

Sentec is a market leader of non-invasive respiratory monitoring solutions who develops, manufactures, and markets patient-centric, cost-effective technologies and products that provide clinicians with greater insight to quickly identify trends, rapidly and more accurately assess patient respiratory status, and make more well-informed, timely care decisions – decisions that can improve patient care. We aim to improve the lives of patients by advancing non-invasive patient care by empowering clinicians with clinically superior monitoring and therapeutic technologies.

[Watch the Sentec Company Video](#)

Summary:

Responsible for registrations of Sentec products in the US and Canada, the Regulatory Affairs Specialist acts as the local representative and contact person for the competent authorities. Will work closely in conjunction with, and as an extension of, the Sentec regulatory compliance team based in Switzerland.

Essential Duties and Responsibilities:

- Continuous monitoring and implementation of updated regulatory requirements and standards relevant to Sentec products.
- Support development of the regulatory strategy to receive product clearances in conjunction with Sentec Swiss regulatory team.
- Compilation of submission dossiers for new product approvals and changes to existing approvals in close cooperation with internal and external stakeholders (e.g., regulatory consultants).
- Serve as the primary local representative and contact to the FDA and Health Canada and other competent authorities.
- Participate in regulatory inspections/audits by internal and external audit authorities and prepare formal responses as warranted.
- Perform risk assessment of the obligation to report incidents and customer complaints in the US and Canada; Report incidents to the authorities and support the implementation of necessary measures internally (CAPAs) and in the market (FSCAs).
- Support partner companies (suppliers, dealers) regarding regulatory issues as needed.
- Act as regulatory representative on cross-functional project teams to develop regulatory strategies, testing requirements, and other documentation to ensure that regulatory submissions are prepared and approved to meet launch timelines for new and modified products.
- Review product, supplier, and manufacturing changes as well as verification and validation activities, for compliance with applicable regulations and procedures.
- Support Quality teams by providing guidance and serving as a resource in the development and implementation of CAPA, internal audit and vendor/supplier audit programs..
- Review and approve of labeling documents with focus of compliance to pre-defined claims and regulatory requirements.
- Travel to Sentec facilities in North America and Switzerland as needed (anticipated 3-6 times annually)

Sentec

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Lincoln, RI 02865
877.425.8746
www.sentec.com



Qualifications and Education:

- Bachelor's degree required.
- A minimum of 5 years' experience in a Regulatory Affairs position specifically within the medical device industry.
- In depth knowledge of the regulatory framework for medical devices with specific expertise for FDA and Health Canada/MDSAP.
- Analytical thinking and ability to compile scientific data and summarize results.
- Open-minded person with hands-on attitude and good team player.
- Fluent in English.

Life at Sentec

Sentec employees have access to competitive benefits packages, paid parental leave, tuition reimbursement and more. Sentec offers a place to thrive and make an impact as a small company with huge potential and an expanding track-record of consistent growth. We know our decisions matter to the future of the company, our voices are heard by leadership and our hard work pays off.

Sentec consists of an eclectic group of people dedicated to help deliver products to healthcare providers that make a difference and improve patient care. We love that we can log off each day knowing we've made a difference.

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

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An orange circular icon containing the text "Care with Confidence" in white.

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