NOVACYT GROUP

INTERNAL VACANCY

Job title : Quality Engineer
Location: Camberley
Closing date : 29th June 2018

Job Summary

Reporting directly to the Snr 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 and Bridport sites. The Quality Engineer shall provide support to other group 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.
- Consulting company personnel in achieving and maintaining regulatory conformity as a prerequisite to worldwide market access of IVD products.
- Supporting the Sr QA/RA Manager with post-market regulatory compliance / surveillance activities for EU and international product approvals.
- Assist with customer complaint investigations.
- Assist with regulatory issues such as recalls or field safety corrective actions and advisory notices.
- 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. Supporting gage R&R studies, as appropriate, with the operations team.
- Assist the operations team in ensuring the correct evaluation of the processes using a risk-based methodology.
- Leading CAPA investigations and being involved in CAPA investigation teams. Completing CAPA Investigation reports and identifying / implementing Corrections, Corrective Actions and Preventive Actions as appropriate.
- Conducting NCR/Quality Issue investigations in conjunction with the operations team and liaising with operations to ensure the appropriate product disposition is implemented. Evaluating Investigations / Investigation Reports to identify suitable Corrections, Corrective Actions and Preventive Actions have taken place.

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- Proactive approach to leading project groups using a structured problem-solving approach to improve the quality of the product/process.
- Monitoring the process and reporting on trends. Generating trend analysis reports and creating Key Performance Indicators for critical products and processes.
- Working with 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 Snr QA/RA Manager.

Qualifications and experience required

Essential

- Strong regulatory background within the IVD industry is essential.
- 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.
- Strong team player providing support, guidance and expertise in achieving regulatory compliance and customer satisfaction by educating, analysing and facilitating improvements through interaction with both internal and external customers.
- 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.
- Root cause analysis techniques, FMEA and risk analysis techniques.
- Applied knowledge of statistical tools: Acceptance Sampling, SPC, etc.
- Computer literate and experienced in the use of Microsoft Office packages.
- Knowledge of Design Control, Risk Management, Product Development processes and Batch Release.
- Ability to read and understand technical material.

Desirable

- Ability to read and understand technical material.
- Previous experience in successfully managing design projects for complex IVD devices.
- Ideally educated with a bachelor's degree or HNC in a relevant scientific discipline.
- Fluent in French, both orally and in writing.
- Experience in international medical device regulatory submission/approval preferred.
- Auditing skills - Internal Auditor to ISO 13485/9001 is desirable.
- Knowledge of GHTF STED, and IVD CTS documentation requirements.
- An approachable style with good communication skills. Good communicator / enquiring, methodical and organized. Good oral and written communication skills.
- Experience with New Product Introduction and R&D team to lead regulatory input in R&D project.
- Knowledge of Lean Manufacturing and/or Six Sigma Methodology.
- Highly motivated, self-starter, and responsible person. Proactive and self-directed. Have the initiative and drive to develop new concepts and carry ideas through.
- 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.

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@novayct.com