sentec.

Sentec is a market leader of non-invasive respiratory monitoring and intrapulmonary percussive ventilation (IPV) solutions who develops, manufactures, and markets patient-centric, cost-effective technologies and products. We aim to improve the lives of patients by advancing non-invasive patient care by empowering clinicians with clinically superior monitoring and therapeutic technologies.

Company Video

Regulatory Affairs Specialist

Key Tasks:

- Product registrations and submissions in the US and Canada, working closely with the regulatory compliance team in Switzerland.
- Review product, supplier, and manufacturing changes for compliance with applicable regulations and procedures.
- Works cross-functionally to develop regulatory strategies, testing requirements, and other documentation.
- Perform risk assessments and if required, report incidents to the authorities.
- Stay abreast of regulatory requirement updates and standards.
- Travel to Sentec facilities in North America and Switzerland as needed (anticipated 3-6 times annually)

Our Offer:

- Working environment in a growing company.
- Directly influence on the quality of our products and make a difference for patients worldwide.
- Opportunities for professional and personal growth.

Your Profile:

- Bachelor's degree required.
- 5 years' experience in a Regulatory Affairs position within the medical device industry.
- In depth knowledge of regulatory framework of medical devices for the FDA and Health Canada/MDSAP.
- Analytical thinking and ability to compile scientific data and summarize results.
- Fluent in English.

To apply, send your resume to jobs.us@sentec.com