

Regulatory Affairs Leader (m/f)

Company

Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in women's health, with a particular focus on fertility, contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its two lead development candidates - a fifth generation oral contraceptive, Estelle®, and a next generation hormone therapy, Donesta®- are built on Mithra's unique natural estrogen platform, E4 (Estetrol). Mithra also develops, manufactures and markets complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its Mithra CDMO.

Mithra was founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra has an approximate headcount of 170 staff members and is headquartered in Liège, Belgium. Further information can be found at: www.mithra.com

Description

Mithra Pharmaceuticals is looking for a Regulatory Affairs Leader to join its R&D department.

Duties/Responsibilities

- Write, submit and ensure the follow up of registration files
- Ensure the daily management and the updates of marketing authorizations and represent Mithra and its records management strategies to public health authorities in Belgium and in Europe (AFMPS, EMA,...)
- Ensure the notification and maintenance of cosmetics, nutrients and medical devices
- Ensure applications for pricing and reimbursement while collaborating with the INAMI or other competent authorities
- Ensure organizational support within the regulatory department (e.g. management meetings, communication with other departments...)
- Manage regulatory issues with customers as well as with subcontractors
- Provide regulatory support to clients

Profile

- Master degree in Pharmaceutical Sciences or a Master in Sciences is required
- Experience of minimum 5 years in the field of regulatory affairs
- Autonomous, meticulous, and proactive
- Good time management, well organized, and able to set priorities
- Leadership skills
- Good knowledge of Microsoft Office (Word, Excel,...)
- Good knowledge of French and of English (spoken, written, read)
- Knowledge in Dutch and / or German is an asset

What we offer

- Varied and motivating responsibilities within a fast growing company
- An attractive salary package in line with your experience

Applications

- Send your CV, copy of your degree and application letter to: belgium.job@mithra.com. Your email must mention following subject: **R&D-RA-012018**