

# ReCor Medical

Ultrasound Denervation Therapies

## **Principal Quality Engineer**

Department: Quality Affairs

Reporting to: Director, Quality Engineering

Location: Palo Alto, CA

## **About ReCor Medical**

At ReCor Medical, we are pioneering Ultrasound Renal Denervation (uRDN) therapy to treat hypertension, the leading cardiovascular risk factor in the world. With our Paradise™ uRDN System, we're on a mission to provide the millions of people who suffer from hypertension with a non-drug and minimally invasive option to lower their blood pressure. Join us on our journey and make a meaningful impact on the lives of people around the globe.

## **Responsibilities and Duties**

- Support company goals and objectives, policies, and procedures
- Support the identification, refinement, and definition of product requirements.
- Support Product Development on creating and/or reviewing design verification and design validation test plans, protocols, procedure, and reports.
- Ensure risk management is effective; perform risk analyses and track to requirements
- Support Cybersecurity for Medical Devices risk management
- Review user interfaces for consistency and functionality and provide support to ensure reliability of the system requirements and software requirements are met.
- Create, revise and review SOPs and Design Control Documentation and manufacturing documentation to maintain compliance with regulations and ISO requirements.
- 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
- Support managing incoming inspections, and final lot release testing as a part of the Design Transfer Process.
  - Determine sampling plans, equipment requirements, measurement techniques, and training requirements.
  - Establish and revise specifications criteria for raw materials, in-process, and final product.
- 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

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## **Requirements**

- Minimum of 10 plus 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 with Risk Management/Cybersecurity of Medical Devices or equivalent
- Experience in working in a team environment.
- Strong communication skills

**Salary range:** \$165K - \$180K (Commensurate with experience, skills, education and training)

## **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.