

# **Job Profile - R&D/QA Engineer**

**JOB TITLE:** R&D/QA Engineer

**LOCATION:** Yokneam

**STATUS:** Full Time

## Position Overview

Serenno Medical, an Israeli Medical Device startup, is developing a novel method to predict, identify, and avoid common, life-threatening ICU complications such as Acute Kidney Injury.

Serenno Medical is looking for a R&D/QA Engineer to join our team - a strong and versatile team member to support the development process, which includes clinical trials, work with regulatory and R&D teams, and high-level strategy.

## Responsibilities:

- Support quality and regulatory aspects of the company and products
- Drafting/Support of quality documentation, including SOPs, test methods, change controls, deviations, corrective actions, out of spec investigations, etc. Do so in close concert with external consultants.
- Familiar with device Frameworks Design Control. Must be able to guide the team through phases, understand documentation and testing requirements, and maintain files.
- Communication and cooperation with vendors, labs, manufacturers, subcontractors etc.
- Coordinating filing and amendments to regulatory agencies
- Reviewing Manufacturing Documents for Material Qualifications and Products.
- Plan and execute V&V tests according to relevant standards (functional & usability tests, failure modes, forces, fatigue, etc.,)
- Collect and analyze external data in preparation for future developments
- Provide actionable recommendations and conclusions from data to shape features and future product road maps
- Evaluate and track complaints from users around the world through complaint process workflow to closure.

## Skills

- Strong organizational and communication skills, both written and presentation.
- Able to work with a diverse group of individuals and styles, internally (employees) and externally (consultants)
- Respect and adherence to timelines
- Excited for start-up culture: adaptability, occasional ambiguity, limited resources, willingness to do what is necessary to get the job done
- Self-motivated, willing to learn

## Qualifications:

- BSc in Mechanical/ Biomedical Engineering or equivalent degree (must)
- Relevant industry experience with medical company - an advantage
- Strong knowledge of FDA / GMP regulations, EU / ICH - an advantage
- Strong technical skills
- CDRH / medical device regulation familiarity also ideal
- Familiarity with MS Office / Google Docs
- Good technical English writer/speaker

Reporting to the VP R&D and COO work in collaboration with QA/RA advisor  
The position is for both men and women

Please send your CV and cover letter to [sagie@serenno-med.com](mailto:sagie@serenno-med.com)