NOVACYT GROUP

VACANCY

Job title: Regulatory Affairs Associate
Location: Camberley

We are Novacyt, a rapidly growing diagnostics group specialising in infectious diseases. We have a number of successful brands and serve a large global customer base, from hospitals to large corporates.

We are now looking for a Regulatory Affairs Associate to join us on a permanent, full time basis in Camberley.

Job Summary

Reporting to the Regulatory and Clinical Manager, the successful candidate will support regulatory activities involving IVD medical devices, food and industrial tests (assays, instruments and ancillary reagents) throughout the product pathway including post market surveillance.

In compliance with applicable standards and regulations, the candidate will have active communication with internal teams on activities such as document creation, review and approval of documents, remediation of technical files towards IVDR and relevant documentation relating to other regulatory submissions globally.

Main duties and responsibilities

- Work with QARA Team and relevant internal teams on IVD device files to include:
  - Intended Use Statements
  - Review and maintenance of Risk Management files
  - Manufacturing Processes
  - Labelling process
  - Product Verification and Validation
  - Performance Evaluation including the generation of performance evaluation plans and reports
  - Post market surveillance process and implementation through post market surveillance plans and reports for each IVD/IVD family
- Support product registrations globally by liaising with Sales Team and relevant distributors
- Work with QARA Team and internal teams to achieve consistent regulatory compliance for all Novacyt devices
- Work with the RA Team on the Novacyt Group Brexit plan for:
  - CE marking
  - UKCA marking
  - Suppliers

Qualifications and experience required

- Degree in science relating to microbiology or biomedical science is preferable
- Knowledge and experience of working to appropriate standards including IVD Directive 98/79/EC and IVD Regulation 2017/746, ISO 13485, ISO 14971 *(FDA 21CFR part 820 desirable)*
- Knowledge of technical documentation towards regulatory submissions or product registrations
- Experience of working with cross-functional teams preferably in an IVD or medical device environment
- Strong communicator
- Excellent organizational skills

- Demonstration of good problem-solving

The Benefits

- Competitive salary
- 25 days' annual leave
- Ability to buy and sell annual leave
- Cycle to work scheme
- Refer a friend scheme
- Life assurance
- Private medical insurance
- Group pension scheme

It's an exciting time to join our team as we are making huge leaps in the fight against COVID-19 and have recently been awarded a Breakthrough of the Year award at the European Mediscience Awards 2020.

We are the best in the world at what we do. If you are looking to learn, grow and succeed as part of a passionate team who are eager to make a difference, we want to hear from you.

Hours of Work	37.5 hours per week
For further information or to apply for this vacancy please e-mail recruitment@novacyt.com	