

VACANCY

Job title: Technical Documentation Officer

Location: Southampton

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.

Primerdesign, part of the Novacyt Group, is a leading provider of RT PCR solutions. We have thousands of happy customers based across the globe and have a real ambition to drive our business forward and achieve even more. We have delivered exceptional products to combat formidable challenges. We developed the world's first swine flu detection kit, played an important part in uncovering the UK's horse meat scandal and are currently producing high-performing detection kits to support the fight against COVID-19.

We're now looking for a Technical Documentation Officer to join our team on a full-time basis working 37.5 hours per week.

Job Summary

The Technical Documentation Officer role is an office-based role working within the Pilot Manufacture Team at Primerdesign. The role requires an enthusiastic candidate with experience in the technical writing field, preferably with experience writing both quality control and manufacturing documentation.

The Technical Documentation Officer will be responsible for preparing, editing, and reviewing standard operating procedures for use in the Quality Control and Manufacture functions based on the results of research projects. This requires the understanding of complex technical concepts, understanding of molecular biology and conversion into clear and easy to follow instructions suitable for laboratory use.

The Technical Documentation Officer will liaise with internal stakeholders across the business to ensure all requirements are met. They will have a key role in the introduction of new products, technologies and processes into our Production and Quality Management (QMS) Systems.

The Technical Documentation Officer will also have the opportunity to contribute to the non-conformance and OOS (out of specification) investigations to keep abreast of developments and findings, and to ensure that the latest outcomes are incorporated into documentation.

Main duties and responsibilities

- Take a lead role in the writing of manufacturing and QC SOPs, documents, and quality procedures.
- Explain scientific and technical ideas in easy-to-understand language suitable for operational purpose.
- Review existing documents and identify improvements.
- Ensure all document updates are made in accordance with our ISO13485 and ISO9001 quality systems.
- Ensure processes and quality control criteria are implemented consistently across the business.
- Communicate with key stakeholders to ensure their requirements are met in the successful technical transfer of new products and technologies into the Manufacture Team.
- Working to challenging deadlines as part of an ambitious pipeline of new product launches.

- Contribute towards the technical transfer of manufacturing processes to sub-contractors and manage SOP updates with subcontractors
- Review and understand technical R&D documentation describing product performance and robustness to enable feedback into manufacturing processes and determination of suitable QC criteria.
- Quickly grasp complex technical concepts and make them easily understandable in context.
- Ensure findings and outcomes identified as part of the Quality Management System (QMS) are introduced into new and existing documentation.
- Coordinate timely development, change and approval of documentation.
- Contribute towards the administration of the Sage 200 production system, to ensure that manufacturing processes are correctly reflected in Bill of Materials and product code structure.
- Training production and QC staff to new SOPs.

Qualifications and experience required

- Degree in life sciences or equivalent
- Minimum of 2 years' experience in a relevant industry
- Advanced knowledge of PCR essential
- Excellent scientific knowledge of molecular biology and ability to apply knowledge to writing manufacturing documentation
- Excellent written communication skills
- Knowledge of QMS, quality procedures and compliance to regulatory standards such as CE IVD
- Knowledge of QC procedures and history of identifying appropriate criteria for performance measurement
- Willingness to learn and challenge existing ideas and practices
- Accuracy and attention to detail

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