Labelling Manager

Reporting to; Labelling & Artwork Team Manager

Location; Harefield

Tenure; full-time, permanent

MAIN PURPOSE:

- The Labelling Manager is responsible for planning and managing all regulatory activity associated with maintenance of Company Core Datasheets (CCDS).
- To coordinate the preparation of high quality documentation for safety submissions (variation, PSURs) and liaising with relevant departments to ensure that regulatory requirements for these submission are met
- To manage the processes through which safety related regulatory activities are planned agreed and progressed.
- To co-ordinate all QMS related regulatory activities to ensure compliance with actions.

KEY RESPONSIBILITIES & ACCOUNTABILITIES:

General

- To manage the preparation of regulatory submissions for those all Norgine products in relation to the maintenance of CCDS and any regulatory activity associated with CCDS changes and safety related variations
- To manage the preparation of high quality documentation for all regulatory submissions, following current best practice standards
- To manage own workload, including responsible delegation, to ensure agreed regulatory timeframes are met
- To liaise with relevant internal departments and external contacts to ensure regulatory requirements for these submissions are met both independently and as directed by line manager
- To manage the process through which safety-related regulatory activities are planned, agreed and progressed
- To manage submission strategies and plans for Labelling Changes
- To represent Regulatory Affairs on the Labelling Committee and provide regulatory advice on safety-related matters
- To coordinate the activities associated with the Labelling Committee,
    - including ensuring that appropriate documentation is provided to the Labelling Committee;
    - that decisions and actions are captured and communicated thereby ensuring all stakeholders are kept informed;
    - and that appropriate systems and files are updated as appropriate
- To anticipate and resolve complex regulatory issues associated with Labelling, independently

- To be the primary regulatory point of contact for all Labelling queries, provide guidance on regulatory labelling requirements, and input into discussions on processes associated with labelling activities, as required
- To represent Regulatory Affairs within and external to Norgine
- To maintain a record of product labelling for all markets in cooperation with local regulatory and commercial contacts
- To create, maintain and withdraw CCDSs as agreed by the Labelling Committee
- To track local SmPC variances
- To manage and coordinate the generation of global SmPC variations, providing high-quality documentation to the appropriate Regulatory Affairs personnel.
- To collate and manage the regulatory input into PSURs and maintain the PSUR Calendar, thus ensuring all PSUR Regulatory Data documents are completed on schedule and all PSURs are submitted on time, according to compliance regulations
- To update relevant Standard Operating Procedures, Working Practices and Supporting Documents as required
- To provide guidance on regulatory labelling requirements, and input into discussions on processes associated with labelling activities, as required
- To co-ordinate all QMS related regulatory activities to ensure compliance with actions:
    - Track QEs, CAPAs and Change Controls
    - Liaise with RA and Quality to ensure timely completion of actions or extensions
    - Report status at the Regulatory Operations Management meeting
- liaise with Quality to oversee the timely completion of QEs, CAPAs and change controls for Regulatory Affairs
- To identify and provide information for incorporation in the Regulatory databases as appropriate
- To maintain the paper and electronic filing systems for the identified responsibilities, following Records Retention procedures
- To guide, manage, coach and mentor direct reports, to deliver Norgine business objectives, ensuring their continued personal development

SKILLS & KNOWLEDGE

Qualifications

Good degree in a relevant life science subject or equivalent,

Competencies

- Broad regulatory experience, part of which should have been gained operating at a senior level, and good knowledge of worldwide regulatory requirements (including GMP, GLP and GCP)
- A full strategic understanding of the drug development and life-cycle management principles and processes
- Demonstrates subject matter expertise, e.g., labelling
- Demonstrates an ability to analyse and summarise data to a high level
- Good awareness of external regulatory environment
- Line management experience
- Focuses on Commercial needs
- Focuses on customer needs, follows up on commitments and requests
- Excellent interpersonal skills
- Excellent verbal and written communication skills
- Leadership skills
- Works cooperatively within a team and leads team as appropriate
- Works collaboratively and effectively both within RA and cross functionally

- Works effectively without supervision
- Exercises considerable autonomy in decision making and objective setting
- 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.