REGULATORY AFFAIRS MANAGER AND LOCAL SAFETY OFFICER IN HUNGARY

WORTH TO KNOW ABOUT US

Founded in 1959 as the successor to Leclerc, Ewopharma's goal from the outset was to build bridges to the pharmaceutical markets of Central and Eastern Europe. The Swiss-based Ewopharma Group currently employs 444 people in 19 countries, with a small and medium-sized enterprise structure.
The Hungarian subsidiary has been present on the Hungarian market for more than 30 years, where Ewopharma contributes to the health of individuals and society by making its own products and the unique products of its international partners available in the fields of pharmaceuticals, dietary supplements, medical devices, and cosmetics.

WHAT CAN YOU EXPECT FROM US

Our knowledgeable, loyal and enthusiastic workforce is our greatest asset. That is why we are committed to supporting their professional development and providing them with a motivating, trusting working environment as a stable and secure place of employment. Our results-oriented, friendly approach is reinforced by mutual respect, support, attentiveness, honest feedback, praise and expressions of gratitude. At Ewopharma Hungary Kft., we have a strong team spirit, we love what we do, and we value expertise, responsibility and long-term partnerships based on a win-win approach. Openness, transparency and entrepreneurship are part of our corporate culture. If these values are important to you, please take a look at our vacancies and send us your CV!

JOB OBJECTIVE

We are looking for an experienced and reliable professional to ensure regulatory compliance of the medicine products of Ewopharma AG and its partners during the registration processes, to perform local pharmacovigilance (PV) and vigilance liaison duties for the products (medicines and other products) in accordance with applicable laws and company regulations.

WHAT TASKS ARE INVOLVED?

Regulatory (RAM) tasks

- Local management of the drug lifecycle (submitting and maintaining up-to-date registration documentation for products) while meeting deadlines
- Coordinating international regulatory procedures (e.g., national, MRP, DCP, CP) at a national level and managing related tasks
- Liaising with regulatory authorities and handling incoming inquiries and documents

- Managing registration dossiers and keeping systems up to date
- Product information management
- Monitoring regulatory requirements and legislative changes
- Close collaboration with other departments
- Preparing reports, participating in budget planning and training sessions

Local Safety Officer (LSO) tasks

- Serving as the local pharmacovigilance liaison in accordance with local and EU legislation and partner expectations
- Receiving, processing, and forwarding drug safety and other product safety information within deadlines
- Ensuring the operation of the local pharmacovigilance system in accordance with applicable laws and local regulations
- Local implementation of PV processes and SOPs, and monitoring compliance
- Organizing and documenting PV training for employees
- Acting as the contact person and responsible individual at the Ewopharma local organization during regulatory inspections and audits
- Actively participating in the preparation of local PV contracts and keeping them up to date
- Performing PV compliance and reporting tasks

PLEASE APPLY IF YOU HAVE:
- A degree in the life sciences (e.g., medicine, pharmacy, biology) or a degree in chemistry or chemical engineering
- At least 3 years of experience in the regulatory and/or pharmacovigilance filed
- Knowledge of relevant regulations
- Confident spoken and written English
- Precise, structured working style
- Excellent organizational skills and time management
- Good communication and cooperation skills
- Proficiency in computer applications (Word, Excel, PowerPoint)

WHAT WE OFFER
- Full-time, permanent contract with a partial home office option
- Additional benefits: cafeteria, life-, accident- and health insurance
- Company car (with private use), laptop, and cell phone
- Employee-friendly work environment
- Inspiring, friendly team

Opportunities for continuous development in a results- and performance-oriented role

WHAT WE SEE AS EXTRA ASSET
- Experience in an international environment

www.ewopharma.com

ewo pharma since 1959

- Experience with audits/inspections
- Familiarity with pharmaceutical PV systems

If you have any questions regarding the advertised position, please feel free to contact our HR Manager, Borbála Pap, at b.pap@ewopharma.hu.

OTHER IMPORTANT INFORMATION

- Address of Ewopharma Hungary Ltd.: 1122 Budapest, Városmajor utca 13.
- Ideal starting date: June 2026
- Data processing: If your CV is interesting for us, we will contact you within 3 weeks of receiving it. If we do not contact you, we will not process or store your data in accordance with data protection regulations, and we will destroy your resume after 3 weeks. If you would like to know more about how we process your personal data, please read our Privacy Policy at https://ewopharma.hu/.