NOVACYT GROUP

INTERNAL VACANCY

Job title: Regulatory Affairs Officer
Location: Camberley

Job Summary

Responsibility for 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 global product registrations.

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.
- Facilitate worldwide product registration activities by compiling appropriate dossiers, submissions and responses to regulatory bodies.
- Provide full support to all registration activities and regulatory submissions throughout the world as required by the company. Managing new submissions as well as the re-registration of the company's products.
- Liaise with personnel in relevant departments within the business to co-ordinate timely applications for regulatory approvals.
- To keep abreast of significant developments in key worldwide regulatory requirements and maintain a working knowledge of regulatory requirements / guidelines.
- Maintain information on worldwide regulatory requirements and the status of the company's local product registrations.
- Liaise directly with local affiliates, distributors or agents to define / clarify submission requirements.
- Assist with regulatory issues such as recalls or field safety corrective actions and advisory notices.
- Participation in QA/RA team meetings and recognized as a knowledgeable resource in regulatory affairs and registration activities across the company.
- 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/RA Manager.

Qualifications and experience required

- Experience in maintaining Technical Documentation for CE marked products.
- Experience with ISO 13485, ISO 9001 and EC certification.
- 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.
- Strong desire to learn and develop within a regulatory role.