documentation for its range of IVD products in accordance with 98/79/EC and other regulatory / company requirements.
- Working under guidance to compile appropriate dossiers, submissions and responses to regulatory bodies.
- Provide support as directed to registration activities and regulatory submissions throughout the world as required by the company.
- Liaise with personnel in relevant departments within the business to support timely applications for regulatory approvals.
- Support the maintenance of information on worldwide regulatory requirements and the status of the company's local product registrations.
- Assist with regulatory issues such as recalls or field safety corrective actions and advisory notices as directed.
- Participation in QA/RA team meetings.
- Working with the rest of 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 QA/Manager

Qualifications and experience required

- 2-3 years' experience in maintaining Technical Documentation for CE marked products.
- A regulatory background within the Medical Device industry would be desirable
- Some experience with ISO 13485, ISO 9001 and EC certification would be a distinct advantage.
- Strong experience in completing regulatory submissions to support global product registration of medical devices.
- Ideally educated with a bachelor's degree or HNC in a relevant scientific discipline.
- Strong team player capable of working with people at all levels of the organization.
- Strong desire to learn and develop within a regulatory role within the Medical Device Industry.

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	