HR One
part of Capenti

QA & RA Specialist

Location	Work model	Contract
Antwerp (Berchem), Belgium	Hybrid (Mon + Fri in office)	Permanent, full-time

The Company

Our client is a medical software company on a mission to change how orthopedic surgeons plan knee replacement surgery. Their AI-powered planning tool gives surgeons a faster, more precise view of what they are dealing with before a single incision is made.

The startup team is small, the product is moving fast, and the regulatory ambition is serious. The company has already selected a notified body for its EU MDR submission and is pursuing FDA market access. Quality is not an afterthought here; it has been a strategic priority from day one.

The office is in Antwerp (Berchem), one minute from the station. The culture is direct, transparent, and built around real collaboration between engineers, orthopaedic surgeons, data scientists and quality professionals working side by side. The way of working is in weekly sprints with an agile development approach.

The Role

You will work directly with the Chief Operating Officer to support the rollout and ongoing operation of the Quality Management System. This is a hands-on position with real ownership from day one. You will be the person who makes sure the quality infrastructure keeps running, the documentation is in order, and the team is audit-ready as they move toward its first regulatory submissions.

This is not a background support role. The company is building something special, and quality is central to that build. You will have direct visibility into product development, work alongside software engineers, data scientists and clinical team members, and grow into a genuine partner on quality and regulatory matters over time.

What You Will Do

- Draft, review, and maintain QMS documentation: SOPs, work instructions, forms, and records
- Support the day-to-day operation of the company's software-based QMS, selected specifically for agile medical device development
- Maintain document control and ensure record-keeping meets ISO 13485 requirements
- Support internal audit preparation, conduct internal audits and regulatory submission activities
- Collaborate with the development team to integrate quality practices into the agile software cycle
- Contribute to data quality activities, including annotation and quality checks on CT scan datasets used for AI model development and validation
- Grow into a broader sparring partner for the Chief Operating Officer on quality and regulatory strategy

What We Are Looking For

You bring

- 2 to 4 years of hands-on QA experience in the medical device industry
- Solid working knowledge of ISO 13485, not just theory but practical day-to-day application
- Experience writing and managing QMS documentation: SOPs, work instructions, forms, and records
- Awareness of the MDR 2017/745 regulatory framework
- A digital-first mindset and genuine openness to working with new tools, including AI-assisted workflows
- Strong communication skills in English; direct, confident, and comfortable in small team discussions. Dutch would be an advantage but not a must.
- A flexible, curious and teachable approach. You ask why, adapt, and are not wedded to the way things were done elsewhere.

It is a plus if you have

- Knowledge of 21 CFR Part 820 (FDA) and/or IEC 62304
- Experience in a software medical device environment or a hardware/software combination device company
- A background in a larger, structured organisation where you have seen a mature QMS in action.

Who You Are

You are someone who finds the idea of building quality infrastructure from the ground up genuinely exciting rather than daunting. You are comfortable not having all the answers, but you know how to find them. You speak up when something is not right, you work well with people who are not quality specialists, and you take pride in making complex processes simple and clear.

The company moves quickly. Startup pace is real here. You will need to be comfortable with that, and you will also get to celebrate the milestones along the way with a team that takes both the work and the culture seriously.

You need to have AI fluency and be comfortable working with AI and other digital tools. Willingness to learn new technology as the landscape continues to evolve.

What the company offers

- A competitive salary and benefits package in line with your experience
- A direct line into the quality, regulatory and clinical leadership of a medtech company with serious backing
- A hybrid work model of Mondays and Fridays in the office that respects your time while keeping team momentum strong
- The rare opportunity to shape a QMS from the ground up in a company where quality is genuinely valued at board level
- A space to grow and learn

Interested?

This search is managed exclusively by HR One. For more information or to apply, contact Marina du Toit at HR One.