

Head of QARA Molecular Diagnostics

Location : Barcelona, SPAIN (or remote)

Type of position : Full time – Permanent contract

Our client is a start-up that develops accelerated solutions for the diagnosis of bacterial infections. As part of its rapid growth and the industrialization of its products, the company is looking for a Head of QARA. You will be responsible of the implementation of company's QMS covering all steps of a product life, from design to manufacturing and post marketing.

Your mission :

As Head of QARA you will be responsible for:

- Leading the regulatory approval in both Europe and USA
- Managing of a team with employees, international partners and consultants involved in the project
- Deploying and maintaining a Quality System compliant with EU (ISO 13485) and USA (cGMP, 21 CFR 820) Design Controls and product development cycle regulations
- Bringing innovative ideas and processes to implement a QMS for a world-class instrument for direct blood pathogen detection and antibiotic susceptibility testing
- Ensuring the process validation of each manufacturing steps, especially for the industrialization stage
- Passing notified bodies regulatory audits

Your profile :

- Solid IVD experience (10 years, preferentially in a leading position for an analytical system QMS development)
- Expertise in leading all documentation efforts needed for regulatory agencies
- Successful track record of deploying and maintaining a Quality System in EU and the USA
- Obtaining at least one European regulatory approval for an IVD system.
- Used to the importance of sterility and contamination control.
- Proven track record of passing notified bodies regulatory audits.
- Experience obtaining Regulatory approvals of molecular diagnostics (PCR) and / or AST (Antimicrobial Susceptibility Testing)
- Leadership and able to build constructive discussions with other company division (Reagents, medical affairs, engineering, and operations)
- Management experience in leading internal teams and external partners (industrial and consultants)

If you want to join a fast-growing start-up developing an innovative IVD solution, contact us !