Position: Regulatory Affairs Coordinator

Departments: Spinologics | Numalogics | Spino Modulation

Supervisor: Director of Quality Assurance and Regulatory Affairs

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Job Summary

Reporting to the Director of Quality Assurance and Regulatory Affairs, the Regulatory Affairs Coordinator will be responsible for the assistance with the preparation, coordination, and compilation of documents for regulatory submission to Health Canada, The FDA, and CE marking for Class I, Class II, and Class III medical devices and to ensure that all regulatory and quality is to the specifications of Spinologics Inc. and subsidiaries' goals.

Company Overview

Founded a little over 10 years ago, Spinologics is now emerging on the local and international stage. Our core expertise is in the development of innovative medical devices for spine surgery, but we are branching out into other orthopedic fields, sports equipment and protective equipment. Currently, our projects are conducted through our 2 very exciting daughter companies:

Computational modeling and simulation have a bright future in the medical world. We have an incredible team of simulation experts that test medical devices in a virtual environment. Our vision is to create a digital human, named "Numa", that is built based on sound biomechanical science and engineering.

spino modulation

A subsidiary of SPINOLOGICS INC

Scoliosis affects 2-3% of the population. For young adolescents that do not respond to brace treatment, we are developing a minimally invasive surgical system that “tethers” the curved spine.

Our Direction

Over the last few years, and during the pandemic, Numalogics and Spino Modulation have been in R&D mode. We are ready to start commercialization and let ourselves be known.

Our Work Environment

“*I have your back*” type of culture. Our group of young, talented, dynamic professionals are inclusive, collaborative, helpful.

Our office is located in Montreal’s trendy Le Plateau district.

Key Responsibilities

- Assist with the preparation, coordination, and compilation of documents for regulatory submission to Health Canada, The FDA, and CE marking for Class I, Class II, and Class III medical devices.
- Knowledge of software regulations an asset.
- Provide leadership to internal stakeholders to ensure collection of data needed for regulatory submission.
- Maintain knowledge on regulations, policies, and guidance documents for medical devices for Health Canada, The Food and Drug Administration, and the European Union for CE marking.
- Maintain knowledge of Spinologics Inc and its subsidiaries products and identify potential regulatory submission pathways.
- Assist with liaising and negotiating with regulatory authorities.
- Keeping up to date with changes in regulatory legislation and guidelines.
- Providing advice about regulations to manufacturers/scientists.
- Offering advice about company policies, practices and systems.
- Assist quality assurance team to ensure company is following Good Manufacturing Practices and to monitor product compliance with applicable regulations and policies.
- Conduct post-marketing surveillance on Medical Devices.
- Participate in internal and external quality audits.
- Perform other duties as assigned.

Qualifications

- 3-5 years of dynamic work experience in Quality/Regulatory Affairs.
- Knowledge and understanding of ISO ISO 13485:2016 is a must.
- Knowledge and understanding of Canadian Medical Device Regulations.
- Knowledge and understanding of the FDA 21 CFR 820 cGMP Requirements.
- Knowledge and understanding of the EU MDR.

Education/Experience Requirements

- B.S. alternative Bachelor degree program.
- 3-5 years of work experience, preferably in regulated industries.
- Medical device, particularly Orthopedic industry, experience preferred.
- Combination of education and experience may be considered (in evaluating experience relative to requirements).

Job Location

Montreal / Remote

To Apply

Email your resume, cover letter, and your portfolio at: HR@spinologics.com
Position will remain open until filled.

Spinologics is a diverse, inclusive, and open-minded workplace. Candidates who identify as a minority are encouraged to apply. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, gender expression, or national origin.