

☀️ Regulatory and Quality Specialist ☀️

📍 **Location:** Barcelona

🕒 **Start Date:** April 2024, negotiable

About Us: Fecundis develops sperm-based technologies that increase the success of infertility treatments. We are an international team at the forefront of innovation in reproductive medicine, with a passion for making a meaningful impact on the lives of millions of patients facing infertility through cutting-edge research.

Your profile: As the Quality and Regulatory Specialist you will play a pivotal role in ensuring that Fecundis operates at the highest standards of quality, security, and regulatory compliance. Your mission is to build and maintain systems that adhere to ISO standards, and navigate regulatory landscapes in EU + US.

You responsibilities:

- Lead the quality and security policies of the company: ensure that the policy is understood, implemented and maintained.
- Implement, maintain and improve the quality management system in order to meet compliance against ISO 13485, EU/MDR, FDA, GDPR and HIPAA.
- Report directly to the CEO on the functioning of the quality management system.
- Ensure the application of the quality system and conduct internal quality audits.
- Support the team in the development of its products from a QA/RA perspective
- Help to manage communications with competent authorities and notified bodies.

What are we looking for:

- Master's degree in law, medicine, pharmacy, engineering, or other relevant subject
- 2+ years of experience in Quality Assurance and/or Regulatory Affairs
- Experience in software medical devices
- Medical device experience
- Good knowledge of ISO13485
- Good knowledge of European regulatory framework for medical devices (EU/MDR).
- Good knowledge of FDA regulation.
- Fluent in English and Spanish.

What we offer:

- Full time, permanent position
- Competitive salary and flexible working hours.
- Remote/or-site to fit your preferences and needs.
- Professional development and career advancement.
- An inclusive work culture that values creativity and collaboration.

How to Apply: candidates should submit a cover letter, CV, and contact information for two references to info@fecundis.com by the deadline of March 15th. Please include "Regulatory - [Your Name]" in the subject line.