NOVACYT GROUP

INTERNAL VACANCY

Job title : QA/RA Manager
Location: Camberley (with regular travel to Bridport)
Closing date : 20 October 2017

Job Summary

- Responsible for the effective maintenance and development of the Quality Management (QM) Systems at the Group's facilities in Camberley and Bridport to meet applicable regulatory requirements
- Manage the transition of the existing QM Systems at each site to meet the forthcoming revised standards and new IVD regulation
- Deputise for the QA/RA Director as required
- Maintain the Quality Policy for the Group for the benefit of its customers, suppliers and employees

Main duties and responsibilities

- Maintain the Quality Management systems at the Camberley and Bridport facilities to meet the requirements of ISO 9001, ISO 13485 and the IVD Directive (98/79/EC) and the company's Quality Policy
- Work with the group Regulatory Compliance Manager and QA/RA Director to develop and upgrade the Quality Management systems at the Camberley and Bridport facilities to comply with ISO 9001:2015, EN ISO 13485:2016 and the forthcoming IVD Regulation
- Management of the company's CE Mark Technical Documentation
- Manage the Internal Audit programmes for the Camberley and Bridport facilities
- Host 3rd party audits taking place at either the Camberley or Bridport facilities
- Manage the QA/RA site teams with regards to all day to day activities and performance reviews
- Act as the Management Representative and host site Management Reviews at the prescribed intervals at the Camberley and Bridport facilities
- Manage the complaint system, and any vigilance activities in accordance with requirements to maintain regulatory compliance e.g. MEDDEV 2.12-1, and be the key contact point for National Competent Authorities and Notified Bodies
- Manage the Post Market Surveillance programmes for the Camberley and Bridport facilities
- Provide relevant guidance from a QA/RA perspective into New Product / Process Introduction programmes at the Camberley and Bridport facilities
- Deliver compliance training to personnel as required to improve the level of understanding of regulatory requirements

Qualifications and experience required

- A minimum of 5 years' previous experience managing QM Systems in accordance with ISO 9001, ISO 13485 and an EU Medical Device Directive. Previous experience with the IVD Directive (98/79/EC) would be a distinct advantage
- A strong team leader with a proven track record of successfully managing and developing effective teams
- Knowledge of CE Mark Technical Documentation, GHTF STED and IVD CTS documentation requirements
- A trained and certified Internal Auditor to ISO 9001 / ISO 13485
- Previous experience in hosting audits with Competent Authorities and Notified Bodies
- Previous experience of managing Post Market Surveillance and Vigilance reporting activities would be an advantage
- Experience in international medical device regulatory submission/approval preferred
- Knowledge of GHTF STED, and IVD CTS documentation requirements
- Knowledge of root cause analysis techniques, FMEA and risk analysis techniques
- Knowledge of Design control, Risk Management, Product Development processes and Batch Release
- Experience with New Product Introduction and R&D team to lead regulatory input in R&D project
- Ideally educated with a bachelor's degree or HNC in a relevant scientific or engineering discipline

Hours of Work	37.5 hours per week

For further information or to apply for this vacancy please e-mail Wendy Karban, Group HR Manager, wendy.karban@novacyt.co.uk

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