Senior RA/QA Engineer

Lausanne, Switzerland

clarisse@elemed.eu

There's no denying Artificial Intelligence is the future of technology and e-Health is the future of healthcare. How would you like the opportunity to work on the most cutting edge of both worlds?

This is your chance to lead a regulatory project at the cutting edge of innovation; software as a medical device and A.I!!

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 devices, all done on-site in Lausanne. You will be responsible for this device in all European and US markets, and participate in the submissions of technical documents. The company has an open culture and you will be working in a young and dynamic team of seven. This is a chance to work in a senior position, with lots of independence and autonomy on a project that will develop you. You will make a difference in the patients' lives with the product you will develop.

It is a great time to join this company as they are looking to expand their scope and the company!

If you want to be part of something truly exceptional this is the right role for you! And on top of it you will be given the flexibility to work a few days remotely!

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The opportunity

This role is to support the development of new software and is required to interact with different departments to ensure the smooth launch of the new technology.
You will be working with quality and regulatory to ensure the compliance of the new innovation.
It's a chance to put forward your knowledge in quality assurance and regulatory as well as your expertise in software development.

As senior quality software engineer you will:

- Be responsible for all Quality Assurance activities in compliance with IEC 62304
- Participate in new product development projects from start to finish working directly with R&D, Quality and marketing
- Support the design verification and validation activities
- Be responsible for co-leading gate reviews and reviewing all NPD document approvals
- Support Software as Medical Device entire lifecycle, from Design files to submission including PMS activities
- Interface with regulatory agencies, consultants and be part of 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
- Support product development projects across the company's software development

The requirements

- 3+ years experience working with software as a medical device
- Previous experience with product development projects, taking a product through CE mark
- Expertise with IEC62304
- Experience in software class B and/or C
- Good level of English

Interested in this position?

For a confidential discussion; please send your CV to clarisse@elemed.eu

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