ReCor Medical
Ultrasound Denervation Therapies

Regulatory Affairs Specialist
Department: Regulatory Affairs

About ReCor Medical

ReCor Medical, headquartered in Palo Alto, CA, is an innovative medical technology company focused on transforming the management of hypertension, the leading cardiovascular risk factor in the world. ReCor has pioneered the innovative, minimally invasive use of ultrasound in renal denervation to lower blood pressure in patients with hypertension. The company is focused on investing in high quality product development efforts, as well as rigorous clinical studies to create a strong foundation for future clinical adoption.

ReCor Medical is a wholly-owned subsidiary of Otsuka Medical Devices Co., Ltd. Otsuka Medical Devices focuses on the global development and commercialization of endovascular therapies that provide new therapeutic options in areas where patient needs cannot be met through pharmaceutical treatment. Otsuka Medical Devices Co., Ltd. is a subsidiary of Otsuka Holdings Co., Ltd., a leading global healthcare group listed on the Tokyo Stock Exchange (JP 4578). With operations in pharmaceuticals, nutraceuticals, medical devices and other health-related businesses, the group generated worldwide sales of app. US$13 billion in the fiscal year ended December 2019 and has a market capitalization of app. US$25 billion.
http://www.omd.otsuka.com/en/ http://www.otsuka.com/en/

Position Summary

The Regulatory Affairs Specialist will join a growing Global Regulatory Affairs Team focused on ultrasound based technology. The RA specialist will join the team to provide additional support on the development of internal processes, product documentation (R&D and manufacturing) and to provide support of all regulatory submissions in the US, UK, EU, and Japan

Responsibilities and Duties

- Responsible for coordinating the planning preparation, assembly, review and publication of regulatory submissions to the FDA, EU Notified Body (MDR compliant) and other agencies as needed.
- Prepare and maintain Technical Documentation (MDR compliant)
- Evaluate and maintain current regulatory policies, processes, procedures.
- Provide input on and reviews protocols and reports for: design verification, design validation, shelf life, process validation etc.
- Assist in EU MDR Implementation

- Assist in the preparation of US IDE submissions
- Assist in the preparation for US PMA submission & panel meetings, as required.
- Provide regulatory input and technical guidance to product development and operations teams.
- Work collaboratively with product development teams.
- Provide support of device labeling/ IFU updates
- Provide support and review of advertising & promotional materials
- Perform other duties as assigned.
- Maintain up-to-date knowledge and understanding of regulatory requirements in the US, UK/EU and rest of world

Requirements:

- Minimum of a Bachelors' degree life sciences, or biomedical engineering
- Prior cardiovascular device industry, 3 years preferred
- Prior regulatory experience in the medical device industry, 3 years preferred
- Strong verbal and written communication skills.
- Individual contributor willing to be part of a team, and willing to work collaboratively

Equal Employment Opportunity

At ReCor Medical, we value bringing together individuals from diverse backgrounds to develop new and innovative solutions for patients. As an equal opportunity employer we do not discriminate on the basis of race, color, religion, national origin, age, sex (including pregnancy), physical or mental disability, medical condition, genetic information gender identity or expression, sexual orientation, marital status, protected veteran status, or any other legally protected characteristic.

Join our growing team! Email resume to careers@recormedical.com