



Regulatory Affairs Conformance Manager – External Networks

Reporting to; Regulatory Conformance Team Manager

Location; Harefield, UK

Tenure; Full time, Permanent

MAIN PURPOSE:

The Regulatory Affairs Conformance Manager is responsible for planning and managing all regulatory conformance activity associated with the manufacture of products for third party MAAs.

KEY RESPONSIBILITIES & ACCOUNTABILITIES:

- Primary regulatory point of contact for third party MAAs, where Norgine is the CMO
- Build strong working relationships with third party MAAs
- Establish process and repository for maintaining visibility of third party registered details required to support product release
- Collaborate with partners to standardise regulatory conformance activities, roles and responsibilities
- Introduce and maintain KPIs that monitor results delivery and customer service
- Identify and implement opportunities for continuous improvement of processes and partnering
- Provide support to business development activities
- Completion of regulatory activities following divestment of product(s) where Norgine retains CMO responsibilities
- Liaise with relevant internal departments and external contacts to ensure regulatory requirements for change controls are met
- Proactively communicate with internal stakeholders to expedite delivery of documentation to support third party needs in line with contractual obligations, for example, new market launches, renewals, variations, RFIs, annual reports and withdrawal
- Facilitate provision of samples and standards in support of agency requests communicated via the MAH
- Ensure MAH approvals and implementation requirements are communicated within Norgine to maintain compliance
- Support any inspections/audits for assigned products/partnerships in relation to regulatory compliance

SKILLS & KNOWLEDGE

Qualifications

Good degree in a relevant life science subject or equivalent.

Competencies

- Broad regulatory/ quality or manufacturing 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
- Good awareness of external regulatory environment
- Demonstrates an ability to analyse and summarise data to a high level
- Excellent problem solving ability
- Effective report writing and proof reading skills
- Focused on customer needs, follows up on commitments and requests
- Excellent interpersonal skills
- Excellent verbal and written communication skills
- Ability to positively influence internal and external stakeholders to reach decisions through effective collaboration
- Experience of working across timelines and also in multi-cultural environment
- Works cooperatively within a team and leads team as appropriate
- Works effectively without supervision
- Exercises considerable autonomy in decision making and objective setting
- Ability to communicate clearly in English

Norgine is a European specialist pharmaceutical company that has been established for over 100 years. In 2015, Norgine's total revenue was EUR 320 million and the company employs over 1,000 people.

Norgine provides expertise and 'know how' in Europe to develop, manufacture and market products that offer real value to healthcare professionals, payers and patients. Norgine's approach and infrastructure is integrated and focused upon ensuring that Norgine wins partnership opportunities for growth.

Norgine is headquartered in the Netherlands and its global operations are based in Amsterdam and in Harefield, UK. Norgine owns a R&D site in Hengoed, Wales and two manufacturing sites, one in Hengoed, Wales and one in Dreux, France.

For more information, please visit www.norgine.com

In 2012, Norgine established a complementary business [Norgine Ventures](http://www.norgineventures.com), 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.