JOB OFFER

Quality Assurance & Regulatory Affairs (QA&RA) technician

MiMARK is an In Vitro Diagnostic (IVD) spin off company from Vall Hebron Research Institute (VHIR) created in 2021 and focused on improving Women's Health. We specialize in the development and validation of clinically impactful biomarkers in gynecological fluids to provide innovative diagnostics across gynecology indications. In MiMARK we envision these fluids as the next liquid biopsy in the gynecological arena to provide easy to access and reliable diagnostics, we have created GyLDa our Gynecological Liquid Diagnostics Platform.

Our first product, GyLDEC is an IVD immunoassay-based technology based on protein biomarkers to aid in endometrial cancer diagnosis. Beyond endometrial cancer the company has already started unveiling biomarkers for other indications, such as endometriosis.

Our company is working under our Quality Management System (QMS) following ISO13485 growing and has recently apply for D&D certification.

We are looking for you!

MiMARK is seeking a **Quality Assurance & Regulatory Affairs technician** to join our team on a temporary basis, as per substitution of our QA&RA manager, who will go on temporary leave.

This role is essential to maintain and evolve our Quality Management System (QMS) – ISO13485 compliant, ensure regulatory compliance across all operations, and support the development and validation of innovative IVD products in gynecological health.

We are looking for someone committed to excellence, organization, collaboration, and a deep respect for quality processes and regulatory rigor. You will work alongside a multidisciplinary team that values shared growth, inclusion, and purpose-driven innovation.

Responsibilities

As a QA&RA Technician you will support MiMARK's Quality and Regulatory operations by undertaking the following tasks:

<u>Quality Management System</u>

- Maintain and improve MiMARK's global Quality Management System (ISO 13485).
- Develop, update, and oversee Standard Operating Procedures (SOPs).
- Ensure a safe, compliant, and audit-ready working environment across the company.
- Provide internal training related to QMS
- Provide guidance to the Scientific Team regarding regulatory and quality documentation
- Communicating quality policy and QMS performance to leadership and collecting organizational feedback.

<u>Regulatory Affairs</u>

- Oversee regulatory processes from product conception to placement on the market.
- Provide guidance to the scientific team on quality and regulatory requirements through all product development phases.
- Provide guidance on EU and US and Regulatory framework.
- Provide support on draft, update, and maintain regulatory Documentation.
- Provide support on reporting to regulatory authorities and Notified Bodies.

Cross-functional support

- Participate actively in Area meetings.
- Ensure continuous data organization, monitoring, and reporting.
- Contribute to fostering a positive, collaborative, and mission-aligned work environment.

Requirements

We are looking for a candidate with the following qualifications, skills, and qualities:

- University degree in Life or Health Sciences or similar.
- Postgraduate training in Quality and/or Regulatory Affairs.
- Experience in Technical Quality role in a medical device or IVD environment.
- Fluent in English (written and spoken).
- Proficiency in Catalan or Spanish.
- Highly organized, detail-oriented, and passionate about quality and order.
- Team-oriented, proactive, adaptable, and committed to MiMARK's principles of equality, care, and scientific rigor.
- Entrepreneurial spirit and willingness to work in a dynamic start-up environment.

Benefits

We would like you to profit from joining a team of talented people who share the passion to develop minimally invasive diagnostics based on gynecological fluids to improve women's health. We offer:

- Part-time contract (substitution); duration to be defined according to the leave coverage.
- Incorporation: early 2026 (adjustable to candidate availability).
- Salary adjusted to candidate experience and qualifications.
- Great location in Barcelona (with optional hybrid work 2-3 days).
- Flexible working hours for a healthy work–life balance.
- Entrepreneurial environment and collaborative team culture.

Selection process

The selection process will follow a merit-based procedure aligned with the Open and Transparent recruitment system of the European Commission.

1. We will first check eligibility criteria according to the requirements in this job offer.
2. Shortlisted candidates will be contacted for an interview.
3. The selected candidate will be formally invited to join MiMARK's team.

If you are **passionate** in joining us,

Apply to the following link.

We look forward to receiving your application **before 28th February 2026**