

# ReCor Medical

Ultrasound Denervation Therapies

## **Manufacturing Engineer, Process Control**

Department: Operations

Reporting to: Sr. Manager, Process Control

Location: Palo Alto, CA

## **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 approximately US\$13 billion in the fiscal year ending December 2021 and has a market capitalization of approximately US\$19 billion.

<http://www.omd.otsuka.com/en/> <http://www.otsuka.com/en/>

## **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 Manager of 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 validation strategies

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- Author validation/qualification protocols and reports for product, process, equipment, and/or software
- Develop manufacturing process controls
- Support production capacity improvements
- Work with suppliers as necessary, to align control 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.

### **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 the innovation of our pioneering technology. **COVID-19 vaccines will be 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 primary series of an FDA-authorized COVID-19 vaccine. **This is a full-time office position.**

### **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.

E-mail resume to HR: [Careers@recormedical.com](mailto:Careers@recormedical.com)