Regulatory Affairs Manager

Reporting to; Regulatory Affairs Associate Director

Location; Harefield

Tenure; Full-time, permanent

MAIN PURPOSE:

The Regulatory Affairs Manager is responsible for the lifecycle management of key Norgine Product post EU approval, ensuring smooth integration of new products following launch and all associated on-going regulatory maintenance activities, this includes:

- Overall Regulatory Strategy and Plan, and providing subject matter expertise at brand team and project team meetings
- Regulatory Impact Assessment of proposed changes and robust strategies for implementation
- Engaging and proactively communicating with key internal stakeholders and the Regulatory Authorities to deliver against objectives set by the business
- Ensuring submissions made are of high quality, in compliance with regulatory requirements, submitted and approved timely in accordance with business need

Further responsibilities

- Co-ordinate QMS related regulatory activities e.g. CAPA's as applicable, to ensure compliance with actions.
- Support inspections and audits, as applicable
- Proactively contribute to the maintenance of robust procedures as applicable
- Supervise more junior staff in relevant tasks, processes and activities as applicable

KEY RESPONSIBILITIES & ACCOUNTABILITIES:

- Maintain up to date knowledge of relevant regulations and guidelines, and propose strategies for effective implementation, knowledge sharing and advice to project teams
- Implement agreed regulatory strategies to plan, anticipate and resolve roadblocks, escalate issues through effective communication
- Proactively communicate with relevant internal stakeholders and external contacts, e.g. partners, and induce a trustful working relationship to ensure regulatory requirements for submissions are met and approvals expedited
- Proactively communicate with regulatory authorities in order to negotiate solutions on issues and request for information, and expedite approval of submissions

- Ensure preparation, submission, approval and maintenance of high quality documentation, following current best practice standards
- Provide expert advice and support to brand teams and other areas of the business
- Provide input into the budgeting process e.g. relating to regulatory fees and CRO support required for prospective regulatory submissions
- Manage own workload to ensure agreed regulatory timeframes are met, and propose solutions to own manager if resource constraints
- Explore opportunities for continuous improvement to enhance business performance
- Manage, coach and mentor peers and direct reports, if applicable, to deliver Norgine business objectives, ensuring their continued personal development
- Maintain data and documentation in compliance with Norgine's regulatory systems and procedures
- 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 with EU regulatory requirements and processes (MRP, DCP and CP) for LCM activities
- Considerable regulatory experience with AU and NZ MAA and LCM regulatory requirements and processes
- Effective negotiation and influencing skills
- Proven ability to manage multiple projects efficiently
- Ability to analyse and interpret complex issues, and develop and communicate strategies and plans to resolve
- Clear communicator, sharing information to ensure successful partnering with internal and external stakeholders. Listens and responds effectively to others
- Responds quickly and positively to customer needs, develops effective collaborative working relationships with customers/external partners
- Shows strong respect and collaborative working with internal and external customers
- Aspires to continuously develop technical/professional knowledge and interpersonal/management expertise to be a good role model.
- Displays commitment and takes responsibility for personal performance and self-development
- Displays integrity, discretion and confidentiality when communicating with others, exhibits sound judgement
- Seeks and accepts responsibility to enhance overall business performance
- Focusses on improving efficiency to ensure cost effective utilisation of both internal and external resources, maintains a flexible and constructive outlook
- Able to contribute to budget preparation and review

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.