Flen Health
advanced skin healing

Flen Health is an international, innovative wound care company.
In a few years' time, it gained a leading position in the Belgian wound care market, its Home market. This result is due to a twofold reason: (1) dedicated people (2) products combining innovation with significant progress in wound care
We are looking for a full time Regulatory Affairs Manager, for immediate start at our headquarter based in Esch-sur-Alzette (Luxembourg) or Kontich (Belgium).
As a Regulatory Affairs manager, you will be responsible for the regulatory affairs processes in countries defined by the Head of Regulatory Affairs and more specifically be in charge of the following tasks in the defined countries:

Regulatory Affairs Manager (m/w)

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

Tasks and responsibilities:

- You are responsible for product registration submissions of Flen Health's products, renewal approvals, product technical dossiers and other regulatory documents
- You are responsible for the regulatory compliance of Flen Health's clinical studies, in close collaboration with clinical department
- You are responsible for the regulatory compliance of communication activities and material regarding Flen Health products, in close collaboration with marketing and sales
- 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 serve as regulatory contact person for Flen Health with distributors and authorities
- You monitor the administrative management of translations of the distributed material
- You perform a regulatory check of all communicated information e.g. packaging material (brochures, packaging, information for users…)
- You will have to work in close collaboration with and report to the Head of Regulatory Affairs

Qualifications:

- Scientific (ideally university) degree
- At least 2 years' experience in international medical devices regulatory affairs; knowledge of regulatory affairs related to FDA and other non-EU regulations is an asset
- 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
- Fluency in English is mandatory
- 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 recruitment@flenhealth.com

Kontakt:

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