

VACANCY

Job title: Senior QA Specialist

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.

Microgen is an expert in the development, manufacture and distribution of high-quality diagnostic products. These include gold standard molecular assays and a growing portfolio of rapid immunoassays for the detection of toxins, bacteria, viral antigens and key indicator proteins.

We're now looking for a Senior QA Specialist to join our team on a full-time basis working 37.5 hours per week.

Job Summary

To assist the Quality Manager in ensuring that all activities on site are in compliance with current ISO13485 and ISO9001, in accordance with company policies, to meet business requirements. To work with company departments to provide guidance and expertise in the resolution of quality issues.

Main Duties and Responsibilities

- To ensure continued compliance of the QMS to ISO13485 and ISO9001, concerning all areas of the product life cycle from product development to discontinuation
- Manage the maintenance, administration and execution of QMS processes through the use of SharePoint and/or Entropy
- Monitor & report on KPIs
- Process owner for non-conformance & CAPA
- Supporting and promoting the company document management systems, and equipment validation and maintenance processes
- Support product release process, including batch record review, generation of CoAs and uploading CoAs to website
- Use professional judgment in all areas of the role to make the appropriate quality decisions and to initiate and promote quality improvements to prevent re-occurrence
- Collate data and prepare presentation for review with Quality Manager prior to Management Review, and assist with minuting review meetings
- Assist with external audits as required
- To perform other duties as required or assigned by the Quality Manager

Qualifications and Experience Required

- Bachelor's degree in Life Science
- Knowledge of microbiology desirable
- Previous experience working in IVD manufacturing environment
- ISO13485 Internal Auditor training
- Team Leader experience desirable
- Written and verbal communication skills

- Analytical problem- solving abilities
- Knowledge and experience of equipment software and process validation
- Awareness of regulatory requirements - IVDD/IVDR

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
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For further information or to apply for this vacancy please e-mail recruitment@novacyt.com