Norgine B.V.
The ‘go to’ European specialist pharma company

Delivering success together

Norgine is an independent pan-European speciality pharmaceutical company, established in 1906. We operate in three therapy areas – gastroenterology, hepatology, critical and supportive care. Norgine is a medium-sized company with short decision-making processes characterized by a cooperative leadership and team-oriented working style.

For our office in Vienna with starting date as soon as possible we are looking for a

Principal Regulatory Affairs Executive (m/f) – Austria and Switzerland

- Full time, 38,5 hours/week,

Permanent role,

reporting directly to Regulatory Affairs Manager Germany, Austria and Switzerland -

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 in Austria Germany and Switzerland.

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.

Your responsibilities:

- 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 coordinate changes in the registration texts and packaging material with all related tasks
- To anticipate and resolve complex regulatory issues
- To actively participate as primary regulatory resource in cross-functional project teams
- 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

Your qualification:

- Good university degree in a relevant life science subject or equivalent
- Well-developed regulatory experience and general knowledge of worldwide regulatory requirements (including GMP, GLP and GCP)
- Working experience and good knowledge of EU and Swiss regulatory environments
- 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
- Experience in regulation of medical devices considered an advantage
- Awareness of external regulatory environment
- Demonstrates a good ability to analyse and summarise data
- Focuses on customer needs, follows up on commitments and requests
- Good interpersonal skills
- Excellent verbal and written communication skills
- Works cooperatively within a team
- Able to work effectively without supervision, very good self-organisation skills
- Excellent command of spoken and written English and German
- Results-orientation, reliable and motivated
- Commitment to detail, thoroughness
- Very good understanding of Microsoft Office (Word, Excel, PowerPoint)
- The role requires occasional travel as and when necessary within Europe

Our offer:

You will be part of a very experienced pan-European team, where we believe our skills, experience and resources can improve patients' lives. Collaboration is a way of life for us. As One Norgine, we are dedicated to working with each other and with our stakeholders. Inventiveness, flexibility and teamwork are at the heart of what we do. It is what makes us different.

Our philosophy is to invest in people who have a high level of qualification, who are open to change and who are willing to work with passion and high commitment. Furthermore we offer an attractive compensation package based on collective agreement of employees in trading firms (salary table A, occupation group 5, salary area Vienna) and a pay for performance approach beyond that. We enable every staff member to contribute to the success of the company.

Do you want to apply?

Please contact Sandra Kupke in our German office for more information at the following number +49 6421 9852-14 or address your application by email to bewerbung@norgine.com.

Norgine

www.norgine.com

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About Norgine

Norgine B.V. is a European specialist pharmaceutical company with a direct presence in 13 European countries, that has been established for over 100 years. Norgine is headquartered in the Netherlands and its global operations are based in Amsterdam and in Harefield, UK.

Norgine’s vision is to be recognised by potential partners as the 'go to' European specialist pharma company, leveraging its 'know how' and One Norgine approach in Europe to develop and commercialise late stage products that offer real value to payers, healthcare professionals and patients.

Date: 27.07.2017.