In Norbrook we pride ourselves in being one of the top companies in Northern Ireland and one of the top veterinary pharmaceutical companies globally. We develop & manufacture veterinary medicines, supplying products to 120 countries globally. With a strong portfolio of existing products and significant investment in R&D to launch new products annually, we have opportunities for individuals to join us and develop their career in a global company.

Our business strategy is supported by our Values – Customer Value, One Team, Results Driven, Excellence, Innovation, and Quality – and we support our employees to live the behaviours that creates our culture. Our on-going success is based on the expertise, knowledge and innovation of our employees. If you are interested in joining our team here at Norbrook and supporting our vision, then apply for this role.

QA GLP Inspector

Job Overview

The QA GLP Inspector is responsible for conducting inspections and generating audit reports within the R&D GLP Division to ensure compliance with Good Laboratory Practice Guidelines (SI 3106) and OECD GLP standards published as OECD Principles on Good Laboratory Practice (Revised 1997, ENV/MC/CHEM (98)17) and the requirements of Directive 2004/9/EC and 2004/10/EC and associated national legislation. Assist in the upkeep of a current and effective Quality Management System in accordance with Regulatory Authority requirements, company standards and best practices.

Main Activities/Tasks

The main tasks are outlined within the following areas, wherein it is expected that the QA Officer will be pro-active rather than reactive:

- Perform live phase and data inspections of the various GLP sections (Laboratories, Animal facility, test article facility, data analysis, study management, archive facility) for compliance with International GLP Guidelines
- Generate deficiency reports, notify relevant parties including QA and Test Facility Management of inspection findings and recommended actions
- Assist in the upkeep of the GLP Change Control, Deviations, CAPA and Laboratory Investigations databases to contribute to the continued development, performance and compliance of the GLP section and quality of new product development and life cycle management.
- Contribute effectively to the regular, documented Quality review process, that includes a review of Quality performance versus key Quality metrics/KPIs, for all key elements of the PQS including:
    - Service Level Agreements with CROs as applicable
    - Document Control, Retention and IT Systems
    - Review and trending of Deviations and Laboratory Investigations
    - Review and tracking of CAPAs

- Clinical Facilities and Study Audit Program
- Change Management

- Conduct of facility audits of the GLP facilities
- Ensure critical phases, data and reports are audited and findings reported as per in house SOPs
- Assist in the control/reconciliation of controlled study and facility documents
- Maintain an awareness of current national and international regulations and requirements for GLP and GCP and other relevant quality related systems and advise on same
- Auditing of the Pharmacovigilance (PV) facility, external PV distributors, external PV service providers and PV satellite offices

Essential Criteria:

Applicants must therefore demonstrate the following essential criteria on their application form in order to be considered:

- Educated to degree level in a relevant life science related discipline or a minimum of two years' relevant experience working within a GLP or GMP environment. (Full training will be provided).
- Experience in maintenance and trending of deviation and laboratory Investigation systems
- Experience in managing Change Control
- Demonstrate the Ability to read and interpret laboratory procedures, methods and data, GLP and regulatory guidance.
- Strong attention to detail
- Excellent organisation and communication skills (written and verbal) across a range of interdepartmental levels
- Demonstrate the ability to work independently on assigned responsibilities as well as part of a team to a high standard to meet deadlines.
- A full driving licence is required

Desirable Criteria:

Due to the nature of the role preference will be given to applicants demonstrating the following desirable criteria:

- Experience working in a QA function in a GLP or GMP environment.
- Experience in the approval, introduction and control of study and facility related documentation.
- Experience developing and maintenance of Excel spreadsheets for tracking purposes.
- Understanding of bio-analysis
- Demonstrable experience in a Clinical setting (in-house and/or CROs etc.,) working on clinical and non-clinical studies operating to GLP
- Understanding of Good Laboratory Practice principles and standards and quality management systems
- Knowledge of FDA/EMA practices and guidelines

- Knowledge of Pharmacovigilance (PV) guidelines and previous experience of conducting PV audits.
- Experience in the trending and interpretation of analytical data
- Experience of preparing responses to regulatory queries

Duration: Full time, permanent

Location: Newry

Additional Information:

- Applicants should be able to provide proof that they have a right to work in the UK at the time of their application. Applicants who are unable to provide this proof will not be considered.
- We regret that applications received after the closing date and time will not be accepted.

Benefits:

- Free Life Assurance
- Company Pension Scheme
- Healthcare cash plan
- 31 days annual leave
- Wedding Leave
- Company Sick Pay
- Employee well-being initiatives
- Employee Assistance Programme
- On-site free parking
- Canteen Facilities
- Employee Perks scheme
- Discounted Car Insurance
- Annual Employee raffle
- Employee Recognition scheme
- Career development opportunities

Contact: recruitment@norbrook.co.uk

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.