Flen Health
advanced skin healing

Flen Health is an international, innovative wound care group with companies based in Luxembourg, Belgium, Netherlands, Germany and UK.
In a few years' time, it gained a leading position in the Belgian wound care market, its Home market and is working towards reaching this on an international level. This result is due to a twofold reason: (1) dedicated people (2) products combining innovation with significant progress in wound care, inspired by our motto: We help you live the life you love.
We are looking for a full time Regulatory Affairs Specialist, for immediate start at our headquarter based in Esch-sur-Alzette (Luxembourg) or Kontich (Belgium).

Regulatory Affairs Specialist (m/w)

Esch-sur-Alzette (Luxembourg) or Kontich (Belgium)

Tasks and responsibilities:

- You support the Regulatory Affairs' department in preparing product technical dossiers and other regulatory documents for registration submissions in and outside EU
- You support the Regulatory Affairs' department in keeping product technical dossiers and other regulatory documents up to date during the lifecycle of Flen's products
- You participate in the implementation of the new Medical Device Regulation within Flen
- You ensure the regulatory compliance of communication activities and materials (brochure, presentation, packaging material etc.) regarding Flen's products, in close collaboration with marketing and sales
- You ensure the regulatory compliance of Flen Health's clinical studies
- You keep abreast of international legislation, guidelines and customer practices by keeping in contact with official institutions
- You identify evolving regulatory trends including international trends that are relevant and ensure that appropriate action is initiated
- You work in close collaboration with and report to the Head of Regulatory Affairs

Qualifications:

- Scientific (ideally university) degree
- Experience in international regulatory affairs is required; knowledge of regulatory affairs related to FDA and other non-EU regulations also
- Experience with the guidelines for clinical evaluation report
- Experience in literature search reports
- Project management knowledge is an asset
- Familiar with MS Office and database applications
- English is mandatory, knowledge of German is a must
- Proficient in written and oral communication
- Accuracy
- Analytical ability
- Planning & organizing
- Quality minded
- Autonomous worker
- Team player
- Diplomatic and open minded

Work at Flen Health:

Flen Health is a young and fast-growing, independent organization with short communication lines, and where entrepreneurship is appreciated. Its products are innovative, patented and are well regarded by the key opinion leaders internationally.

Several highly motivated and enthusiastic colleagues have already joined Flen Health and contribute to its success. As an expending company, we offer possibilities for personal development and growth.

You are interested?

Please send your detailed application to jobs@flenhealth.com

Kontakt:

Flen Health SA
Rue Henri Koch 29
L-4354 Esch-sur-Alzette
www.flenhealth.com