

Senior quality engineer/ QA Manager

Reporting to VP QA/RA

Qualifications:

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

Responsibilities:

- Work in cooperation with the design team, QC team and operations and manufacturing department.
- 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.
- Approval of incoming inspection reports and release of final products
- Supplier audits as part of annual plan
- Monitoring of company validation activities
- Involvement in ECO, CAPA, MRB processes as needed.

Note: the QA/RA department includes currently three employees (QC not included- under Operations responsibilities) :

1. QA Manager/ Senior engineer
2. Documents /Training controller and more... (Senior)
3. VP QA/RA

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