Regulatory & Study Support Officer

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 Regulatory & Study Support Officer who shares our mission to transform cardiac care through innovation and engineering excellence.

Role Overview
In this role, you will contribute to the planning, execution and follow-up of clinical studies. Ensuring they meet scientific, ethical and regulatory standards.
You will also support the development and implementation of our regulatory strategy, helping to translate innovation into compliant, real-world solutions. Working closely with multidisciplinary teams, you will ensure all documentation, data and processes align with medical regulatory and quality requirements. Supporting the safe and effective deployment of 3.LIFE's technologies.

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

- Support the planning, execution, and reporting of clinical studies, ensuring alignment with MDR, FDA and applicable ethical and regulatory requirements.
- Maintain and update technical and regulatory documentation in accordance with EU MDR, FDA 21 CFR Part 820 and CE marking requirements.

- Prepare and coordinate ethical, regulatory, and competent authority submissions, including documentation for FDA pre-submissions and clinical study approvals.
- Contribute to communication with notified bodies, competent authorities, and the FDA, supporting responses, data reviews and compliance activities.
- Collaborate with Quality, R&D, and Clinical teams on documentation, risk management, design control and clinical evaluation reports (CERs).
- Monitor and interpret changes to global regulatory frameworks, ensuring internal processes remain current with evolving EU and US medical device legislation and guidance.

Qualifications & Skills

At 3.LIFE, we value curiosity and collaboration. We believe the best candidates combine scientific understanding with regulatory awareness and a drive to deliver impact. We're looking for someone with:

- A Master's degree in Biomedical Sciences, Life Sciences, Industrial Engineering (Biochemistry, Chemistry, or Biomedical Technology), Regulatory Affairs, or a related discipline.
    - *Degrees such as Master of Science in Pharmaceutical Sciences, Master in Medical and Pharmaceutical Research, or Postgraduate in Regulatory Affairs are highly relevant.*
- Solid understanding of European and U.S. medical device regulations, including MDR, ISO 14155, GCP, and FDA 21 CFR Part 820.
- Familiarity with FDA 510(k) submissions, technical documentation, and CE marking processes.
- Strong organizational, analytical, and documentation skills, with meticulous attention to structure, clarity, and compliance.
- Experience supporting clinical studies, regulatory filings, or quality management systems within the medical deviceor healthcare sector.
- A detail-oriented, communicative, and proactive mindset, able to work collaboratively across scientific, quality, and regulatory teams.
- 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.