QUALITY 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

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

Role Requirements

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.

Sept 2020