ReCor Medical
Ultrasound Denervation Therapies

Clinical Regulatory Affairs Manager
Department: Regulatory Affairs
Reporting to: Director, Regulatory Affairs
Location: Palo Alto (Hybrid)

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 Clinical Regulatory Affairs manager will join the ReCor Medical Regulatory team and report to the Director Regulatory Affairs. The Manager will work closely with the Director on supporting the clinical programs at ReCor Medical. The individual will be responsible for supporting project teams in planning and execution of activities in support of the clinical programs and ensure regulatory compliance.

Responsibilities and Duties
- Collaborate with Clinical Study Managers in the preparation and development of study protocols and data collection strategies to aid global regulatory commitments and marketing claims; make recommendations for statistical analyses.
- Plan, coordinate, and prepare clinical regulatory submissions.
- Prepare IDE. IDE/S, IDE AR as necessary, for US FDA and EU clinical studies.
- Keep abreast of changes in agency regulations and requirements, and train stakeholders accordingly.
- Contribute to EU MDR and MEDDEV compliant Clinical Evaluation documents for new products and maintain/update existing company Clinical Evaluation Plans (CEPs), Clinical Evaluation Reports (CERs), and Post Market Clinical Follow Up (PMCF) Plans/Reports in alignment with applicable clinical and regulatory standards and business needs.
- Partner with cross-functional stakeholders to compile data from multiple sources including clinical trials, medical literature, design verification/validation data, and product complaint data. Includes development of literature search strategies and methodical evaluation of medical literature for submission to regulatory bodies.
- Identify potential clinical evidence gaps and contribute to development of prospective evidence strategies to address gaps.
- Ensure alignment of clinical data with risk documentation and contribute to product labeling.
- Represent regulatory in clinical program teams and communicate regulatory strategies.
- Lead the development of internal procedures, templates, style guides and departmental continuous improvement initiatives as they relate to the function.

- Maintains knowledge of regulatory environment, regulations, and guidelines.
- 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 and 2 years with CEP, CER, PMCF.
- Prior experience with US IDE submissions, CER, PMS, PMCF
- Prior Experience with reviewing promotional material.
- Experience/knowledge of MDR requirements and Clinical evaluation requirements
- 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.

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 based on 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.