Quality Engineer

Location
Gent (or Brussels / Belgium) – Hybrid / On-site / Remote as relevant

About 3.LIFE
At 3.LIFE, we are redefining cardiovascular health with reACT: a smart, versatile, handheld ECG device designed for diagnostics, monitoring and acute care. By combining advanced AI with personalized reference data, reACT enables earlier detection, continuous monitoring and more responsive treatment for heart disease.

We're expanding our team and looking for a Quality Engineer who shares our mission to transform cardiac care through innovation and engineering excellence.

Role Overview
As a Quality Engineer at 3.LIFE, you will lead the implementation and continuous improvement of our Quality Management System (QMS). Contributing across the full product lifecycle: from design and validation to production and post-market activities. Working closely with R&D, regulatory and clinical teams, you will help bridge engineering excellence with quality assurance, enabling our mission to deliver trusted healthcare technology.

Key Responsibilities
Your role will be diverse and hands-on to the success of our mission. You will:

- Establish, maintain, and continuously improve the QMS.
- Ensure compliance with ISO 13485**,** MDR and applicable international standards.
- Support design control, risk management, and software lifecycle documentation.
- Prepare for and support internal and external audits.
- Collaborate with R&D and regulatory teams on technical documentation and submissions.
- Lead investigations, CAPA and root cause analysis to drive continuous improvement.

- Contribute to supplier evaluation, qualification and monitoring.
- Support process validation, verification and production quality control activities
- Participate in post-market surveillance and complaint handling processes.
- Train and mentor team members in quality and compliance best practices.

Qualifications & Skills

At 3.LIFE, we value curiosity and collaboration. We believe the best candidates are not only technically strong but also motivated by impact and a willingness to grow. We're looking for someone with:

- A degree in Life Sciences, Industrial Engineering, Biomedical Sciences, or a related field (Master's preferred).
- Experience in quality assurance or engineering or assurance within the medical device, biotech, pharmaceutical or regulated helathcare industry.
- Working knowledge of ISO 13485, MDR, GCP or ISO27001 standards.
- Strong understanding of design control, risk management, and audit processes.
- Excellent organizational, analytical and documentation skills, with a focus on accuracy and clarity.
- Ability to interpret regulatory and technical requirements and translate them into practical, efficient quality solutions.
- A collaborative, proactive and detail-oriented mindset, driven to uphold high standards of safety, reliability and compliance.
- Strong communication skills (in English; Dutch is a plus) and the ability to work effectively in a cross-disciplinary environment.

What We Offer

You won't just be joining our company, you'll be joining a mission-driven team that wants to save lives with technology. We aim to give you the environment and tools you need to thrive:

- The chance to work on a life-changing product that impacts real patients.
- A dynamic, cross-disciplinary environment where innovation and collaboration are the norm.

- Opportunities for professional development, continuous learning and true ownership of your work.
- A competitive salary and benefits package tailored to your local context.
- Flexible working arrangements to support your work-life balance.

Ready to make an impact in cardiovascular health?

At 3.LIFE, we're not just building technology, we're shaping better futures for millions of people living with cardiovascular disease.
We believe innovation thrives on diverse perspectives. That's why we warmly welcome candidates from all backgrounds and experiences to apply.
If our mission excites you and you can see yourself contributing, we'd love to hear your story.

Every journey begins with a first step, perhaps this is yours.