Principal Regulatory Affairs Executive

Reporting to; Regulatory Affairs Manager (UK&IE)

Location; Harefield

Tenure; Full-time, permanent

MAIN PURPOSE:

- The Principal Regulatory Affairs Executive is responsible for preparing high quality documentation for all regulatory submissions; liaising with relevant departments to ensure regulatory requirements for these submissions are met; proactively communicating with regulatory authorities in order to expedite approval of these submissions.
- The Principal Regulatory Affairs Executive may also be responsible for planning regulatory submissions, mentoring and/or supervising the work of junior Regulatory Affairs staff, and may be required to lead cross-functional project teams as required.

KEY RESPONSIBILITIES & ACCOUNTABILITIES:

- To prepare and submit high quality documentation for all regulatory submissions, following current best practice standards
- To liaise with relevant internal departments and external contacts to ensure regulatory requirements for these submissions are met and to proactively communicate with regulatory authorities in order to expedite approval of submissions
- To provide regulatory advice and support to other areas of the Company
- To prepare and maintain product labelling for appropriate markets in cooperation with local regulatory and commercial contacts
- To anticipate and resolve complex regulatory issues
- To actively participate as primary regulatory resource in cross-functional project teams
- To guide and manage direct reports, if appropriate
- To prepare and review plans for submissions within agreed timelines and ensuring alignment with agreed strategy
- To identify and provide information for incorporation in the Regulatory databases as appropriate
- To provide information on expenditure against budget for inclusion in periodic financial reports
- To maintain the paper and electronic filing systems for assigned products/countries, following Records Retention procedures
- To interact with industry trade associations and external consultants as necessary
- To liaise with Norgine manufacturing sites to ensure all site manufacturing licences are kept in compliance
- To mentor and support junior members of the team (with possible line management responsibilities)

SKILLS & KNOWLEDGE

Qualifications

Good degree in a relevant life science subject or equivalent

Competencies

- Considerable regulatory experience and general knowledge of worldwide regulatory requirements (including GMP, GLP and GCP)
- A full strategic understanding of the drug development principles and processes
- Awareness, understanding and an ability to interpret the ICH guidelines relevant to his/her technical/functional responsibilities, specifically those related to developing a Target Product Profile and delivering a product at the end of the development process
- Demonstrates an ability to analyse and summarise data to a high level
- Awareness of external regulatory environment
- Focuses on customer needs, follows up on commitments and requests
- Excellent interpersonal skills
- Excellent verbal and written communication skills
- Works cooperatively within a team and leads team as appropriate
- Able to work effectively without supervision
- Ability to communicate clearly in English

Norgine is a leading European specialist pharmaceutical company with a direct commercial presence in all major European markets. In 2016, Norgine's total revenue was EUR 368 million. Norgine employs over 1,000 people across its commercial, development and manufacturing operations and manages all aspects of product development, production, marketing, sale and supply.

Norgine specialises in gastroenterology, hepatology, cancer and supportive care.

Norgine is headquartered in the Netherlands. Norgine owns a R&D site in Hengoed, Wales and two manufacturing sites in Hengoed, Wales and Dreux, France.

For more information, please visit www.norgine.com

In 2012, Norgine established a complementary business Norgine Ventures, supporting innovative healthcare companies through the provision of debt-like financing in Europe and the US. For more information, please visit www.norgineventures.com.

Please note that we do try to provide specific feedback to all applications, however sometimes due to the volume of applications received we can respond only to those candidates who best match the position requirements.