

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.

Maintain alignment with US and International regulations and standards.

Prepare company to ISO13485 and FDA certification and audits.

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