Spino Modulation is a privately held company founded in 2010 and based in Montreal, Quebec, Canada. Its core expertise revolves around the design, development, evaluation, and manufacturing of medical devices for orthopedics and spine applications in children and adults.
Our goal is to provide patients with innovative, performant, and safe spinal care solutions.

Job Summary:

Title: Quality Specialist

Reporting to the Director of Quality Assurance, this role is integral to maintaining the integrity and compliance of our quality system documentation. The ideal candidate will have over 5 years of experience in the medical device industry, with a strong focus on configuration management, document control, and change control.

Key Responsibilities:

As part of the Quality Assurance team at Spino Modulation, the roles and responsibilities include but are not limited to:

- Configuration and Document Management:
  - Process change orders to quality system documentation, ensuring compliance with local procedures and ISO 13485 standards.
  - Serve as the document owner for numerous quality system documents, conducting periodic reviews to ensure alignment with updated regulations.
- Audit and Compliance Support:
  - Provide experienced support during ISO notified body audits, FDA inspections, and compliance audits.
  - Act as an internal auditor for the quality system under ISO 13485.
  - Support the Regulatory response team, addressing deficiencies and assisting in inspections and MDSAP audits.
- Training and Development:
  - Serve as a Training Specialist, focusing on onboarding new users eQMS environments.
  - Implement and coordinate a comprehensive training system, improving new employee onboarding processes.

Candidate Requirements

- 5+ years of experience in the medical device industry, with a focus on configuration management, document control, and change control.
- In-depth knowledge of GxP, MDSAP, ISO13485 and Quality Systems.
- Proven track record in processing change orders and maintaining compliance with ISO 13485.
- Extensive experience supporting ISO notified body audits, FDA inspections, compliance audits.
- Certified Internal Auditor.
- Experience in training and onboarding new employees, with a focus on eQMS system
- Strong organizational and communication skills.

Please submit your application, including a cover letter, to HR@spinologics.com