Regulatory Affairs Manager - Mylan Germany

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.

For our Regulatory Affairs Team in Bad Homburg we are looking for a new and motivated member.

Your core responsibilities:

- Maintain Life cycle management related tasks for German national registered pharmaceutical products for Mylan dura GmbH and MEDA Pharma GmbH or Mylan Healthcare GmbH
- Manage regulatory-related tasks during the launch process of Mylan commercialized products
- Communicate with the local health authorities (e.g. BfArM) on questions and topics related to Marketing Authorizations held by Mylan dura, MEDA Pharma GmbH or Mylan Healthcare for example on translation issues during the national phase.
- Maintain local and global regulatory-related databases (e.g. DuiT, Trackwise, MyPortfolio) to ensure regulatory compliance

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 health care.
Here are the minimum qualifications and essential functions for this position:

- Experiences in Labeling (update of product information texts)
- Experiences in Artwork review and approval
- Submission of variation packages to Bfarm (CESP/Pharm.Net)
- CMC package compiling and CMC writing
- Fluent in English

Educational requirements:

- Master's degree or equal in natural science or related/equivalent area
- 3 years of experience in Regulatory Affairs Lifecycle Management required
- 3 years of experience preferably in Product Information & labelling
- 1 year of experience preferably in CMC variations for national products
- Understanding of German Drug Law
- Strong IT Skills (MS Office and regulatory-related databases, Trackwise Change Control and Documentation Management System e.g. Documentum DCM/D2)

Why Mylan?
If you want to be part of a global health care company that is making a difference and changing lives, Mylan may be the place for you. With a workforce of more than 35,000 worldwide, we can make a difference. We encourage you to visit Mylan.com to learn more about our unconventional culture, our approach to doing business and how we plan to set new standards in health care.

Mylan offers competitive salary, excellent benefits and an environment conducive to professional growth and advancement. Mylan is an Equal Opportunity Employer

Interested? Please send your complete application documents in English to career@medapharma.de

All information received will be handled carefully and treated with confidentiality.