Role – Regulatory Affairs Associate

Austria / Germany / Switzerland (M/F/D)

Reporting to : Regulatory Affairs Manager Austria, Germany and Switzerland

Location : Vienna, Austria, or Wettenberg, Germany

Tenure : Full Time - Permanent

MAIN PURPOSE:

The Regulatory Affairs Associate is responsible for assisting the Regulatory Affairs team for Austria, Germany and Switzerland.

KEY RESPONSIBILITIES & ACCOUNTABILITIES:

- To support the Regulatory Affairs team with the preparation and submission of high quality documentation for 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 communicate with regulatory authorities in order to expedite approval of submissions, as directed by line manager
- To assist in the preparation and maintenance of product labelling for appropriate markets in cooperation with local regulatory, medical and commercial contacts, including translation of text changes
- To assure implementation of Artwork according to legal timelines by coordination with relevant functions/partners
- To maintain the paper and electronic filing systems for assigned submissions, following Records Retention procedures
- To assist in the resolution of straightforward regulatory issues
- To work under supervision on uncomplicated projects, and to progress to working more independently
- To provide regulatory service to the Regulatory Affairs team as required by their team, including, but not limited to: monitoring of license databases, IFA-notifications, collation and provision of regulatory intelligence information, monitoring of sunset clause deadlines

You will be acting in this capacity on behalf of Norgine Pharma GmbH/ Vienna, Norgine GmbH/ Wettenberg, Marpha GmbH/ Wettenberg, and Norgine AG/Luzern.

YOUR PROFILE:

- Degree with some experience in the pharmaceutical industry, or similar
- Proven experience in Document management and Regulatory Affairs in at least one of the DACH countries
- An awareness of the drug development process
- A keen interest in developing regulatory knowledge
- A keen interest in developing product knowledge
- Demonstrates an ability to analyse data, strong attention to details, very organised
- Focuses on customer needs, follows up on commitments and requests

- Good interpersonal skills
- Clear verbal and written communication skills in English and in German, ideally French as well
- Capacity to work cooperatively within a team

Liegen Sie mit uns auf einer Wellenlänge?

Dann senden Sie Ihre aussagekräftigen Bewerbungsunterlagen direkt per E-Mail an Frau Frederique Becker unter fbecker@norgine.com.