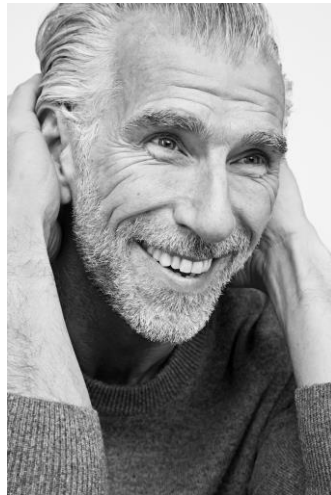


Smart choices for everyday healthcare

Karo Pharma offers a portfolio of everyday healthcare products and services that help prevent illness and treat health problems. With a wide range of trusted, documented, and original brands, backed by services for partners, customers, and consumers, we provide people with the options, knowledge, and access they need to stay healthy. We call it smart choices for everyday healthcare. We specialize in seven product categories: skin health, intimate health, digestive health, foot health, wellness, pain, cough and cold and specialty products such as Rx pharma care. Across these categories we own a range of differentiated brands in both prescription drugs (Rx) and consumer products (OTC).

Karo Pharma's products and services are present in over 60 countries with own subsidiaries in over 11 European countries. Karo Pharma has a revenue of SEK 2,9 bn in 2020, is headquartered in Stockholm and listed on NASDAQ First North Growth.



Scientific Affairs Manager

📍 Maidenhead (UK) / hybrid

Scientific Affairs at Karo Pharma

The local role is essential for Scientific Affairs to stay close to its most important stakeholders: the customers, patients, consumers and HCPs and execute regulatory and quality compliance matters on the local market of UK/IE. . It involves being the local specialist towards all stakeholders in the affiliate/region for Karo local product portfolio of well-established consumer healthcare brands – both internally in relation to the Global Scientific Affairs and Local commercial organisation as well as externally towards health authority and customers, consumers, and patients.

To establish and maintain great relationship with MHRA in relations to regulatory, quality and post Brexit impacts on global strategies.

Roles & Responsibilities:

There are several areas that this role would cover. Below, we try to describe it as detailed as possible to provide a solid overview of the project complexity.

QA:

- Be Responsible Person (RP) UK WDA and execute on compliance for the WDA in relation to global as well as local processes, as well as oversee the compliance of local 3PLs and their import and RPi function.
- Be responsible for MHRA communication and compliance as well as for sourcing the import and RPi activities which will be outsourced.
- Assist the senior management within Karo UK Ltd. with the strategic goals of obtaining and maintaining a Wholesale Distribution authorisation for Great Britain to allow Karo to import Qualified Person certified medicines from the European Economic Area.
- Ensure Supply chain security by also ensuring that the product is not the subject of a recall or reported as stolen and is available on the market within the listed country's licensed supply chain.
- Be responsible, Affiliate RP, for the sourcing of the local 3PL and qualification of the same including their RPi activities.
- Support in the coordination and prompt recall operations for medicinal products that have been received in the UK or placed on the market in the UK.
- Ensure that the Karo QMS is implemented and maintained in compliance with the WDA and GDP requirements through effective communication, approvals and training on respective procedures relevant to GDP activities.
- Develop relations and communication with MHRA.

RA:

- Execute regional regulatory portfolio compliance of Karos UK/IE portfolio of consumer Healthcare (Medical Device, Cosmetics, Food) and Rx in relations to license maintenance.
- Support Karo distributors in CA, ZA, AUS in regulatory compliance as applicable when support is needed from the Global team located in Sweden.
- Manage launch compliance execution.
- Be responsible for the local product information and timely roll-out of label updates into the local market, including updates to texts, submission as applicable and implementation following approval. Duties are performed in collaboration and with support from Global functions.
- Review and approve of local labeling (mock-ups) of the products.
- Maintain of local databases such as eMC, dm+d and medicines.ie.
- Coordinate local regulatory activities for UK, IE, CA, AU/NZ, ZA and MT as instructed by the Global team.
- Support management and procedures of E45 portfolio available in UK, IE, ZA and AU
- Maintain/renew CPNP registrations in UK.
- Diligently manage named patient basis in the UK. Duties include ensuring timely actions towards health care professionals to obtain consent, the manufacturer, MHRA and the importer of unlicensed medicine as well as internally handling both the duties related to both RA and QA.
- Act as direct contact with UK Notified Body for medical devices marketed in UK.
- Work with the global RA CHC (consumer healthcare) team towards compliance of the CHC portfolio on the UK market according to UK regulations for medical devices and cosmetics.

Commercial compliance

- Be responsible for commercial compliance according to the Blue Guide and EFPIA and support both the Global team located in UK and the local Affiliate team in execution of commercial compliance (advertisement, KOL engagement, agreements, reporting etc).

- Support development of promotional material according to claims and label, and be the sparring partner to the colleagues in the marketing department.
- Approve material according to the Blue guide
- Support compliant go-to-market strategies in UK/IE including local KOL activities and reporting of the same as applicable.
- Support the global marketing team members present in the UK office in developing compliant material together with the global medical affairs team located in Sweden responsible for commercial compliance in the company.

Qualifications and education:

- University degree or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science.
- 7 years of experience within Life science Industry.

Qualifications for RP:

- 2 years experience within a pharmaceutical distribution environment.
- Formal GDP training.

Qualifications for RA:

- Experience from regulatory affairs procedure and variation management

Qualifications for Commercial Compliance

- Knowledge and experience from working with Blue guide requirements and approval of promotional material

Personal Profile:

- Professional verbal and written communication skills.
- Enjoy solving problems and mediate issues that may arise.
- Structural sense and good documentation skills with ability to work towards and reach set up goals.
- Ability to lead & train others.
- Courageous personality that can guardian and guide regulatory compliance in a high paced and marketing focused environment.
- Able to work in a multidisciplinary team while being able to plan and perform and manage practical work independently.
- Collaborative, supportive, good communicator and advisor.
- Show strong evidence of our Karo values.

We offer:

- Opportunity to create, grow, and encourage
- Flexible schedule and life work balance
- Responsibility for exciting and challenging projects that have a direct, visible impact on our customers and the industry
- Very positive work environment in a young, international, and motivated team

Welcome with your application by latest on date year.



Karo Pharma has a Diverse & Inclusive environment. We are looking for qualified candidates irrespective of gender, gender identity, sexual orientation, ethnicity, race, religion, national origin, disability or age.