Job Description: SENIOR QUALITY ENGINEER

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 Senior Quality / Regulatory Manager, the position will be challenging and will require an ability to work autonomously

PRINCIPLE RESPONSIBILITIES/DUTIES

The Senior Quality Engineer will be principally engaged in the following tasks:

- Act as the QA representative on Design Services Projects supporting new product introductions, qualification of new suppliers, development and approval of new product documentation.
- Develop and maintain documentation in compliance with FDA, ISO, MDD requirements
- Initiate / Approve Validation protocols and reports (IQ, OQ, PQ)
- Initiate / Approve Engineering Change notices
- Process Customer Complaints and manage customer replies
- Actively participate in the Documentation control process
- 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
- Champion continuous improvement through CAPA system, handling of complaints, analysing key performance indicators etc.
- 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

- Support activities associated with Sterilization
- Act as the QA representative for Supplier Quality management activities
- Collate and trend Key performance indicator data
- Actively participate in Management Review & Compliance meetings
- Act as delegate for Quality Manager when required
- Performs other related duties, as assigned

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.
- 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.