

Vacancy notice | Regulatory Officer

Vacancy: Regulatory Officer (Telematics, Digital)

Start date: October/November 2021 **Application deadline EXTENDED – Wednesday 15 Sept 2021**

Location: Brussels, Belgium

Medicines for Europe is recruiting a **Regulatory Officer** to be based at its office in Brussels.

Medicines for Europe represents pharmaceutical companies supplying the largest share of prescription medicines across Europe and is the voice of the generic, biosimilar and value added medicines industries. As a leading partner for better healthcare, we aim to increase the health and wellbeing of all Europeans through better access to high quality medicines. The portfolios of Medicines for Europe members cover 80% of therapy areas, and in so doing, safeguard the sustainability of Europe's healthcare systems for future generations.

The **successful candidate** will work within the **Regulatory and Scientific Affairs team** in shaping policies on regulatory topics, supporting internal and external outreach.

Key Tasks and Responsibilities

Job Summary:

Manage essential European regulatory and policy initiatives and projects with a key emphasis on telematic tools, digital regulatory infrastructure and systems, electronic Product Information (e-leaflet) and digital health strategy. Interact with membership and external partners including health authorities and EU institutions. Support the Regulatory and Scientific Team for projects and events.

Job structure:

Reporting to the **Regulatory Policy and Operations Manager**, the **Regulatory Officer** will:

- Support the projects and workstreams related to:
 - Monitor, analyse, advise on a number of regulatory and policy areas related to (off-patent) medicines: telematic tools, digital regulatory infrastructure and systems, electronic Product Information (e-leaflet) and digital health strategy.
 - Research and monitor policy developments and key topics in support of the broader regulatory & science strategy of Medicines for Europe.
 - Coordinate the corresponding internal committee, working groups and task forces, including drafting of agendas, minutes, reports and briefing notes, as well as data collection.
 - Represent Medicines for Europe and advocate on its behalf on these issues towards the relevant external decision makers and other stakeholders such as the European Commission, National Competent Authorities, EMA and others.
 - Liaise & collaborate with other European industry trade associations and other stakeholders on common policy issues on behalf of Medicines for Europe.
 - Inform and support other Medicines for Europe Sector Groups, Committees and Working Groups on horizontal issues.
 - Provide feedback to the Executive and Board on the issues indicated above, as appropriate.

- Support the organisation and programme development of conferences (events, sessions, workshops) on key advocacy topics.
- Develop the response to external public consultations (e.g. draft guidelines), produce position papers and communications, develop and conduct surveys amongst different working groups and inform association members of developments in the areas indicated above.
- Contribute to the development of communication and educational materials as needed.

Requirements

- Fluency in English.
- Knowledge of marketing authorisation regulatory processes and the IT tools supporting them
- Proficiency in Microsoft Office applications such as Word, PowerPoint, Excel, and similar software
- Dynamic, entrepreneurial (proactive & autonomous) and high self-motivated personality with a “can-do” mentality
- Excellent administrative and project management skills including ability to handle multiple parallel projects and flexibility to adapt and reprioritise time sensitive issues
- Strong communication and coordination skills, specifically good writing, presentation skills, ability to simplify complex or technical matters.
- Comfortable working in a multi-cultural, international environment.
- An appropriate university degree (e.g. master’s degree in a scientific domain, regulatory affairs)

Desired skills

- Up to 2 years’ experience in European health/pharmaceutical policy, pharmaceutical industry, regulatory authority or in any other organisation dealing with the above areas will be an advantage
- Experience in advocating towards decision makers would be an asset.
- Competence in other European languages.

How to apply: Please email your CV and cover letter (maximum one page) to Jocelyne Jados

(jjados@medicinesforeurope.com) by **Friday 9 July 2021**

Contract: 1 Year, renewable

Location: Rue d’Arlon 50, 1000 Brussels, Belgium

Conditions: This is an entry-level, full-time position. Salary commensurate with experience. EU working permit needed for non-EU citizens.

GDPR Compliance:

As a data subject, you have certain rights. You can:

- access and obtain a copy of your data on request.
- require the association to change incorrect or incomplete data.
- require the association to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing.

Please note that we will keep your information in a secured server and if your application for employment is unsuccessful, the organisation will hold your data on file for 6 (six) months following the relevant recruitment process. If you agree to allow us to keep your personal data on file, we will do so for a further 6 (six) months for consideration for future employment opportunities. At the end of that period, or once you withdraw your consent, your data will be deleted or destroyed.