ReCor Medical
Ultrasound Denervation Therapies

Staff Quality Engineer
Department: Quality Affairs
Reporting to: Director, Quality Engineering
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/

Responsibilities and Duties

- Support company goals and objectives, policies, and procedures
- Support the identification, refinement, and definition of product requirements.
- Ensure risk management is effective; perform risk analyses and track to requirements
- Support Product Development on creating and/or reviewing design verification and validation test plans, protocols, procedures, and reports
- Review user interfaces for consistency and functionality and provide support to ensure reliability of the system requirements and software requirements are met.
- Support Operations on process validation and manufacturing process controls
    - Develop validation strategies, so that all appropriate requirements are being met from planning, protocol objective, leading execution of the protocol, analyzing and reporting results and defining procedures and training requirements, completing the report and obtaining approval
    - Evaluate 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

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- Update and maintain proper Quality System records, reports, and statistics
- Uses in-depth professional knowledge to resolve complex issues and understands the interrelationships of different disciplines

Requirements

- Minimum of 8 years' experience in the Medical Device or related field, preferably minimally invasive medical devices.
- Proven ability to make informed and independent decisions after careful evaluation of data
- BS in Engineering or Biological Science or equivalent.
- Experience with Statistical Tools such as JMP, Minitab
- Working knowledge of Risk Management ISO 14971
- Working knowledge of ISO 13485
- Experience in working in a team environment
- Strong communication skills

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