QUALITY & REGULATORY AFFAIRS MANAGER

Medicines for Europe is currently recruiting a **Quality & Regulatory Affairs Manager** to be based at our offices in Brussels.

Medicines for Europe represents the pharmaceutical companies supplying the largest share of medicines across Europe and is the voice of the generic, biosimilar and value added 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. Medicines for Europe members' portfolio cover 80% of therapy areas, and in so doing, safeguards the sustainability of Europe's healthcare systems for future generations.

Key Tasks and Responsibilities

- Monitor, analyse, advise, and act as working groups' coordinator in a number of key scientific, regulatory and policy areas related to **quality and development of medicines**- covering a broad spectrum of topics: **quality standards, GXPs, inspections, quality variations, ASMF** as well as **scientific topics related to clinical trials supporting MA applications (i.e. bioequivalence, product/ pharmaceutical forms' specific guidelines, clinical trials)**
- Draw up the EGA's response to draft guidelines, develop position papers and communications, and inform association members of developments in the areas indicated above
- Advocate on these issues on behalf of the Medicines for Europe to the relevant decision makers and other stakeholders such as National Competent Authorities, the EMA QWP, EMA GCP and GM/DP, EMA PKWP, EDQM, WHO, PIC/S and others
- Liaise with other European Trade associations (i.e. APIC, EFPIA) and other stakeholders such as patients, consumers, doctors, pharmacists on common policy issues on behalf of the Medicines for Europe.
- Support the Head of Regulatory affairs in other regulatory areas
- Liaise with and provide support to other Medicines for Europe's Committees and Working Groups on horizontal issues
- Be responsible for the Conference programme related to the areas indicated above
- Provide feedback to the Executive and Board on the issues indicated above

Requirements

- A minimum of three years relevant experience in the Quality and Regulatory Affairs area, either working in the European pharmaceutical industry, a Regulatory Authority or in any other organisation dealing with the above-defined policy areas
- Fluency in English, ability in other European languages would also be an advantage.
- An understanding and knowledge of the pharmaceutical industry

- Experience in advocating towards decision makers would be an asset
- Good communication and coordination skills
- An appropriate university degree (e.g. Masters degree in a scientific domain).

Contract: Permanent

Location: Brussels, Belgium

Conditions: This is a full time position involving travel mainly within the EU. Salary commensurate with experience.

How to apply: Send a cover letter and a CV to Diogo Piedade: dpiedade@medicinesforeurope.com by 18 October 2017