NOVACYT GROUP

INTERNAL VACANCY

Job title : Regulatory Affairs Officer
Location: Camberley
Closing date : 7th August 2018

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 managing regulatory submissions in support of 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.
- 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

- A minimum of 5 years' experience in maintaining Technical Documentation for CE marked products.
- Strong regulatory background essential, ideally experienced with IVDs.
- Strong experience with ISO 13485, ISO 9001 and EC certification.
- 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.
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- Strong Team play capable of working with people at all levels of the organisation.

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	