Clinical Method Development and Validation Lead

Job Overview:

We are currently recruiting for the role of Clinical Method Development & Validation Lead. The successful candidate will lead the team in the development and validation of accurate, precise, robust bioanalytical methods of analysis within the GLP Clinical Research Section of R&D.

The successful candidate will provide expertise in method development planning and execution and ensure all validation activity conducted within the laboratory is in compliance with GLP, VICH guidance and in-house SOPs/SOMS. All work under their direction will be conducted in compliance with H&S requirements and other quality standards detailed within the Research Division GLP Policy Document. The job holder will effectively manage staff and their work schedules within the GLP Laboratory to ensure delivery.

Main Activities/Tasks

- Subject matter expert in method development and validation.
- Provide expert guidance on wide range of analytical extraction techniques to accurately and reliably extract analytes of interest from various matrices e.g. protein precipitation, SPE, Liquid-Liquid techniques.
- Provide expert guidance on optimisation of analytical system settings (e.g. HPLC, UPLC, LCMS) to deliver reliable chromatographic methods suitable to measure low levels of analytes in a range of matrices.
- Provide expert guidance on LC column selection appropriate to reliably separate various analytes from sample components and matrix.
- Daily supervision, technical and managerial guidance of the Method Development and validation team.
- Provide expertise and training to deliver methods and validations to facilitate delivery of the New Product Development bioanalytical programme.
- Plan, lead and manage all bioanalytical method development and validation within the clinical laboratory in line with GLP, protocols, SOPs, VICH and other relevant international guidance.
- Lead troubleshooting and root cause analysis of new and existing bioanalytical methods.
- Maintain laboratory compliance with GLP, SOPs, company standards and relevant guidance.
- Assist with management and control of the laboratory consumable spend.
- Maintain audit readiness and an awareness of relevant regulatory guidance/current thinking and act on changes to ensure compliance, quality and efficiency.
- Ensure the quality, accuracy and integrity of all data generated within the Method Development and Validation team and oversee the accurate, contemporaneous completion of facility records and documentation.
- Produce robust validated bioanalytical methods and reports and provide to the internal customer within agreed timelines.
- Write and approve Methods of Analysis for routine use within the laboratory.
- Ensure bioanalytical methods are suitably transferred to the analytical group.
- Assessment of method performance after validation to identify and implement continuous improvements within the department.
- Support preparation of documentation and responses to regulatory submissions and queries.
- Conduct thorough investigations on deviations and analytical failures to determine root cause and suitable CAPAs.
- Proactively propose CAPAs, drive completion of actions and effectiveness checks to monitor and measure impact of change.
- Oversee on time in full responses to QA audit reports.

- Assist in the preparation, implementation and review of GLP SOPs and ensure adherence to same within the laboratory
- Ensure adherence to the relevant H&S and GLP Guidelines in the Laboratory at all times.
- Participate in cross functional H&S meetings; proactively review working practices in the laboratory for adherence to up to date H&S requirements and to continually improve on safe working practices for the analytical team.
- Recruit analytical staff and provide training plans, competency assessments, development plans, performance objectives/indicators and mentoring to facilitate staff development, growth and retention and to ensure required skills are available to meet the business needs.
- Identify and implement continuous improvements within the department
- Hold regular team and one to one meetings to mentor, lead and further engage and support staff and build team skills.
- Provide progress updates to management on bioanalytical and method development and validation programs
- Keep up to date with technology and regulatory expectations in the field of analytical method development and validation

Essential Criteria:

- A relevant Biochemistry, Biomedical or other applicable Science based degree or a minimum of 5 year's relevant experience.
- At least four years lab experience in a GxP laboratory, 2 years consisting of management.
- Proven ability to problem solve and troubleshoot complex problems with methods and equipment.
- Excellent analytical technique.
- Highly motivated and able to demonstrate experience and knowledge of a range of analytical extraction techniques e.g. protein precipitation, SPE, Liquid-Liquid techniques.
- Good knowledge of Regulatory Guidelines.
- Excellent oral and written communication and time management skills.
- Demonstrated ability to work in a high pressured environment.
- Ability to organise multiple projects and deadlines.
- Experience of preparing and reviewing validation protocols, SOMs & SOPs
- Competence in Microsoft packages; specifically Word, Excel and Powerpoint

Desirable Criteria:

- Experienced in DOE approach to method development.
- Experience in use of Minitab or equivalent.
- Working knowledge of GLP laboratory requirements.
- Empower Chromatography Data management system experience
- LCMS experience
- GC experience
- Experience in regulatory inspections and preparing regulatory responses.
- Knowledge of Regulatory Guidelines applicable to the Clinical Laboratories.

Norbrook Laboratories Limited employs a workforce with members of all sections of the community and is committed to appointing people purely on the basis of merit. In accordance with our equal opportunities policy we would particularly like to welcome applicants from the Protestant Community.