Will-Pharma S.A., located in Wavre, is a pharmaceutical company that develops, manufactures and markets a wide range of medicines and other types of health products, mainly through partnerships.

Currently we are looking for an experienced Regulatory Affairs Manager to strengthen our team.

**FUNCTION**

As part of the Quality and Regulatory Affairs team, your mission will be to ensure regulatory compliance of all product dossiers related to medicinal products, medical devices, food supplements and cosmetics within Europe and for Export.

In order to achieve this, this role will require both strategical thinking as operational preparatory activities for new submissions and product life cycle maintenance.

Being part of a larger virtual organization and because we are a growing company, the role will require significant collaboration with external partners and governmental departments. Travelling abroad is limited.

**RESPONSIBILITIES**

A. **Regulatory strategy**

✓ You advise on the regulatory strategy and planning for new products and existing portfolio.
✓ You identify opportunities to keep the regulatory framework and processes as efficient as possible.
✓ You identify potential risks in submissions and pro-actively look for contingency plans.

B. **Scientific/Technical Analysis**

✓ For in-licensed products, as part of due diligence, you advise on the content of the regulatory dossier.
✓ For existing products, you ensure together with Quality that module 3 of the regulatory dossier is according to current standards, that risks are identified, and potential issues get solved.
✓ Where external scientific/technical advice is required, you partner with industry experts to obtain the best possible results.
✓ You will evaluate and advise on product and process changes that are submitted during the life cycle of a product.

C. **Submission/Project Management**

✓ You coordinate all steps of the registration process
✓ You create and maintain to current standards all registration dossiers in e-CTD format (new products, product variations, 5-year renewals) for medicinal products.
✓ You create and maintain to current standards all notifications for other healthcare products
✓ You communicate submission quality standards and requirements to project teams and serve as the regulatory expert.
✓ You collaborate closely with Governmental agencies in order to ensure timely approval

D. Internal and External Influence and Advocacy

✓ You will be required to interpret existing regulations and guidance documents within the regulatory department and as part of project teams.
✓ You will analyze the impact of changes in the applicable regulations and communicate your recommendations to the management and relevant departments.
✓ You will prepare the regulatory impact of changes to existing products and discuss with the management and other internal and external parties.

EXPERIENCE & COMPETENCES

You have a Scientific master’s degree.

You have a profound understanding of the end-to-end pharmaceutical lifecycle and other health care products.

You have a deep knowledge of EU regulatory procedures (national, MRP, DCP, centralized) and development of medicinal products. By preference as well any experience for medical devices, food supplements and cosmetics.

English, Dutch and French hold no secrets from you, and you can effectively and fluently communicate in these 3 languages.

You can prioritize and coordinate tasks with others for timely completion and to avoid setbacks.

You are highly analytical, detail oriented and accurate.

You are able to incorporate regulatory compliance in a pragmatic way, keeping the right balance between patient safety, product quality and commercial activity.

OFFER

You will be part of a small and growing family-owned company where we achieve and grow together through our values (passion, entrepreneurship, respect, quality, success) and through innovation, personal relations, collaboration and customer service.

Will-Pharma offers you a market competitive remuneration package based on your experiences and competencies.

To apply and be considered for the role please send your CV and your cover letter to Mrs Henrot: cecile.henrot@willpharma.com