Senior Quality Assurance Lead Engineer

The position of Senior Quality Assurance Lead Engineer requires an experienced and proven candidate with a background in Quality Control, Quality Assurance and Regulatory compliance 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.

Responsibility and Authority

Quality Control

- Provide Leadership / Direction and Support to the QC Inspection team including:
  - Maintenance of fully compliant documents and procedures
  - Management of training/development needs
  - Co-ordination of QC inspection schedules aligned to support and deliver Quality /Manufacturing/Design Services -NPI/ Customer deadlines
  - Management of environmental monitoring activities, Endotoxin (LAL) and Product Bioburden sampling program
  - Management of QC Inspection record review / release, including final product release
  - Complete customer and supplier notification change assessments and appropriate follow on actions
  - Co-ordination & Review of Key performance Indicator data for presentation to Management
  - Co-ordinate Customer Complaint processing (investigations and customer response)
  - Co-ordinate Internal audits of Clean Room (Line audits)

Additional QA related activities that may also apply to QC responsibilities are outlined below.

Quality Assurance / Regulatory Compliance

- 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
    - Material / Product testing requirements (e.g. ISO10993)

- 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.
- 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
- 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
- Collate and trend Key performance indicator data
- Actively participate in Management Review & Compliance meetings
- Act as delegate for Quality Manager when required
- Perform additional duties as required by the role and management

Role Requirements

- Minimum degree in Quality Engineering, Manufacturing engineering, Life science or related field.
- Minimum of 5 yrs. experience at Senior Engineer level within the Medical Device Industry including at least 2yrs. proven People management experience.
- 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