There's no denying Artificial Intelligence is the future of technology and E-Health is the future of healthcare.

SOFTWARE/ AI DEVICE

Senior Regulatory Affairs Specialist

LAUSANNE, SWITZERLAND

How would you like the opportunity to work on the most cutting edge of BOTH worlds?

THE COMPANY

With a strong heritage in research and innovation, this company is heavily investing for the next 3 years in new product development projects and upgrading their existing software device, all done on-site in Lausanne.

You will be responsible for this device in all European and US markets and develop the regulatory strategies, submissions and technical documents. The company has an open culture and you will be working in a young and dynamic multinational team of 7.

This is a chance to work in a senior position, with lots of independence and autonomy on a project that will stretch you as a regulatory professional; you will be responsible for navigating complex regulations like MDR, GDPR and cyber security.

As Senior Regulatory Affairs Specialist you will:

• Be responsible for your portfolio, in all major markets and from pre-post market.

• Lead new product development projects from cradle to grave working directly with R&D, Quality, marketing, based in Lausanne

• Develop regulatory requirements and strategies for your portfolio for New Product Introduction

• Maintain the existing technical files for CE mark and 510(k)

• Participate in notified body audits and other inspections

• Interface with regulatory agencies, consultants and be part of on multidisciplinary project teams; R&D, Marketing, Quality & management

• Ensure the proper maintenance of product approvals and resubmissions

• Support the Risk management process together with the Risk management expert

• Become the subject matter expert and manage activities for Human Factors across all devices for the company & coordinate expert consultants (human factor experience not necessary but a desire to learn a new skill is!)

• Support product development projects across the company's portfolio of devices, as the human factor expert (human factor experience not necessary but a desire to learn a new skill is!)

Requirements:

- Previous experience working with software as a medical device, active devices containing software or IVD software devices

- Previous experience with product development projects, taking a product through to CE mark.

- Ability to be autonomous, an independent learner and to be an “out of the box” thinker.

For more information send your CV to hello@elemed.eu