SEDA
Clinical Manufacturing Services

Job Description – Senior QC Scientist: Analytical

Job Title: Senior QC Scientist: Analytical
Reports to: QC Team Leader
Location: Cheadle Royal Business Park, Cheadle

Job purpose:
To lead hands-on QC testing, ensure GMP compliance of finished products, and actively contribute to the development and continuous improvement of QC systems, methods, and regulatory readiness in a clinical manufacturing environment.

Key responsibilities:

- Perform analytical testing using HPLC/UHPLC (Assay, Related Substances & Cleaning Verification methods) and dissolution testing including method transfers, validations, and troubleshooting.
- Perform compendial testing (FTIR, Appearance, pH, Content Uniformity, Water Content, etc.)
- Actively contribute to GMP implementation and inspection readiness activities, including preparation and support for both regulatory and customer audits, ensuring full adherence to quality and compliance standards.
- Actively participate in continuous improvement initiatives to 'lean' processes and documentation to cGMP.
- Write, review and provide technical oversight of analytical methods, validation protocols and reports, cleaning assessments and certificates of analysis, ensuring scientific robustness and regulatory compliance.
- Manage finished product stability studies from initiation to completion, including preparing protocols, liaising with third-party stability service providers, arranging sample shipments, requesting stability pulls, and compiling results into formal stability study reports
- Support activities for on-boarding of QC instrumentation including IQ/OQ/PQ along with identification of routine performance checks
- Draft, review, and maintain SOPs, Work Instructions, and laboratory quality documents as controlled under the eQMS, ensuring continuous compliance and clarity.
- Supervise, train and mentor junior scientists, delivering structured technical training across analytical techniques (e.g., HPLC, Dissolution, FTIR) and formally sign off their competency as an approved trainer, thereby building long-term laboratory capability.
- Manage laboratory organization, maintenance, and inventory, driving continuous operational improvements.
- Perform GEMBA walks, support laboratory inspections (5s) and SHE assessments to monitor compliance and drive continuous improvement.
- Assist in QC team workload and resource planning by forecasting tasks and ensuring timely allocation of resources to complete tasks on time and to budget.
- Drive QC process innovation and strengthen workflows to enhance the efficiency and reliability of the QC pipeline.
- Work collaboratively with all members of staff to foster and contribute to building a positive culture within the company.
- Adapt and contribute to growing and nurturing the culture across all departments by demonstrating collaboration and emotional intelligence.

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Qualifications, Experience, Skills & Capabilities

- **Educational Background**: Degree-qualified in a relevant scientific discipline such as Pharmaceutical Sciences, Chemistry, Biochemistry, or related field.
- **Industry Experience**: Over 5 years of hands-on experience in the pharmaceutical sector, specifically within GMP-compliant development environments. Demonstration of direct experience in a QC Laboratory is preferrable but acknowledgement of transferrable skills from other previous roles will also be strongly considered.
- **Analytical Expertise**: Proven experience working in an analytical laboratory with a strong grasp of regulatory frameworks (e.g. Eudralex Volume 4, ICH, etc.).
- **GMP Proficiency**: Demonstrable experience in a GMP laboratory setting, ensuring compliance with quality standards and cGMP documentation practices.
- **Data Management**: Skilled in managing product stability programs, trend analysis, and control chart datasets to support product lifecycle and quality assurance.
- **Documentation & Reporting**: Highly diligent in scientific writing, documentation, and reporting, with meticulous attention to detail and accuracy.
- **Communication Skills**: Excellent verbal and written communication abilities, capable of conveying complex scientific information clearly to cross-functional teams.
- **Collaboration & Leadership**: Strong team player with a collaborative mindset, willing to work across departments and supervise and mentor junior staff when needed. The ability to work adaptively as a team and independently as required is essential.
- **Adaptability & Initiative**: Proactive and flexible approach to work, with the ability to adapt to changing priorities and drive continuous improvement. The ability to multi-task should be demonstrable.
- **Time Management**: Exceptional organizational and time management skills, capable of handling multiple projects and meeting tight deadlines.