NeoCoil

NeoCoil, LLC is a leader in MRI coils and imaging accessories designed for better patient comfort and experience. Our focus, through innovation and precision, is to engineer and manufacture the highest quality coils and accessories for the medical industry. We are seeking an experienced **Quality Engineer** to join our team.

As a Quality Engineer you will collaboratively guide new product development and sustaining engineering teams in a manner that incorporates quality principles into the everyday work of the teams, ensuring compliance while fostering continuous improvement. Having a solid understanding of applicable medical device regulations (i.e. FDA, MDD/MDR, Health Canada), you will provide quality engineering expertise during development, review and approval of project deliverables and in support of correction/containment and continuous improvement initiatives.

Primary Responsibilities:

- Review and approve project deliverables (i.e. 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 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.

Minimum Requirements and Characteristics:

- A minimum of 3-5 years' Quality or Regulatory experience in the medical device industry.
- Bachelor's Degree in Engineering (Electrical or Mechanical preferred) or related field.
- **Analytical problem solving.** The ability to go beyond just fixing to identify root causes, evaluate optimal solutions, and recommend comprehensive upgrades to prevent future issues.
- **Motivation.** An individual who brings strategic direction and inner drive for execution to ensure products are developed, launched, and sustained with precision.
- **Collaboration.** The ability to build and leverage cross-functional relationships to bring together ideas, information, use cases, and industry analyses to develop best practices.

- Ability to read/interpret electrical and/or mechanical specifications.
- High level of attention to detail and the ability to manage several concurrently assigned tasks.
- Ability to serve as a mentor, promoting the development of others within the organization.
- Possess good interpersonal and communication skills; promote a collaborative environment.
- Ability to exercise judgment within broadly defined practices and policies in selecting methods, techniques, and evaluation criteria for obtaining results.
- Expertise in the operation of quality control systems, application and analysis of testing and inspection procedures.
- Understanding of usability, familiarity with quality costs, concepts and techniques, and auditing of quality systems for deficiency identification and correction.
- Expertise in risk analysis processes including FMEA, FTA, and others.
- Working knowledge and proficiency with MS Office including Outlook, Word, Excel, etc.

Desired Experience:

- Certified Quality Engineer.
- Experience participating in external audits (MDSAP).
- Experience using Minitab or other statistical analysis modalities.
- Familiar with enterprise resource planning (ERP) software and defect tracking software.

Physical demands: While performing duties of job, employee is frequently required to type, sit, stand, walk, use hands and fingers, handle, reach with hands and arms, talk and hear. Employee must occasionally balance, stoop, and lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, depth perception, and the ability to adjust focus.

If you are interested in joining a growing organization with a vision for the future, please send us your resume. We are a fast-paced work environment, offering competitive compensation, family-friendly benefits and so much more. Please visit www.neocoil.com for more information. Interested applicants should submit a cover letter and resume, including salary requirements, to liz.sielaff@neocoil.com

NeoCoil LLC is committed to a policy of equal employment opportunity. The Company conducts all employment practices without regard to race, sex, color, religion, national origin, age, disability, protected veteran's status, sexual orientation or any other basis prohibited by law. NeoCoil participates in E-Verify.