

VACANCY



Flen Health; Where Vision meets Reality.

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 Quality Assurance Specialist, for immediate start, based in Kontich.

Tasks and responsibilities

You will work within the quality team, you will take the lead for the agreed parts of some processes and you support the Head of Quality concerning the maintenance of the internal quality management system in order to be compatible to ISO and other regulations. You do the necessary registrations, gather info and make analyses to check the effectiveness of the Quality management system.

Primary activities include, but are not limited to:

- Review on regular base all Corrective action and Preventive action registrations: suggested actions, taken actions, final verifications + used evidence, verification of the effectiveness of the taken actions and document this.
- Assist in the optimization of the root cause analysis process.
- Do analyses and follow up of quality related processes (corrective actions, complaints, returned goods, third partie info ...).
- Lead and participate in the development and improvement of third party reviews (suppliers, warehouses, manufacturing subcontractor, distributors).
- Take the lead to gather info and to prepare audits from certified/notified body and official institutions in Belgium in close cooperation with the Head of Quality and Quality Assistant. Follow up the defined actions.
- Manage Quality administration, playing an intermediate role in harmony with other Flen Health actors on any Quality arrangements,
- Respect the quality and company procedures that are related to the whole Quality process and follow up administration.

Qualifications requirement:

- Experience in medical devices or pharma
- Fluency in English and Dutch
 - Required languages:
 - English: C1 - C2
 - Dutch: C1 - C2
 - French: would be an advantage,
- Quality and result orientation
- High autonomy: ability to work independently as well as a team player
- Proficiency in analytical skills and problem solving ability,
- Planning & organizing, quality minded,
- Good organizational skills and attention to detail required,
- Must be able to handle multiple assignments concurrently and have the capacity to produce high quality results across multiple projects while working under pressure of short deadlines,
- Respect deadlines

Education:

- Degree in pharmacy or equivalent/related subject
- 5 or more years of work experience in a quality discipline
- Good knowledge of a quality management standard (ISO 13485 or ISO 9001,...)

Overall knowledge:

- Good knowledge of MS Office (MS Word, MS Excel (including pivot tables and analyses and MS Powerpoint), knowledge of MS Visio is a plus
- Experience of quality management documentation software system (knowledge of Vivaldi is a benefit).

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 expanding company, we offer possibilities for personal development and growth.

We look forward to receive your application at the following email address:

Liesbet.Saen@flenhealth.com