

Senior Quality Engineer – Medisize B.V.

We are looking for a Senior Quality Engineer for a full time position based in our office in Hoofddorp, The Netherlands.

Position

As a Senior Quality Engineer, you contribute to a permanent state of inspection readiness in quality and regulatory compliance in the Medisize organization in cooperation with the Global RA/QA manager. You lead or participate in QA projects (improvements) and develop training and train employees to grow QA awareness.

The key responsibilities for the Senior Quality Engineer are:

1. Complaint handling
 - Control and manage complaint handling system
 - Monitor and issue and approve of non-conformances, CAPA's, deviations, RMA and rational report
 - Investigate and initiate and manage corrective and preventive actions
 - Handle, manage Post Market Surveillance review and execute the activities related
 - Review complaint handling process and timelines, take action where needed.
2. QMS
 - Establish and maintain the QMS and policy according to applicable standards and the corporate guidelines
 - Compose and control quality/regulatory documentation, including regulatory files.
 - Review product specifications and archive to product file
 - Enforce good manufacturing practices (GMP)
 - Perform internal/external audits and follow up
 - Work /communicate/coordinate with NB (Notified Bodies)
3. Product/process assessment & release
 - Approve and release commercial products
 - Collect data and prepare submissions to regulatory agencies
 - Coordination of Quality agreements and Questionnaires with suppliers and/or subcontractors.
 - Contribute to releases of products by assisting in reporting and applying for certificates, 510 K submissions (a.o.)
 - Provide administrative support to the change control process
 - Identify and resolve problems related to products and processes
4. Improvement
 - Provide QA expertise to other colleagues within the organization
 - Assist in scoping, planning and scheduling QA activities for various projects
 - Support the effective roll-out and implementation of all elements of the QMS within the Medisize organization
5. Reporting
 - Monitor and analyze and report the effectiveness of the QMS

- Review and assess essential requirements and report
 - Keep Global RA/QA Manager informed on latest changes in QMS
 - Come up with improvement proposals related to reporting
6. Customer Focus
- Coordinate and review QA agreements
 - Schedule/Coordinate/ handle Customer and Regulatory Body audits
7. Team Building
- Act as a strong team builder
 - Show professional can do attitude towards the internal as well as the external organization and develop direct reports into the same direction

Communication

Internal:

- Global Flexicare organization

External:

- Customers
- Suppliers
- All other service providers

Required Knowledge, Skills and Experience

Education:

- Bachelor degree (HBO/WO)

Knowledge:

- Quality Management Systems (in particular ISO13485/ISO9001)
- Medical Device Directives(MDD93/42 EEC or similar)
- Risk Management
- Auditing
- Complaint management
- Trade business
- Sterilization
- Cleanrooms
- Process validation

General skills:

- Influencing skills
- (Time-) Management skills
- Work accurate according to procedures, rules and regulations

- Excellent interpersonal and communication skills
- Team player
- Ability to grow and develop
- Auditing
- Presentation skills
- Thinking in solutions

Personal skills:

- Ethical, open minded, diplomatic
- Tenacious, decisive, influential
- The ability to perform under pressure
- Fluent in Dutch and English
- Computer (ERP/Office) skills

Experience:

- At least 5 years work experience in quality and/or regulatory related activities
- Experience working in a Trade and medical business is regarded as a pre.
- Relevant and proven experience working effectively across boundaries of home country

Specific requirements:

- Can understand the main ideas of complex text on both concrete and abstract topics, including technical discussions in his/her field of specialization.
- Can interact with a degree of fluency and spontaneity that makes regular interaction with native speakers quite possible without strain for either party.
- Can produce clear, detailed text on a wide range of subjects and explain a viewpoint on a topical issue giving the advantages and disadvantages of various options

If you are interested in this job, please send your resume and motivation to jack.vangaans@medisize.com. If you would like to receive more information about this job, please call 088 774 4555.