ARE YOU THE ONE?
WE ARE LOOKING FOR

Regulatory Affairs Associate

(Temporary consultancy role)

Terhulpsesteenweg 6, 1560 Hoeilaart, Belgium

For Us, It's A Mission

At Mylan, we mean it when we say we work every day to provide access to high quality medicines to the world's 7 billion people. If you are unconventional, relentless and passionate. If you believe in doing what's right, not what's easy. If you are a doer and have a passion for serving others, we want to talk to you.

Make a Difference

At Mylan, each person has the ability to make a difference. From the providers who sell and market our products, to the producers who develop and manufacture them and finally to our business partners who support the providers and producers, we all have a mission critical role. Here's how this role will help:

Make Our Values Your Values:

Mylan hires only the best. People who thrive in a culture of innovation and empowerment. People who are active learners and have a positive attitude. People who are leaders and know that by working together we can run faster, reach higher and achieve more. By doing so, we will continue to set new standards in healthcare. Here are the minimum qualifications and essential functions for this temporary project :

POSITION PURPOSE

The Regulatory Affairs Associate has the operational responsibility for registration of dossiers and maintenance of registrations related to the Mylan Group entities in Belgium. He/she has a key role to ensure products could be marketed in accordance with regulatory requirements and guidelines.

ESSENTIAL DUTIES AND RESPONSABILITIES

Registration & Submission Dossiers

- Responsible for the optimal preparation, submission and follow-up of registrations (NP, MRP, DCP). Always be pro-active and inform your direct Line Manager and/or the Central Regulatory Affairs group about issues. In case of issues, actively propose solutions. Ensure maintenance of registration dossiers (variations, renewals, PSURS) for which you are responsible
- Interaction and close collaboration with other departments of the local (QA/PV/Medical Affairs) and European Central RA Organization to collect information necessary for submissions.
- Administrative support for pricing and reimbursement procedures, in line with the pricing and reimbursement strategy defined by the company.

Management of Regulatory Projects

Actively participate in the management of regulatory projects and implement these. Interaction with other departments in the organization, RA colleagues in affiliated companies and headquarters.

Procedures & Compliance

Create RA procedures and work according to those procedures/guidelines within the department.

Assure a good collaboration between the RA department and QA and PV department in order to assure the compliance of marketed products with the current approved registration file. Ensure compliance with all regulatory requirements.

QUALIFICATIONS / KNOWLEDGE

- Bachelor or Masters Degree in Health Sciences or proven experience in the pharmaceutical industry
- 2 to 5 years of relevant experience in Regulatory Affairs with knowledge of national and international regulatory requirements and guidelines on pharmaceutical products
- Experience in an international pharmaceutical environment
- IT skills: NeeS & eCTD, CESP submissions, Microsoft Office (word, excel, power-point, access, …)
- Good trilingual (write, read, speak): Dutch, French and English. German is an asset.

COMPETENCIES

- Excellent organization and project management skills
- Capable to adapt in a fast-moving environment and able to deal with tight deadlines
- Excellent interpersonal skills to assist in liaison with other departments within/outside the group in order to support regulatory requirements
- Able to work pro-actively
- Be able to work autonomously
- Sense of responsibility and accuracy.

Interested? thanks for sending your CV at HR_Belgium@mylan.be

Mylan
Better Health for a Better World