ReCor Medical
Ultrasound Denervation Therapies

Senior Process Quality Engineer
Department: Operations
Reporting to: 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 provide support to the Operations team to maintain and continuously improve the Products and advance commercial control and readiness activities for our manufacturing. They will provide support to ensure delivery of the safest and highest quality products while maintaining full regulatory compliance. Position reports to the Manager, Process Control.

Responsibilities and Duties
- Manage multi-discipline groups for project execution and implementation
- Review/author validation/qualification protocols and reports for the product, process, equipment, and software
- Hands-on development, qualification, and implementation of new production systems integrating mechanics, electronics, and software
- Support Operations on process validation and manufacturing process controls including:
    - Developing validation strategies
    - Evaluating existing processes and scale-up activities for process improvements and economy-of-scale efficiencies to improve cost-savings and product quality while managing technical and compliance risks

- Support production capacity improvements
- Support qualification of alternate supply sources or new vendors
- Support engineering investigations and root cause analysis
- Supports the regulatory submission process in compliance with all ISO, MDD/MDR, and FDA regulations and requirements
- Support in-process inspections by establishing/revising specifications and/or inspection methods.
- Support equipment calibration and preventative maintenance program
- Update and maintain proper Quality System records, reports, and statistics

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 or related field with a proven track record of transitioning products from NPI to volume production.
- Working knowledge of design controls, process validation, statistics, and design of experiments.
- Proven record of product engineering leadership resulting in quantifiable improvements in quality, yield, cost, or process.
- Effective verbal and written communication skills; ability to write clear procedures
- Exhibit good problem solving and analytical skills
- Self-motivated, action-oriented, and result-oriented.
- 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 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 >=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