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.

Job Overview

To provide support to the pharmaceutical development team in relation to the design, execution and reporting of stability studies for new products in accordance with current guidelines. To ensure that protocols are ready in a timely manner and that the team are aware of the expectations of each study. At times this may be extended to include stability studies for post approval products. It is expected that the post holder will be experienced in the field of stability and be aware of all current guidelines within this field in specific VICH, EMA and FDA guidelines. The post holder must ensure that all work is carried out in accordance with the Company's Quality Manual, Standard Operating Procedures and H&S requirements.

Main Activities/Tasks

- To oversee New Product Stability activities in support of Pharmaceutical Development and New Product Registration.
- Activities to include but not limited to:
    - Scheduling and supervising stability studies
    - Preparation of Stability Protocols and Reports with the requirements of the relevant regulatory guidelines and requirements of the sponsor
    - Set down of samples on stability, including calculation of study numbers and labelling of samples
    - Ensuring the integrity of raw data for Stability studies
    - Ensuring adequate documentation of studies
    - Preparation of documentation and responses to regulatory submissions and queries
    - Keep Line Manager/Project Management informed of the progress of pre-approval stability studies
- To ensure that Standard Operating Procedures, protocols and GMP are being adhered to at all times
- Support the preparation and review of Standard Operating Procedures relating to stability.
- Ensure that Out of Specification and Out of Trend results are fully investigated in line with the company's SOP's and Quality Management System
- Trending of stability data
- Coordinate with stability lab to ensure work is carried out in support of projects to agreed timelines

- Coordinate with partner lines to effectively progress new product development
- To maintain an awareness of current guidance's (USP, Ph Eur, (V)ICH), and industry best practice for stability studies of pharmaceutical products activities
- To implement continuous improvements; e.g. protocol/report templates and establishing of data trending practices within the department in line with company procedures
- Ensure compliance with EHS policy, cGMP and other business regulations and participate in risk assessments, audits and incident investigations.

Essential Criteria:

- A science degree (please detail the degree modules on the application form)
- Previous Experience working in a cGMP environment
- Knowledge of VICH Guidelines
- Experience of HPLC, IC,GC, UHPLC and physical test methods
- Practical working knowledge of stability studies
- Experience in the preparation of protocols, reports and interpreting raw data
- Previous relevant experience in stability work in a pharmaceutical company
- Excellent knowledge of Microsoft packages

Desirable Criteria:

- A degree in chemistry or closely related subject
- At least 2 years' experience in a GMP environment
- Previous experience managing a stability programme
- Previous practical experience of trending results and identifying impurities

Duration: Full Time, Permanent

Location: Newry, Co. Down

Remuneration: Salary Attractive

Benefits: Free Life Assurance, Company Pension Scheme, 30 days annual leave, Wedding Leave, Employee well-being initiatives, Healthcare plan, Company Sick Pay, Employee Assistance Programme, On-site free parking, Canteen Facilities, Employee Perks scheme, Discounted Car Insurance, Annual Employee raffle, employee recognition scheme, career development opportunities and much more…

Contact: The Human Resources Department

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.