Senior Quality Engineer

About Aran Biomedical:

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.

About the Role:

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:

- Collaborate with the Project teams to facilitate the successful execution of the Design Services process and Commercialization of new products.
- Provide expertise in the areas of Quality Assurance, Design Controls, Risk Management, Statistical Techniques, and Regulatory Compliance and Submissions
- Lead and Support Design Services engineering activities (including but not limited to)
    - New product introductions
    - Development and approval of new product documentation.
    - Qualification of new suppliers/ requalification of existing suppliers
    - dFMEA , Risk management activities

- Provide expertise for new product introduction / product development / process changes with respect to:
    - Acceptance criteria development
    - Test method development/validation activities
    - Product / process validation protocol development and execution (IQ, OQ, PQ)
    - pFMEA , Risk management activities

- Ensure that new medical device product development / new product introduction and changes to existing products are conducted in compliance with global regulations and internal procedures.
- Participate in change review process for existing medical device products and new products under development.
- Review Design History Files and Technical Files for conformance to applicable requirements.
- Contribute to process improvement efforts by developing and updating procedures and work instructions.
- Develop and maintain documentation in compliance with FDA, ISO, MDD/MDR requirements
- Provide on-going support to manufacturing site(s) for commercially available products
- Process Customer Complaints and manage customer replies
- Initiate / Approve Non-Conformance Reports & Lead Root Cause analysis investigations
- Initiate / Support implementation of effective Corrective / Preventive Actions
- Champion continuous improvement through CAPA system, handling of complaints, analysing key performance indicators etc.
- Act as the QA representative for Supplier Quality management activities
- Represent QA as part of the Material Review Board
- Perform Internal and Supplier Audits
- Support Notified Body / Regulatory Agency / Customer Audits
- Review / Approve / Release final product documentation
- Support the Environmental monitoring process and activities associated with Sterilization
- Collate and trend Key performance indicator data
- Actively participate in Management Review & Compliance meetings
- Act as delegate for Quality Manager when required

Key Requirements for the Role:

- A degree in manufacturing engineering, quality engineering, life science or related field and a minimum of 5 yrs. experience within the Medical Device Industry at a senior level.
- Proven record of handling multiple tasks simultaneously and ability to manage project timelines
- Proven record of policy and procedure development
- Can demonstrate understanding and application of quality philosophies, principles, systems, methods, tools, and standards
- Must be highly motivated with excellent communication skills and proven ability to work effectively as part of a team and interact professionally with all organizational levels
- Act as a mentor to less experienced colleagues
- Quality Certification and Lead Auditor Certification is a plus
- Supplier Quality engineering experience is a plus
- Sterilization / Microbiology experience is a plus
- Ability to travel is a requirement