Janssen Pharmaceutica N.V. is looking for a **Regulatory Affairs Specialist**

Description:

You are a regulatory affairs expert for a broad range of regulatory activities for registered products, cosmetics and medical devices in the Benelux.

We are looking for a talented person who can manage a defined product portfolio and will work closely with local peers and regional project teams.

The ideal candidate brings a level of experience within the Benelux regulatory affairs environment. The candidate has problem-solving capabilities that enable successful development of local strategies and brings technical solutions to support the business. The candidate has excellent interpersonal, negotiation and communication skills.

Key responsibilities:

- Ensure marketing authorisations and lifecycle management compliant with regulatory requirements
- Prepare and manage local submissions, assure timely execution and compliance
- Prepare artwork, manage proofreading for launch
- Ensure timely and pro-active communication of the authorisation status within the organisation.
- Build and sustain a positive relationship with the health authorities
- Follow-up of regulatory legislation; evaluate impact on business
- Provide regulatory requirements and intelligence to Regional and European organisation

Qualifications:

- University degree – medical or paramedical (pharmacy, biology, veterinary, biomedical sciences) or equivalent by experience
- Preferred Knowledge of Benelux pharmaceutical legislation and experience in EU regulatory procedures is an advantage
- Preferred experience of working in cross-functional teams, working in a matrix organisation
- Excellent oral and written communication skills
- Fluent English, French and Dutch (speaking, reading and writing), basic understanding of German.
- Positive mindset

Primary location Beerse 2 – Antwerpseweg

Please send your application for the attention of:

Ivelina Guneva
Talent Aqusition Partner BeNE
Johnson & Johnson Global Services
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