

Vacancy: QA/RA Officer

You will contribute to the development and continuous improvement of the quality management system (QMS) of a growing medical technology company Prolira. You will make sure that product development and delivery to hospitals takes place according to the latest regulations and guidelines. You will get many possibilities to learn on the job and follow courses to increase your value. We work closely in a network of Utrecht based medical technology start-ups in which we share our QA knowledge, documents, and people.

What you tell at birthdays about your job

"I work at a very promising medical technology company. We ensure that brain activity measurements can be used by nurses at the bedside to adequately treat a serious complication called delirium. Other companies I work with make software for pacemakers to be implanted at exactly the right position by the cardiac surgeon, and software to create unique bone-MRI images that help doctors to better diagnose and cure their patients. We save lives."

What you actually will be doing

Prolira, CART-Tech, and MRIguidance all developing, improving, and certify their ISO13485 QMS and are working on CE certification of their medical (software) devices. You will primarily work at Prolira, but since multiple teams in close vicinity of each other go through similar processes, the companies work closely together. As a QA Officer you will help with the implementation and improvement of the QMS and the technical file for CE certification, also for the FDA (USA).

Your responsibilities:

- maintenance and improvement of quality systems and CE technical files;
- ensure all teams work according to the latest medical device regulations;
- keep adequate administration;
- work with experienced QA/RA consultants;
- work with auditors and other people from notified bodies and regulatory authorities.

Qualifications

Minimum qualifications:

- Life Science or technical graduate (University level or equivalent);
- ambition and capability to grow towards senior level;
- knowledge of ISO 13485 and regulatory landscape;
- ability to speak and write in English fluently.

Preferred qualifications:

- experience in Quality Management of Medical Devices
- experience with medical hardware and software;
- problem solving attitude and skills;
- easy learner;
- ability to communicate and collaborate effectively with researchers and clinical specialists;
- the desire to work in a dynamic start-up environment.



About Prolira

Prolira is a medical device start-up, a spin-off of the University Medical Center Utrecht. Our device has its roots in landmark clinical research led by neurologist-intensivist Prof. Dr. Arjen Slooter. The company was raised by Rutger van Merkerk and Annemarie Willems in 2015. We are backed by professional venture capital firms as well as business angels with experience of the field. In 2019, we will implement our solution in routine practice of our many clinical partners and customers. Prolira has its office at the dynamic environment of business incubator UtrechtInc at Utrecht Science Park.

www.prolira.com

About CART-Tech

CART-Tech is a spin-out of the Division Heart and Lung of the University Medical Center in Utrecht. The company finds its roots in the Dutch Biomedical Materials program, a public-private consortium under which a broad research program was carried out by international technology companies and Dutch Universities. Together with experienced entrepreneur Paul Leufkens, biomedical engineer Frebus van Slochteren founded CART-Tech 3 years ago.

www.cart-tech.com

About MRIGuidance

During their research MRI physicist Peter Seevinck and medical image scientist Marijn van Stralen identified great unused potential for MRI-based medical imaging technologies. Together with Roel Raatgever, former director of Europe's no.6 academic business incubator UtrechtInc, they have founded UMC Utrecht spin-off company MRIGuidance. The team of MRIGuidance actively collaborates with hospitals in the Netherlands and abroad to develop and validate their image processing software. MRIGuidance recently became founding partner of the Fieldlab 3DMedical. The images of MRIGuidance will form the basis for 3D printed implants and medical devices.

www.mriguidance.com

Our offer

This is what we offer you:

- a market conform salary;
- three days per week job, with the potential to grow to full-time;
- a unique opportunity to, already at an early stage, to become part of not one, but multiple med-tech companies with vast growth potential;
- work that has a positive impact on people's health and life;
- work in a team of smart, ambitious, and like-minded people;
- work with and learn from experienced QA consultants;
- the ability to learn on the job and improve your knowledge and skills with relevant trainings;
- freedom and responsibility;
- work in inspiring environments.



Additional information

For more information about this position please contact Rutger van Merkerk by email (r.vanmerkerk@prolira.com) or simply give us a call (+31 6 4776 2936). To apply, please send a motivation letter and your CV. Application closes December 10th, 2018.