ComplianceAcuity®

Quality System & Regulatory Specialist – QSRS1908

(medical devices)

Type:

Part-time **Contract** with Potential for Conversion to Full-Time

Core Competencies and Responsibilities:

Quality Management Systems:

- Implement and advise revision of medical device quality management systems.
- Must be fluent with, and know the practical implementation of, ISO 13485:2016 and FDA's 21 CFR part 820.
- Experienced in achieving ISO 13485 registration as adapted for European MDR as well as MDSAP compliance.
- Build and/or revise Risk Management systems to comply with ISO 14971.
- Perform ISO 13485 and FDA GMP audits and oversee resulting corrective actions.
- Ensure employee training is conducted and effective for company personnel.
- Assure proper supplier controls and GMP compliance with respect to major processes outsourced to contract manufacturers.
- Review supplier agreements to be sure they properly position the company to carry out its ultimate accountability for product quality and regulatory compliance.
- Assure effective Production and Process Controls internally and at contract manufacturing sites.
- Perform effective root cause investigations related to nonconformities.
- Devise and implement effective corrective & preventive actions in response to product, process, and quality system nonconformities.
- Process and Software validation experience is a plus.
- Improve the document control mechanism; operate automated document / change control process including change initiation, routing, approval, release, archiving, etc.
- Build and operate a complaint handling process.
- Function as a QA/RA contributor on new-product design & development teams.
- Establishes quality metrics and conducts trend analysis to measure and monitor the effectiveness of the QMS. Publishes performance reports.
- Act as deputy Management Representative.

Regulatory:

- Gather relevant documentation and assemble comprehensive, well-organized premarket dossiers including but not limited to, U.S. 510(k), European CE Marking & Technical Files; and Canadian Device and Establishment License Applications and Amendments.
- Develop / revise written global adverse event reporting and recall procedures.
- Prepare Formal Responses to FDA-483 citations and Warning Letters, Notified Body/Registrar nonconformities, and other analogous international agency citations.
- Tactfully assess regulatory compliance of advertising and promotional materials.

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Minimum Qualifications:

- Certified Quality Auditor (CQA) or other similar certification such as IRCA, RABQSA, etc.
- Regulatory Affairs Certification (RAC) preferred
- Bachelor's degree in Engineering or Science
- Medical device experience including thorough understanding of FDA Quality System Regulation, ISO 13485:2016, the EU Medical Device Regulations (MDR), Canadian Medical Devices Regulations and other medical device standards is required. Knowledge of other international regulations (Latin America, Australia, Asia, etc.) is desired.
- Minimum of 5 years of HANDS-ON experience in global medical device quality systems and regulatory affairs
- Effective and dynamic people-management/leadership skills, particularly in a small company, technically-oriented environment
- Strong interpersonal and communications skills (written & verbal)
- Proven technical report-writing skills
- Good technical judgment and problem solving abilities
- Excellent organizational skills; ability to plan and manage multiple priorities
- Must be comfortable working within a challenging organizational structure
- Good understanding of computer systems (MS Office, databases)
- The successful candidate will be a motivated self-starter requiring minimal supervision

Note: This job description is not intended to be an exhaustive list of all duties, responsibilities or qualifications associated with this position.

If Interested:

Please send resume to info@complianceacuity.com . Include job code QSRS1908.