Job Description – QC Scientist: Analytical

Job Title: QC Scientist: Analytical

Reports to: QC Director

Location: Cheadle Royal Business Park, Cheadle

Job purpose:
Seda Pharmaceutical Development Services is a well-established and highly regarded Contract Research Organisation (CRO). We provide integrated Pharmaceutical Development and Clinical Pharmacology services to enable our clients to progress their novel new chemical entities through the drug development process. We aim to offer our clients the very highest level of scientific rigour aligned with expert knowledge of the regulatory landscape. For our colleagues we offer the opportunity of a rewarding career, making a real impact on the development of life changing medicines, with scope for outstanding personal growth.

The company was formed ten years ago and has undergone a rapid growth phase. We are at an exciting juncture in our development journey as we are establishing a new division, Seda Clinical Manufacturing services, to enable GMP supply and testing of the products we design in our established state of the art development facility.

The key purpose of this role is to carry out the hands-on analytical testing to ensure that the products manufactured in our facility comply with GMP standards and meet appropriate quality standards.

Key responsibilities:
- Execute hands-on U/HPLC method transfer, validation, and contribute to method development (Assay, Purity & Imps methods, Cleaning methods).
- Conduct dissolution method transfer and validation, with a lesser focus on method development.
- Perform pharmacopeial methods such as IR, Appearance, pH, CU, and water content.
- Adherence to Good Manufacturing Practice (GMP) standards using a new electronic Quality System.
- Contribute to the setup of the CDS and laboratory and actively participate in building the LIMS system.
- Preparation of Quality reports, including analytical reports and Certificates of Analysis (CoA) for raw materials and finished products.
- Writing validation protocols and reports, primarily for HPLC and Dissolution methodologies.
- Writing stability protocols and reports.
- Support activities to qualify equipment required for QC testing, ensuring compliance with current European Pharmacopoeia and ICH requirements, and participate in the calibration of analytical equipment as needed.
- Contribute to the creation and review of Plans, Methodologies, Work Instructions, and Standard Operating Procedures (SOPs).
- Adapt and contribute to a new way of working within a growing team.
- Hands-on contribution to building a LIMS system to transition to a paper-free lab.
- Work collaboratively with all members of staff to foster and contribute to building a positive culture within the company.

Qualifications, Experience, Skills & Capabilities
- Educated to Degree level in a relevant scientific discipline.
- Minimum of 1-2 years' experience in pharmaceutical sciences within GMP development.

- Experience in an analytical laboratory environment with a sound understanding of regulatory requirements.
- Familiarity with OpenLab is desired
- Diligence in writing, documenting, and reporting, with meticulous attention to detail.
- Advanced computer literacy.
- Previous experience in a GMP laboratory setting.
- Previous experience in managing product stability/trend/control chart datasets.
- Excellent verbal and written communication skills.
- Strong time management skills.