NOVACYT GROUP

VACANCY

Job title : Quality Engineer
Location: Camberley (Microgen)
Closing date : 23rd April 2019

Job Summary

Reporting directly to the Sr QA/RA Manager, the Quality Engineer 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 Quality Engineer shall be responsible for the upkeep and improvement of the quality management systems and key processes ensuring the company meets quality and regulatory compliance in the Camberley, Bridport and Axminster sites. The Quality Engineer shall also provide support to other group company sites as necessary.

The Quality Engineer 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. The Quality Engineer, working as part of a team, shall maintain and develop the existing Quality Management System procedures and processes through Continuous Improvement projects.

Main duties and responsibilities

- The upkeep and further improvement of the Quality Management System and key processes to ensure optimum compliance with relevant corporate and regulatory policies.
- 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.
- Supporting the Sr QA/RA Manager with post-market regulatory compliance / surveillance activities for EU and international product approvals.
- Perform internal audits as required.
- 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.
- Involvement in the planning and preparation of projects which require Validation Activities. Working with the development teams and/or production in the preparation and execution of validation protocols.
- Leading CAPA/NCR/Customer Complaint investigations and being involved in investigation teams. Completing Investigation reports and identifying / implementing Corrections, Corrective Actions and Preventive Actions as appropriate.
- Working with the quality team to maintain compliance with laws and regulations ensuring the Camberley, Bridport and Axminster 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.
- Experience with ISO 13485, ISO 9001 and EC certification. Knowledge of and experience with Quality Management Systems and eQMS systems. Knowledge of FDA current GMP/QSR Regulation.
- Auditing skills - Internal Auditor to ISO 13485/9001 is desirable.

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Qualifications and experience required cont

- A driver, communicator and influencer, whilst quality will be top of their agenda it may not be the priority for other members of the team. Strength of character but able to achieve objectives through influence rather than confrontation.
- 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.
- Root cause analysis techniques, FMEA and risk analysis techniques.
- Computer literate and experienced in the use of Microsoft Office packages.
- Ability to read and understand technical material

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	