Principal Regulatory Affairs Executive Merus

Reporting to; Lifecycle Team Manager

Location; Harefield

Tenure; 12 month secondment or FTC

MAIN PURPOSE:

- The Principal Regulatory Affairs Executive is responsible for preparing high quality documentation for all regulatory submissions, primarily medicinal products, with minimum supervision; liaising with relevant departments, service providers and partners 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, including the preparation, when applicable, of ASMFs and submission of CEP applications.
- 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 liaise with Partners for in licenced and out licenced products and secure that Marketing Authorisations are supported and/or maintained in accordance with agreements.
- 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 input into the budgeting process this may include information relating to regulatory fees required for prospective regulatory submissions
- 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

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)
- Understanding of legislation in relation to foods and nutritional supplements
- 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
- Proven experience in the life cycle maintenance of Centrally Authorised products
- 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.