Regulatory Affairs Manager

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.
- 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.
- Attend relevant product team meetings with cross-divisional colleagues to provide technical guidance and support for teams as necessary. Ensure teams understand the potential opportunities and constraints that the latest legislation/upcoming changes to legislation might create for their commercial activities.
- As assigned, attend Clinical Trial team meetings (kick-off meetings, submission strategy meetings,…) with CTA submissions Hub manager to provide local requirements/time lines and support. Ensure CTA submissions Hub manager understands the potential opportunities and constraints that the latest legislation/upcoming changes to legislation might create for the clinical trial application.
- Build personal expertise through management of specified products within one or more therapy areas.
- Keep cross-functional colleagues and key stakeholders informed of progress with regulatory submissions.
- Work with GRA-I regional strategists to provide country input into Global and European Regulatory Strategies as required (e.g. labelling discussion prior to submission).
- 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. Master's Degree, Post Graduate Diploma or PhD preferred
- Strong knowledge of the Belux and European environment, rules, regulations and procedures, and how this impacts regulatory strategy and implementation. A minimum of 5 years' experience within a regulatory affairs role is required.
- Insight and understanding of internal and external shareholders needs and requirements. Previous experience in bringing new products to the market and working cross functionally to achieve this, is an asset.
- 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.

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

#LI-PFE