ReCor Medical
Ultrasound Denervation Therapies

Manager, Regulatory Affairs
Department: Regulatory Affairs
Reporting to: Director, Regulatory Affairs
Location: Palo Alto

About ReCor Medical
At ReCor Medical, we are pioneering Ultrasound Renal Denervation (uRDN) therapy to treat hypertension, the leading cardiovascular risk factor in the world. With our Paradise™ uRDN System, we're on a mission to provide the millions of people who suffer from hypertension with a non-drug and minimally invasive option to lower their blood pressure safely and effectively. Join us on our journey and make a meaningful impact on the lives of people around the globe.

Position Summary
The Manager, Regulatory will join the ReCor Medical Regulatory team and report to the Director, Regulatory 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 ensure 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 in new product development teams and develops regulatory strategies.
- Maintain regulatory correspondence and submissions/registrations.
- Knowledgeable in US and international 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

Salary Range: $120K - $155K (Commensurate with experience, skills, education and training)

COVID-19 vaccination requirements

At ReCor Medical, we care, we collaborate, we challenge, and we create. Pursuant to these core values, we are focused on the health and safety of our employees, as well as the teamwork essential for innovation of our pioneering technology.

COVID19 vaccines are required for all ReCor US office employees effective June 10, 2021, as well as all new US office employees joining our company. Fully vaccinated persons are those who are >=14 days post-completion of the recommended series of an FDA-authorized COVID-19 vaccine.

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.