ReCor Medical
Ultrasound Denervation Therapies

Manager, Regulatory Affairs
Department: Regulatory Affairs
Reporting to: Director, 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 Manager, Regulatory will join the ReCor Medical Regulatory team and report to the Director, Reguatory Affairs. The Manager will work closely with the Director on the implementation of global regulatory strategies. The individual will be responsible for the preparation of US and International regulatory submissions/ product registrations for Class II and Class III medical devices.

Responsibilities and Duties

- Prepare IDE, PMA, design dossiers and technical files, for US FDA and other international markets.
- Assist /lead EU MDR implementation.
- Plan, coordinate, and prepare regulatory submissions
- Develop and manage regulatory timelines to ensue timely submissions.
- Interface with Regulatory Agencies, such as FDA, Notified Body and competent authorities as required.
- Assist in preparation for PMA panels, as required
- Review and approve internal engineering documents

- Assist with review of advertising & promotion materials
- Keep abreast of changes in agency regulations and requirements; and train team accordingly
- Provide regulatory guidance with preparation, review, and approval of advertising and promotional materials
- Interact collaboratively with Clinical, R&D, and Quality, and coordinate regulatory priorities across the company
- Participate on new product development teams and develops regulatory strategies.
- Maintain regulatory correspondence and submissions/registrations.
- Knowledgeable in US and international in medical device regulations.
- Continuously evaluate, recommend and implement improvements as needed.
- Willingness to perform other responsibilities as assigned.

Requirements

- Minimum of a Bachelors' degree preferably in life sciences and/or biomedical engineering
- Minimum of 5 years cardiovascular device industry
- Minimum of 5 years experience in regulatory within medical device industry
- Prior experience with US IDE submissions, PMA experience preferred
- Experience/knowledge of MDR
- Independent and proactive personality; able to think critically and work collaboratively in a global environment
- Strong verbal and written communication skills
- Ability to think strategically and critically
- Self-motivated with excellent time management skills
- Strong team player; 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.