Quality Engineer

Aran Biomedical design, develop and manufacture implantable medical devices, as an outsource partner to many of the leading, global medical device companies. Our innovative technology focus and biomaterials expertise foster a dynamic culture, which delivers next-generation implantable solutions. Aran Biomedical's facility is situated along the Wild Atlantic Way in Spiddal, overlooking the Galway Bay and is just 20 minutes from Galway City by car. As we continue to grow and expand our facilities, we are looking for like-minded people to come and join our team.



The position requires an experienced and proven candidate with a background in Quality and Regulatory control of Medical Devices. The successful candidate will work as part of a team to maintain high quality/performance standards across the company.

Reporting to the Snr QE Lead, the position will be challenging and will require an ability to work autonomously

Duties and Responsibilities

The Quality Engineer shall:

- Develop and maintain documentation in compliance with FDA , ISO, MDD requirements
- Actively participate in the Documentation control process
- Review / Approve / Release final product documentation
- Initiate / Approve Non-Conformance Reports & Lead Root Cause analysis investigations
- Participate / Lead Risk Analysis initiatives e.g. FMEA
- Initiate / Approve Reworks
- Initiate / Support implementation of effective Corrective / Preventive Actions
- Support the Environmental monitoring process
- Support activities associated with Sterilization
- Act as the QA representative for Supplier Quality management activities
- Represent QA as part of the Material Review Board
- Act as the QA representative on Design Services Projects / Changes
- Initiate / Approve Validation protocols and reports (IQ, OQ, PQ)

- Initiate / Approve Engineering Change notices
- Process Customer Complaints and manage customer replies
- Support Notified Body / Regulatory Agency / Customer Audits
- Perform Internal and Supplier Audits
- Collate and trend Key performance indicator data on a monthly basis
- Actively participate in Management Review & Compliance meetings
- Performs other related duties, as assigned

Key Requirements for the role

A degree in manufacturing engineering, quality engineering, life science or related field and a minimum of 3 yrs. experience of working as a Quality Engineer within the Medical Device Industry.

Candidate must be highly motivated with excellent communication skills and proven ability to work as part of a team.

Experience of using Lean Manufacturing Tools and Techniques an advantage

Quality Certification and Lead Auditor Certification while not mandatory would be an advantage.