



MANINA MEDTECH

Boosting IVF Success

REGULATORY AFFAIRS AND QMS SPECIALIST - MEDICAL DEVICES

Company Description

Manina Medtech is a femtech start-up founded in Barcelona in 2021, with the goal of maximizing the success rates of in vitro fertilization (IVF) treatments, improving their accessibility, and reducing the health risks associated with these procedures.

In Vitro Fertilization (IVF) success rates remain below 40%, with embryo implantation being the primary cause of failure. The missing link is timing: there's currently no method to confirm uterine readiness for embryo implantation at embryo transfer. In Manina Medtech, we developed Seedchrony: a non-invasive medical device that detects uterine readiness in real time, ensuring embryo transfer happens at the optimal moment. No biopsy, no waiting days, no pain, no mock cycles. Seedchrony improves IVF outcomes, reduces failure rates, and gives clinics a competitive edge in the growing fertility market.

Role Description

We are looking for a Regulatory and Quality Assurance Specialist to join the Manina team. Your main responsibilities will include executing the regulatory strategy, preparing and updating the Technical Documentation for Manina's products, ensuring maintenance of the QMS under ISO 13485, and supporting the design and execution of Manina's clinical research activities. You will work closely with the Regulatory and Clinical Research leads. The position is based in our Barcelona office. We offer a hybrid work model, with the possibility of working from home a few days per week, but this is not a remote position.

Responsibilities

- Maintenance of the QMS under ISO 13485, including the annual management review report.
- Authoring and control of QMS documentation (procedures, work instructions, records), staff training, and continuous improvement.
- Regulatory compliance oversight for medical devices (MDR/FDA).
- Complaints, nonconformities, and CAPA: intake, investigation, trend analysis, and reporting.
- Internal/external audits (including suppliers/Notified Bodies) and supplier qualification.
- Risk management and product traceability across the product lifecycle.
- Quality control oversight of raw materials, in-process, and finished products.
- Support Clinical Evaluation, Clinical Investigation, and Post-Market Surveillance for Manina's products.

- Update and maintain the Technical Documentation/Technical File for Manina's products.
- Align regulatory approval requirements with development and validation stages; partner with scientific, engineering, and clinical teams to generate evidence.

Requirements

Education:

- Degree in Health Sciences or Biomedical Engineering or a related field (Chemistry, Pharmacy, Biology, Biochemistry, Medicine, Surgery, and/or Biomedical, Electronic, or Mechanical Engineering).
- A PhD in Health Sciences or Biomedical Engineering will be positively valued.

Specific Knowledge:

- 5 years of experience as a Quality Assurance technician in medical devices.
- Experience in medical device regulatory affairs (CE Mark and FDA).
- Experience in audits with Notified Bodies.
- Knowledge of ISO 13485, ISO 14971, ISO 14155, MDR, and GMP.
- Fluency in English and Spanish.

Soft skills:

- Attention to detail to detect errors and deviations in products, processes, and documentation.
- Analytical thinking to interpret data and reports to identify patterns or issues.
- Teamwork and proactivity.
- Adaptability and willingness to learn and grow professionally.
- Excellent written and verbal communication skills.
- Professional ethics to ensure the integrity and safety of Manina Medtech's products, and strict adherence to regulations and standards.

Offer:

- Full-time permanent contract.
- Immediate start.
- Salary according to experience.
- Flexible working hours, as we aim to balance work responsibilities with personal life.
- Based in Barcelona with the possibility of remote work (hybrid model).
- Professional and organizational development opportunities.
- Join the team at an early stage of growth in a company with broad expansion and development potential.
- Innovative project with a real impact on the health of people affected by infertility.

Interested candidates should send their CV and cover letter to info@maninamedtech.com