Regulatory Affairs Associate

Belgium – Elsene

Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for people. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

Interested to join our dynamic Pfizer's Regulatory Affairs Belux Team that is dedicated to bring **Breakthrough's that change patient's lives** to the Belgium and Luxembourg market? Then check this job opening within our team!

The purpose of this position is to allow Pfizer to legally study, manufacture, market and supply medicines by obtaining, managing and maintaining product Marketing Authorizations in line with business goals and legal requirements.

The Position

- In line with defined product responsibilities, utilise regulatory expertise to develop and deliver optimal regulatory strategies and plans to support the achievement of Pfizer's business goals for both licensed and development products, with support of the Regulatory Affairs Executive and Team Leader.
- Provide regulatory input to regulatory and commercial strategic and operating planning process, as well as to other divisions, e.g. Corporate Affairs, Medical Affairs and Global Heath & Value.
- Work with Global Regulatory Affairs-International (GRA-I) regional strategists to provide country input into Global and European Regulatory Strategies as required.
- With support from the Regulatory Affairs Team Leader or Regulatory Affairs Executive and in partnership with above-country operational hubs where applicable, review, co-ordinate and where required create necessary national data to support country submissions Review Module 3 documents and provide feedback to the CMC strategist to ensure compliance with European and/or local regulatory requirements.
- Provide support to the local Clinical Trial Applications (CTA) administrative colleague for the preparation of the local documents in partnership with the CTA submissions Hub manager throughout the lifecycle of the CTA (initial application, amendments and other maintenance activities)
- Proactively take opportunities to develop or enhance working relationships with Regulatory Authorities and trade associations.
- Responsible for database entry and the document management of regulatory transactions as applicable and/or ensuring notification and instructions to the Change Control Administrator to update local/global systems.
- Ensure timely communication about regulatory approvals and implementation dates and liaise with responsible for Artwork coordination and/or Supply/Demand and other logistics functions to plan for component updates and to ensure their introduction within required regulatory compliance timelines.
- This is an individual contributor role.
- Possible location : Brussels, Avenue de la Plaine. For this position we do not offer relocation. Please note this is not a remote role.

Your skills

- Life sciences or chemistry graduate to honours level or equivalent through work experience. Masters Degree, Post Graduate Diploma or PhD preferred
- Member of Healixia preferred
- Strong knowledge of the Belux and European environment, rules, regulations and procedures, and how this impacts regulatory strategy and implementation.
- Insight and understanding of internal and external shareholders needs and requirements.

- Computer literacy: good knowledge on use of MS Word, Excel, PowerPoint, Outlook. Experience in using electronic document management systems and other electronic tools
- Ability to work under minimal supervision and in a team
- Accurate, organised and problem solving; resilient, able to meet concurring deadlines
- Ability to communicate effectively verbally and in writing, good negotiation and influencing skills
- Analytical thinking; quality and compliance oriented
- Languages: Fluent in written and spoken Dutch, French and English. German knowledge is an asset.

What we can offer
At Pfizer we are a patient centric company, guided by our four values: **courage, joy, equity and excellence.** Our breakthrough culture lends itself to our dedication to transforming millions of lives. Pfizer's open-door policy is an integrated part of our culture across all levels of seniority.

- Permanent contract
- Flexibility: homeworking 2-3 days per week and flexible working hours
- Competitive salary and benefits : meal vouchers, hospitalization insurance and DKV, pension plan, 100% reimbursement of public transport
- Career growth opportunities
- Holidays : 20 legal holidays, 6 RTT/ADV, 3 extra-legal holidays.

We believe that a diverse and inclusive workforce is crucial to building a successful business. As an employer, Pfizer is committed to celebrating this, in all its forms – allowing for us to be as diverse as the patients and communities we serve. Together, we continue to build a culture that encourages, supports and empowers our employees. Should you have any question or specific needs regarding this hiring process, please contact : Albena.Zabtcheva@Pfizer.com

This position on LinkedIn: : https://www.linkedin.com/jobs/view/2638831593

"For our projects regarding diversity and inclusion on the work floor, Pfizer is closely collaborating with Actiris."

About Us
Pfizer discovers, develops, manufactures and distributes medicines and vaccines. Pfizer wants to contribute to better health and wellness for everyone, at every stage of life. Pfizer works with the government and other health partners to provide quality and accessible healthcare. The patient is central to this story.

Pfizer has four offices in Belgium with which it supports its Belgian and international activities: 1) Anderlecht, where the Pfizer Clinical Research Unit is located. This is a fully equipped phase 1 research center. With that of New Haven (US), it is one of two Phase 1 Pfizer research centers in the world, 2) Elsene, the Belgian headquarters, 3) Puurs, Pfizer's production and packaging site, and 4) Zaventem, the international Pfizer's Logistics Center.

More information can be found at www.pfizer.com, www.pfizer.be and on Facebook and Twitter.

Regulatory Affairs