**Senior Director of QA**

The company is looking to hire a senior level director of who will assume responsibility for the over- all quality of product and procedures in both sites and evolve the quality management system from an R&D focus to larger scale manufacturing operations.

**Requirements:**

- Engineering or scientific degree.
- Considerable and broad experience managing quality in the medical device industry.
- Clean room operations and EtO sterilization experience required.
- Experience in a global / corporate company required.
- Experience in Regulatory Affairs, specifically FDA – an advantage.
- Superb Hebrew and English communication skills.

**Responsibilities:**

- Provide overall leadership for Quality policies, approaches, and standard practices for the Israel and US sites.
- Management and maintenance of QMS system which currently include Agile PLM and electronic record keeping.
- Create, review and approve company documents, specifications, drawing, ECO’s and procedures.
- Supervise the document control, CAPA, MRB/Nonconforming activities, and training activities.
- Supervise Incoming and in process inspection activities.
- DHR review and approval.
- Clean room and sterilization activities - monitoring and re/validations
- Supplier approval and monitoring.
- Cooperative cross- functional work to guide all company’s departments to meet the quality requirements
- Maintain positive and cooperative communications and collaboration with all levels of employees, customers, contractors, and vendors.
- Prepare company to ISO13485 and FDA certification and audits.

michal@insighthr.co.il