ReCor Medical
Ultrasound Denervation Therapies

Senior Quality Engineer
Department: Operations
Reporting to: Manager, Quality Systems Operations
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 app. US$13 billion in the fiscal year ended December 2019 and has a market capitalization of app. US$25 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 Operations Quality Manager.

Responsibilities and Duties
- Manage multi discipline groups for project execution and implementation
- Review/author validation/qualification protocols and reports for 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 incoming inspections and final lot release testing
  - Establish and revise specifications for raw materials, in-process and final product
  - Review inspection reports
- 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).

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