



LUKA GLOBAL

LIFE SCIENCES & TECHNOLOGY

Our client, a dynamic Digital Health / Artificial Intelligence start-up based at Barcelona's premier Mediterranean waterfront tech-hub workspaces, has recently raised a healthy seed round and is ready for business. innovative AI medical imaging (CT) software diagnoses cerebrovascular events and recommends targeted treatments for stroke victims.

As part of their accelerated growth strategy, they seek a quality assurance specialist to represent QA with cross-functional Software as a medical device product development teams and execute Quality System requirements to ensure products are developed, tested, and released in compliance with worldwide Medical Device Regulations.

Your responsibilities:

- perform QA activities related to Software as a Medical Device (SaMD) Development
- ensure compliance with software development lifecycle requirements, policies, and procedures
- design control and risk management activities
- support the creation of regulatory submission documentation
- identify gaps/improvement opportunities within the DHF and Risk Management
- actively lead and participate in the development, resolving quality issues, and taking corrective and preventative actions
- write/review policies/processes/procedures and related documents for the development of SaMD's in compliance with IEC 62304, 21 CFR 820.30 and EU MDR, CE Mark & FDA 510(k), ISO 13485
- support regulatory agency and internal audits

Requirements:

- Bachelor's degree in science/engineering/technical area
- Willingness to learn and develop within QA/RA department
- Ambitious, driven and strong team player
- great communication, presentation, and interpersonal skills
- business fluent in English

Benefits

This is an amazing opportunity for junior candidates to join an elite start-up, to work on an impactful healthcare project. You also have the chance to parachute into one of Europe's most dynamic entrepreneurial life science ecosystems and enjoy the best quality of life that Europe has to offer.

You will be working for a talented, focused, and visionary team of leaders who put employee satisfaction, professional development and a fun, motivating workplace at the top of their agenda. You will have world-class access to experts in the field of SaMD quality assurance to learn from.

Your workplace is 5 minutes' walk from the iconic Barceloneta beach in one direction and the historic centre of old Barcelona in the other. This fast-growing company offers growth opportunities in line with their ambitious expansion plans.

If this sounds like the right opportunity for you, send your CV to Sandra Tawfiq - sandra@lukabio.com.