Regulatory Affairs Manager Benelux at Elanco Animal Health
Location: Antwerp

Elanco is a world leader in developing products and services that enhance animal health, wellness and performance. Elanco products contribute to the production of an affordable and abundant supply of food, while also helping to ensure the safety of that food. Innovative new pet products help companion animals live longer, healthier, happier lives. Our half-century of innovative products, services and global partnerships help to fulfill our vision of food and companionship enriching life.

This role contributes to ensure regulatory compliance of existing products by planning, preparing, coordinating, and delivering registration documentation to the competent authorities in Belgium, Netherlands and Luxemburg.

Key Leadership Responsibilities

- Responsibility for Agency relations by maintaining close contacts to the relevant authorities. Responsible for thorough understanding of local requirements and in the turntable function you have general understanding and knowledge of regulatory requirements for the countries supported. Competent authority interactions may range from written communications to in-person meetings within the scope of responsibility.
- Responsibility for ensuring professional planning, competent RA input, efficient registration and maintenance of the registrations of existing marketing authorizations in accordance with business needs, directions and strategies. You plan, direct and coordinate regulatory activities of the Elanco portfolio identified as area of responsibility.
- Ensure regulatory compliance by creating awareness of requirements and guidelines, facilitating timely submissions and strict participation in the global/local change control operations. Ensure regulatory compliance by on-time submission and follow-up of all relevant documentation.
- Work effectively and flexibly within and across all Elanco teams and external collaborators to achieve overall Elanco deliverables.
- Create a positive work environment that is aligned with company objectives.
- Provide information to facilitate accurate and timely project and budget forecasts, as appropriate.

Key Technical Responsibilities

- Be accountable for the submission of variations and renewal applications for registered products and the maintenance of existing licenses.
- Ensure complete approval in Benelux countries of Promotional Material and Labels. Actively monitor the external regulatory and competitive environment to anticipate trends and potential benefits/threats to the business; Understanding and communication of strategic implications of regulatory events.
- Understand the technical aspects and science of the products on the market.
- Coordinate translations within Benelux for all products, as appropriate.
- Contribution to on-time fulfillment of health authorities post approval commitments.

Requirements

University degree in science related field
Min. 2 years of regulatory experience within a pharmaceutical company
Solid knowledge of regulatory processes in the Benelux
Fluent in Dutch and English
Good working knowledge of French
Excellent communication skills
Ability to work in cross-functional teams
Thorough project management and problem solving skills
Limited Travel Required (approx. 10 %) within the region

Interested?

Please e-mail your application letter and resume to jobs_lillybelgium@lilly.com.