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Regulatory Affairs Manager Benelux

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Company: Elanco

Location: Antwerp

Category: other-general

As a leading global animal health company, Elanco delivers innovative products and services to improve the health of pets and farm animals around the world because we believe making animals' lives better, makes life better. Since 1954, we have provided solutions that support veterinarians, farmers and pet owners to advance our vision of Food and Companionship Enriching Life. Elanco's promise to employees: Together, we foster an inclusive culture where everyone can make a difference, encouraging ownership, growth and well-being.

Position Description

The main purpose of this position is to contribute to the maintenance of existing and registration of new animal health products (veterinary medicinal products, feed additives, biocides and care products) through ensuring regulatory compliance and continuity of supply in accordance with business needs, directions and strategies in the European area with a special focus on Benelux.

This role works with various Elanco departments, such as other regulatory functions, pharmacovigilance, quality, supply chain, manufacturing, business as well as with external parties like health agencies, distributors, national institutes, etc.

Functions, Duties, Tasks

Ensure compliance with regulatory requirements (timely submission of regulatory procedures including Variations, Renewals, Referrals) for existing and upcoming portfolio (Pharmaceuticals, Vaccines, Feed-Additives, Biocides)

Update of the various regulatory Information management programs (Vault RIM/Pharao)

and documentation repositories in agreement with regulatory management & internal procedures.

Coordinate and/or conduct packaging development as part of ALRP responsibilities in Benelux, including release of production artwork in BLUE.

Contribute to project forecast and prioritization and regulatory strategy in Benelux

Provide leadership in the coordination of Benelux issues, submissions, packaging updates and other national tasks

Regulatory review and approval of promotional materials in PromoMats

Monitor regulatory environment including updates of national regulations and other European regulations/guidelines applicable locally

Build and maintain good relationships with the Competent Authorities of Benelux countries, with a focus on established products

Work effectively, efficiently and flexibly within and across all Elanco teams and external collaborators to achieve overall Elanco registration deliverables.

Identify and utilize methods to deliver individual objectives in a high quality, timely, cost-effective manner.

Provide information to facilitate accurate and timely project and budget forecasts

Perform other regulatory related duties/assignments, support BeNeNo Team and lead BeNeNo Regulatory Affairs projects on a as needed basis when required by business and directed by management

Minimum Qualification (education, experience and/or training, required certifications)
Advanced degree in life sciences (, veterinary medicine, toxicology, pharmacy, chemistry, etc.) or equivalent.

Good computer skills (Word, Excel, knowledge of data management)

Excellent interpersonal and communication skills

Strong attention to detail

Good planning and organizational skills

Fluent English language and Dutch language (written and verbal)

Additional Preferences

Previous experience in hands-on working in regulatory affairs, ideally in a similar position

Fluency in French (written and verbal) is an asset

Open-mindedness and team player

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