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.

Head of Late Stage Formulations

Job Overview

The successful candidate will be a technical expert in the field of formulation development to manage the Late-Stage Formulation team. Responsible for developing and optimising formulations for new veterinary pharmaceutical products taking account of quality by design principles, ensuring robustness, scalability, and readiness for commercial manufacture. Managing technical risk and cross-functional coordination is a key element of the role.

Main Activities/Tasks

- Responsible for the development of Late-Stage formulation studies for veterinary drug products in accordance with relevant current (V)ICH guidelines.
- Transfer small-scale laboratory processes from early-stage development for scale-up and technology transfer.
- Apply quality by design principles to aid process understanding and strengthen risk assessments, while optimising and locking down critical process parameters (CPP) to ensure a robust, commercially viable manufacturing process.
- Liaise cross-functionally with Operations, Quality and other teams to support scale-up activities and ensure the smooth handover of new products and technologies into manufacturing.
- Responsible for reverse engineering activities, product characterisation and stability studies.
- To maintain an awareness of current trends and developing technologies, including collaborations with universities and external laboratories / partners.
- To maintain an awareness of the status of patents/intellectual property rights affecting the development of pharmaceutical products and provide technical input to the patent/intellectual property portfolio.
- Preparation and support of submission documents and regulatory response in consideration of (V) ICH guidelines, Ph. Eur., BP, USP monographs and appropriate guidance documents such as CDER.
- Authors and review of technical documents, such as protocols, reports, batch records in support of Regulatory submissions.
- To identify areas for continuous improvement within the team and bring to Head of R&D for review and approval

- To ensure that the Late Stage Formulation Section operate to a high quality standard, including the generation and adherence to appropriate SOP's and associated documentation
- Ensure a clean and safe working environment within the laboratories, following all COSHH and other Health and Safety requirements; liaise with the company Health and Safety teams as required in line with departmental and company-wide SOPs.
- Training of laboratory staff in SOP's, manufacturing processes and operation techniques and responsible for maintaining and reviewing team's training curriculum
- Any other duties as deemed necessary by management

Essential Criteria:

- Post graduate Degree in a relevant field e.g. Chemistry, Pharmaceutical Sciences, Pharmacy related discipline.
- At least 5 years experience of drug product formulation development, manufacture, scale-up and analytical processes of a variety of dosage forms within human or veterinary.
- Excellent computer skills including Microsoft Office suite.
- Working knowledge of GMP and regulatory requirements, including FDA, EMEA, VICH/ICH regulations.
- Enthusiastic and hard-working individual, highly motivated to achieve technical targets.
- Ability to multitask.
- Strong communication skills with a demonstrable record of working cross functionally.
- Proven experience in leading, developing, and motivating scientific teams, with a strong track record of effective people management.

Duration: 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.
- We are unable to sponsor or take over sponsorship of a Visa at this time.
- This role is based on a site that produces penicillin and as such, would not be suitable for those with a penicillin allergy.

Benefits:

- Free life assurance
- Company pension scheme
- Healthcare cash plan
- 32 days annual leave
- Wedding leave
- Company sick pay
- Employee well-being initiatives
- Employee assistance programme

- On-site free parking
- Subsidised canteen facilities
- WeCare programme – supporting the local community
- Employee perks scheme
- Employee recognition scheme
- Career development opportunities

Contact: recruitment@norbrook.co.uk

Norbook 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.