(Senior) Manager Regulatory Affairs (m/f/d)

As (Senior) Manager Regulatory Affairs you will serve as a core member of the Austrian Affiliate Regulatory Team interacting with local Regulatory Authorities and other stakeholders to ensure that the company complies with country's applicable legislations and regulations so that the medicinal products can be developed, authorized and maintained on the market.
Within Gilead Sciences Austria GmbH local Pharmacovigilance activities are covered by the Regulatory Affairs Department therefore knowledge of pharmacovigilance legislation and experience in performing PV activities is highly desirable for this function.

Responsibilities

- Manage interactions and communication with the Health Authorities HAs and act as the main point of contact for the local HAs for specific topics under their responsibility.
- Co-ordinate responses to local HAs involving input from other departments/functions and acts as subject matter expert and/or assists with the management of local HA inspections (as required)
- Manage regulatory submissions to local HAs, in line with local HA expectations, Gilead SOPs and business objectives for assigned product(s) or projects
- Serve as a core member of the Affiliate Regulatory Team to ensure compliance with local law and regulation and consistency with global procedural documents.
- Serve as a core member of the Affiliate Regulatory team to manage Regulatory Compliance audits within the affiliate and interact with other departments and support the process as needed.
- Promotional material review and approval
- Ensure compliant labeling for Gilead medicinal products (SmPC, PIL, packaging) and manage timely updates for assigned product(s).
- Serve as a core member of the Local Regulatory team to help manage negotiations with local HAs with regards to development products and questions on clinical trial applications.
- Contribute in the monitoring and report of external relevant changes to concerned stakeholders within the company at local and global level if applicable. That applies for local requirements to be explained at the local and International level but also for changes or new information at International level affecting affiliates.
- Maintain knowledge of complex regulatory requirements, contribute to preparation of new local regulatory guidance when applicable, comments on draft regulatory guidance and communicates changes in regulatory information to Intl RA.
- Act as a core member of the Local Regulatory team for the RA organization at the country level in line with global RA, the Regulatory Head and the local Affiliate Visions.
- Ensure responsibilities of Applicant and/or License Holder defined in legislation or regulatory for assigned product(s) or projects
- Optimum execution of Intl RA registration strategies and plans with different functional areas in the affiliate
- Ensure good and strong relationships with functional areas of the local organization (Medical Affairs, Commercial, Market Access, Legal, etc.) and with Gilead Sciences Intl RA in order to ensure the success

Professional Experience / Key Skills

- Typically requires a PhD or Masters in Pharmaceutical Sciences or equivalent discipline and several years of relevant experience in regulatory affairs.
- Knowledge of pharmacovigilance legislation and experience in performing PV activities is highly desirable
- Good influencing and negotiating skills. Must be capable of developing and implementing regulatory initiatives and managing negotiations with Regulatory Authorities.
- Demonstrates leadership skills with a sphere of influence externally, cross-functionally and within the RA and the affiliate.
- Experience working with Regulatory Authorities essential.
- Excellent verbal, written, organization skills and interpersonal communication skills required.
- Excellent German and English language required.

The minimum salary for this position is €66,400 with a flexibility for higher salary based on qualification and experience.

Should you be interested in this position please apply directly using the following link:

https://gilead.wd1.myworkdayjobs.com/gileadcareers/job/Austria---Vienna/Senior-Manager--Regulatory-Affairs_R0010681-1