

## **Title: Manufacturing Engineer, Process Control**

Department: Operations

Reporting to: Megan Lopez

Location: Palo Alto

## **About ReCor Medical**

ReCor Medical is a medical device company that designs and manufactures the Paradise System, a proprietary ultrasound ablation system for renal denervation (RDN). RDN is a new potential therapeutic approach for the treatment of hypertension, one of the most prevalent medical conditions. The Paradise System is approved for sale in the EU and bears a CE mark, but is not approved for sale in the United States. The System's intravascular catheters denervate renal nerves by combining the protection of water-based cooling of the renal artery with high intensity ultrasound energy for circumferential renal nerve ablation. The Paradise System has been studied in clinical trials of approximately 300 patients to date. Following the positive outcomes of the RADIANCE-HTN SOLO trial, ReCor will continue its evaluations of Paradise in RADIANCE-HTN TRIO (a feasibility study of patients with resistant hypertension), REQUIRE (a pivotal study of patients with resistant hypertension in Japan and Korea), and most recently with the launch the RADIANCE II pivotal study (a study of patients with moderate hypertension) in the United States and Europe.

## **Position Summary**

This is a hands-on position, which the right candidate will be able to adapt quickly to changing priorities and manage multiple projects simultaneously. They will organize cross-functional teams to develop and implement systems that help ReCor gather, record, and trend data in order to streamline processes, monitor, and continuously improve products. The goal of this position is to advance commercial control and readiness activities for manufacturing. Position reports to the Sr. Manager, Process Control.

## **Responsibilities and Duties**

- Manage multi discipline groups for project scoping, execution, and implementation
- Hands on development, qualification and implementation of new systems pre/during/and post-production, integrating mechanics, electronics, and software
- Evaluate existing processes and scale-up activities for process improvements and economy-of-scale efficiencies
- Implement improvements for cost-savings and product quality while managing technical and compliance risks
- Develop strategies for test method validations, software validations, and process validations
- Author validation/qualification protocols and reports for product, process, equipment, and/or software

# ReCor Medical

## Ultrasound Denervation Therapies

- Develop manufacturing process controls
- Support production capacity improvements
- Work with suppliers as necessary to align control requirements
- Support Equipment Control, review/revise equipment specifications and qualification requirements
- Support the regulatory submission process in compliance with all ISO, MDD/MDR and FDA regulations and requirements

### **Requirements**

- Minimum 5+ years in a regulated environment such as medical devices with an understanding of domestic and international regulatory standards (i.e. FDA QSR, ISO 13485 and MDD/MDR).
- Bachelor of Science degree in Engineering.
- Working knowledge of design controls, process validation, statistics, and design of experiments.
- Proven track record of product engineering leadership resulting in quantifiable improvements in quality, yield, cost, or process.
- Effective verbal and written communication skills.
- Exhibit good problem solving and analytical skills.
- Self-motivated, action oriented and result oriented.
- Proficient in the use of Microsoft Office Suite.
- Proficient in the use of Microsoft Office Suite and statistical software (i.e. JMP, MiniTab, etc).

### **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  $\geq 14$  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.