



## Head of Medical Affairs, QA & RA

### About PainDrainer:

PainDrainer is a start-up company in Lund that aims to facilitate and improve the lives of millions of chronic pain patients.

The company has a total of eleven employees, including consultants. We have our office in The Spark at Medicon Village in Lund.

Read more about us at: <https://www.paindrainer.com>.

We are now looking for a Head of Medical Affairs, QA and RA who will join us on this exiting journey and be part of a leading eHealth company.

### About the role:

- Responsible for the company's clinical studies globally, which includes:
  - Production of all documentation required for ethical and IRB approval
  - Development of Investigator Binders etc.
  - Communication with the various clinical administrators
  - Follow-up of ongoing issues during the study
  - Compilation, evaluation and reporting of clinical data
- Develop and maintain the regulatory strategy and provide advice to other departments on quality and regulatory issues with a focus on both medical devices (CE and FDA) and clinical studies.
- In collaboration with the CEO, define, develop and implement the quality management system, QMS in accordance with ISO9001.
- Communicate with authorities, customers and partners about regulatory issues.
- Promote awareness of applicable legal requirements and Quality Management System requirements in the organization.
- Be an integral part of the development team when launching product and service
- Responsible for labeling products and services
- Responsibility for monitoring the risk management process

### About you:

- Master's degree or higher education in technology or Life Science.
- Extensive knowledge and experience within ISO 13485 and ISO 9001.
- Good knowledge of MDD and EU MDR
- Independent and experienced decision-maker with at least 10 years of experience in medical technology development work.
- A good communicator who is used talking to authorities and customers.
- Extensive experience of training and teaching staff
- Experience from implementing a Quality Management System is an advantage.
- Experience of clinical studies in a medical technology business
- Extensive experience of risk assessments and systems for quality improvements in a small organization.
- Unpretentious, creative and sees opportunities before limitations.

### Opportunity:

In the PainDrainer team, you will be part of a highly competent and diverse team with an entrepreneurial mind-set and great ambitions. You will have a key role in the company and be part of the Management team. You will work closely with other functions such as Product development, Sales & Marketing and Business Development. PainDrainer can offer you work in a small, non-bureaucratic environment with fast decision-making.

In this recruitment, continuous selection is applied. Warm welcome with your application via email to [ingela.kronsell@paindrainer.com](mailto:ingela.kronsell@paindrainer.com). Unfortunately, we are not able to receive questions via telephone but please email us.