DESCRIPTION

A little about Nordic Pharma:

Nordic Pharma is a mid-size privately-owned international pharmaceutical company which focuses on the development and commercialization of niche hospital and orphan products to address unmet medical needs. Nordic Pharma's expertise relies on the development and sales of its own products, but also on partner products acquired at various stages of development. Today, Nordic Pharma has a range of highly specialized proprietary and in-licensed products in the following therapeutic areas: Rheumatology, Gastroenterology, Women's Health, Opthalmology and Critical Care (Anaesthesia, Haematology, Oncology).

Nordic Pharma's values of Commitment, Ambition, Respect, Reliability, Integrity and Agility describe our culture and standards and guide us in our way of working.

Title:	**Corporate Regulatory Affairs Trainee**
Department :	**Corporate Regulatory Affairs**
Reporting to :	**Corporate Regulatory Affairs Manager**
Location :	**Paris 7^{e} arrondissement**

General description :

Corporate Regulatory Affairs Trainee :

Assist the Corporate Regulatory Affairs Manager in his various missions and activities for the registration and maintenance of the product registrations in Europe and worldwide territories, to support the Nordic Pharma (Company) business strategy.

Main activities and responsibilities :

- Take part in the regulatory activities of various products of the company :
  - Assist with preparation, submission, and monitoring the marketing authorisations and medical device files and their maintenance in worldwide territories as European Union, US, Canada, Japan etc. : variations, safety reports, renewals, answers to questions and requests from supervisory authorities; to ensure there launch and their maintenance in compliance with the local regulation and the company business strategy.
  - Contribute to the development and the elaboration of the local prescribing information (SmPC, patient leaflet and labeling) for drugs and medical devices, in line with the local regulations and the internal processes.
  - Ensure the adequate information are provided to allow the elaboration mock-ups for drugs and medical devices in line with local regulation and the Company business strategy.
  - Ensure the regular information about the progress of the dossiers under the scope of responsibilities,
  - Ensure the provision in due time of the approved prescribing information to the relevant departments,
  - Participate in the regulatory compliance review of the corporate promotional materials (internal documents, website, applications);
- Participate in the creation, update, and review of regulatory training, and provide regulatory training for Nordic Pharma employees.
- Participate in the regulatory intelligence for the product and territories under the scope of the responsibility and in the adequate communication of the information.
- Assist the relevant departments and partners on the drug / medical device regulations related to the products under the scope of responsibilities.
- Participate in the creation, updating and revision of regulatory standard operating procedures related to the activities under the scope of responsibilities.
- Responsible of the data integrity and compliance in the regulatory Database systems for the product / projects under the scope of responsibilities.

Responsibilities are:

- Timely submission of regulatory dossiers and their follow-up up to the authority's decision and implantation in production (when relevant)
- Provide response/advice to other departments on regulatory related issues under the supervision of a Corporate Regulatory Affairs Manager
- Dispatch the adequate Drug MA/ Medical device related information.
- Ensure the regulatory intelligence (regulation), assist in the regulatory interpretation, and ensure their adequate dispatch.
- Guarantee data integrity and data compliance in the regulatory Database systems for the product / projects under the scope of activities.
- The contacts established exclusively allow to answer specific questions on the technical / scientific / regulatory level. Lack of promotional activities in its possible contacts with health professionals when contact with health professionals is required.

The trainee is responsible to comply with Nordic SOPs and guidelines

Essential Competencies :

- Knowledge of (global) RA (relevant regulation/guidelines)
- Be committed (compliance with timeline and decision taken by the company)
- Be precise and accurate (administrative skills)
- Good communication skill, including in English language

Qualifications, experience and skills needed :

Qualifications / Education : Science or Pharmacy student in regulatory affairs Master

Previous Relevant Work Experience / Years of Experience : one previous training in pharmaceutical company or medical device company

Other Job Requirements : Fluent in English language

Joining us means :

- Joining a fast-growing pharmaceutical laboratory and taking part in a dynamic development process;
- Choosing to work for a company with strong values, offering a genuine culture of expertise, and a wide range of benefits (50% teleworking possible, luncheon vouchers and RIE etc.).

We are convinced that diversity is a source of fulfillment, social balance and complementarity for our employees and trainees, so our offers are open to all without restriction.

So don't wait any longer and join us, by sending your application (CV / covering letter) under reference 2024-CorpRA-Training to emilie.lecocq@nordicpharma.com