**SENIOR QUALITY ASSURANCE ENGINEER**

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 Director QA/RA, the position will be challenging and will require an ability to work autonomously.

**Roles & 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

**Role Requirements**

- 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