Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. Gilead strive to transform and simplify care for people with life-threatening illnesses around the world. Gilead's portfolio of products and pipeline of investigational drugs includes treatments for HIV/AIDS, liver diseases, cancer, inflammatory and respiratory diseases, and cardiovascular conditions.

Associate Manager Regulatory Affairs & RP, Nordics

Gilead Sciences Sweden is now seeking a top performing candidate for the position as Associate Manager Regulatory Affairs, Nordics based at the Nordic HQ in Solna. In this stimulating role you are a core member of the Nordic Regulatory team, interacting with Health Authorities (HAs) and other relevant stakeholders in regulatory matters, to ensure that Gilead's medicinal products can be developed, authorized and maintained on the market. You will also act as the Nordic QA Lead, en-suring quality oversight and full compliance with applicable legislations in the Nordic countries. In addition, you will also be acting as the Gilead RP (Responsible Person) for one or more of the Nor-dic countries. Internally, you will manage several cross-functional interactions in order to support the organization in the delivery of regulatory excellence, as well as take part in achieving set busi-ness goals. The position requires a highly capable and motivated individual, with excellent opera-tional- and interpersonal skills, and with an ambition for further personal development. You will be part of a very competent, exciting and fast developing organization where you will have the oppor-tunity to contribute in Gilead's success. The role reports to Head of Regulatory Affairs Nordics, located at the Nordic HQ office in Solna.

Principal responsibilities

- Manage interactions and communication with the local HAs and act as the main point of contact for the local HAs for specific topics under their responsibility.
- Manage regulatory submissions to local HAs, in line with local HA expectations, Gilead SOPs and business objectives for assigned product(s) or projects.
- Marketing Authorisation (MA) applications.
- Variations and other MA maintenance applications.
- Clinical trials applications, amendments and other clinical trials submissions.
- Ensure compliant labeling for Gilead medicinal products (SmPC, PIL, packaging) and manage timely updates for assigned product(s).
- Compassionate Use & Early Access applications.
- Support the national implementation of Risk Management Plans (RMP) for applicable products.
- Support the Regulatory Head on National Scientific Advice and pre-submission meeting preparat-ion and follow-up.
- Contribute in Regulatory Intelligence and report of external relevant changes to concerned stake-holders.
- Leadership role in conducting risk assessments on specific local regulatory issues.
- As RP & QA Lead, maintain GDP license and ensuring QA oversight and full compliance with applicable legislation in all the Nordic countries.
- Management/support of quality defects/falsified or counterfeit products/batch recall management and management/support of product out of stock situations.
- Promotional material review and approval.
- Serves as a core member of the country brand/launch team or international working group as the representative of regulatory affiliate.
- Ensure good and strong relationships with functional areas of the local organization (Medical Af-fairs, Commercial, Market Access, Legal, etc.) and with Gilead Sciences Int RA in order to ensure the success of local and international business results.
- Actively contributes to local and or global process improve ments which have a significant impact on Gilead.

Qualifications

- Degree in pharmacy, or other degree qualifying for being an RP according to Swedish Medical Product Agency.
- Minimum 5 years experience from working in Regulatory Affairs, in the Pharmaceutical Industry.
- Strong experience in understanding the role and impact of Regulatory Affairs, regulatory requirements in Pharmaceutical Industry including ICH requirements.
- Excellent communication skills, verbal and written, in English and in at least one Nordic langu-age, preferably Swedish.

Success factors

You are a confident regulatory professional with an ability to work independently, as well as being a supportive team player which enjoy and is able to form strong cross-functional relationships, externally as well as internally. You are passionate about regulatory affairs, where your eye for de-tails and effective execution skills has led to great results in your previous positions. You are curious and eager to learn more in your competence areas and strives for personal development. You have a proactive mindset where you are able to solve problems in a creative manner and have the capacity for strategic thinking and confident decision making.

Your application

This recruitment is handled by our recruitment partner Scientific Solutions (www.scientificsolutions.se). Send your electronic application, with a CV and personal letter, to henrik@scientificsolutions.se. It is important that you send your application as soon as possible since the selection process will be on going.

For more information about the role, please contact;

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