Job Title: Sr. Quality Systems & Regulatory Specialist

Job Location: Pewaukee, WI

Major Responsibilities: Supports the ongoing effectiveness and compliance of NeoCoil's Quality Management System (QMS) across all functional areas of the organization in accordance with applicable international and regulatory requirements including but not limited to review and approval of project deliverables (e.g. design input requirements, risk management, equipment qualifications, design verification and validation plans, procedures and results). Review and approve mechanical and electrical device master record specifications. Author project deliverables consistent with the demands of project teams. Ensure the integrity of the Design History File and Device Master Record, including requirements and records traceability and compliance with NeoCoil's Quality System requirements. Support compilation and ongoing maintenance of technical documentation (i.e. FDA 510(k)s and EU Technical Files) for completeness, regulatory compliance and standards satisfaction. Interpret industry standards to provide guidance to project teams to ensure quality system and regulatory compliance throughout the project/product lifecycle. Support Risk Management and Risk Mitigation activities in accordance with ISO 14971. Initiate, review and approve Change Requests/Change Orders for Quality System documentation and product changes. Support/lead internal and supplier audits. Initiate/lead continuous improvement opportunities. Support/lead investigations and implementation of planned actions stemming from the Corrective and Preventive Action program. Telecommuting allowed. Less than 10% domestic travel.

Job Requirements: Applicant must possess a Bachelor of Science degree, or foreign equivalent, in Electrical Engineering, Mechanical Engineering, Biomedical Engineering, or related technical field and 10 years Quality Systems and/or Regulatory experience in the medical device industry or another related field that is federally and/or internationally regulated. Alternatively, the employer will accept Associates with 15 years of experience in the medical device industry or other related field that is federally and/or internationally regulated. Additionally, the applicant must have professional experience with: 1) Working knowledge of international medical device standards and regulations (e.g., ISO 13485, ISO 10993-x, IEC 60601-x, U.S FDA 21 CFR 820, MDSAP, EU MDR, etc.); 2) Interprets and assesses regulatory requirements for applicability to applicable products and quality system processes and/or liaise with external regulatory resources/services; 3) Communicates with international regulatory entities and customers regarding licensing inquiries, product registrations, import & export regulations; 4) Supporting external audits and regulatory inspections; 5) Supporting new product development teams by establishing product regulatory strategy for applicable markets; 6) Applies a risk-based approach in providing options and regulatory recommendations for engineering changes throughout the product lifecycle; 7) Preparing initial product registrations and submissions, device listings, and applicable renewals when required; 8) Reviewing and approves product labeling and product literature for compliance with applicable international standards and regulations; 9) Maintains documentation needed to support regulated product throughout the product's lifecycle, including but not limited to, technical file maintenance, recall coordination and medical device reporting; 10) Supports creation and maintenance of technical documentation and Declarations of Conformity in support of international product registrations (e.g., CE marking of conformity); 11) Establishes and manages corrective and preventive actions (CAPA) systems and processes, acts as CAPA Review Board Chair (CRB), clinical evaluations and literature searches; 12) Implements corrective and preventive actions, and corrections, as necessary to address nonconformities and prevent their recurrence. Mentors less experienced staff on the appropriate CAPA methodologies; 13) Manages the internal audit program, as required, to determine QMS effectiveness and to ensure compliance with the established regulatory requirements. Acts as lead internal auditor; 14) Participates in Quality Planning; leads Quality Planning meetings; and 15) Supports preparation for and participate in Clinical Evaluations, Management Reviews, External Audits and other duties as assigned.

To apply: Email resume to liz.cieminski@neocoil.com

Eligible for employee referral program.