

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 lead compliance for Norbrook Laboratories Ltd in relation to GxP computer systems quality assurance. To ensure that all GxP computer systems in use at Norbrook Laboratories Ltd are identified, evaluated, validated, maintained and periodically assessed in accordance with cGMP and company procedures.

Main Activities/Tasks

- Provide leadership and guidance to the company with respect to compliance of GxP computer systems quality assurance.
- To conduct independent review of validation and qualification documentation for GxP computer systems. To ensure that an overall list of GxP computer systems exists and is maintained as current.
- Accountable for scheduling, tracking, reporting and achieving project deadlines.
- Provide expert input into the core aspects of Operations, Qualification and Validation SOPs with respect to GxP computer systems. Serve as a CSV representative for internal technical group discussions.
- Mentor the Quality Systems Managers / Quality Assurance Officers as assigned and ensure that they are appropriately trained and performing their functions in relation to review of GxP Computer systems.
- Attends departmental and team meetings focused on CSV activities and actively contribute to project teams.
- Understanding and applying industry specific compliance standards/regulations to all Commissioning/Qualification activities for GxP computer systems.
- Ensuring that planned periodic reviews of systems are performed and that implementation of any remedial actions necessary is planned and implemented.
- To ensure that Health and Safety practices and procedures are followed in the incumbent's area of responsibility.
- Any other tasks as deemed necessary.

Essential Criteria:

- Third level qualification in a scientific, information technology or engineering discipline with a strong information technology background.

- Good working knowledge of current Good Manufacturing Practices (cGMP) and current Good Laboratory Practices (cGLP).
- At least five years' experience in the field of GxP computer systems quality assurance.

Desirable Criteria:

- Knowledge of Pharmaceutical product manufacturing and filling processes
- Knowledge of Computer System GxP requirements including GAMP5 and 21CFR Part 11 requirements.
- Knowledge of software coding, experience in the implementation of a risk based validation approach, experience with process control & building management systems.

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.