

Senior quality engineer/ QA Manager

Qualifications:

- A first degree certification (or higher) in academic institute
- At least 5 years as Senior quality engineer or QA manager in the medical devices industry (class IIa and higher)
- Experience with ISO 13485: 2016 Quality system implementation and maintenance.
- Good knowledge in EU Regulatory affairs requirements MDD/MDR (US-FDA an advantage)
- Quality auditor qualifications (lead auditor certification, an advantage)
- Experience with quality and QC aspects in clean room environment

Responsibilities:

- Work in cooperation with R&D, QC, Operations, S&M, and manufacturing departments.
- Assisting the VP QA/RA on the department activities such as yearly goals, objectives, identify of the areas of opportunity and implementation of Quality Systems according to Nanomedic quality policy and regulatory requirements.
- Release of final products
- Supplier audits /Internal Audits
- Trainings
- Monitoring of company validation activities
- ECO, CAPA, MRB, and Complaints Management.
- Preparation for an external audits
- Assist in regulatory submissions

Reporting to VP QA/RA

michal@insighthr.co.il