

Title: Sr Quality Engineer, Production Support

Department: Quality

Reporting to: Sr Manager, Quality

Location: Palo Alto, CA

About ReCor Medical

ReCor Medical is a medical device company that designs and manufactures the Paradise System, a proprietary ultrasound ablation system for renal denervation (RDN). RDN is a new potential therapeutic approach for the treatment of hypertension, one of the most prevalent medical conditions. The Paradise System is approved for sale in the EU and bears a CE mark, but is not approved for sale in the United States. The System's intravascular catheters denervate renal nerves by combining the protection of water-based cooling of the renal artery with high intensity ultrasound energy for circumferential renal nerve ablation. The Paradise System has been studied in clinical trials of approximately 300 patients to date. Following the positive outcomes of the RADIANCE-HTN SOLO trial, ReCor will continue its evaluations of Paradise in RADIANCE-HTN TRIO (a feasibility study of patients with resistant hypertension), REQUIRE (a pivotal study of patients with resistant hypertension in Japan and Korea), and most recently with the launch the RADIANCE II pivotal study (a study of patients with moderate hypertension) in the United States and Europe.

Position Summary

In this hands-on role, the right candidate will apply diversified knowledge of engineering and quality principles/practices for production support and ensuring quality system compliance. The candidate shall bring expertise in risk management, sustaining design changes, supplier management, and process validations and provides guidance to and interacts with Manufacturing Engineering and management in solving product and process quality issues. Also identifies opportunities for improvement and mitigates risks in process deployment and sustaining process capability.

Responsibilities and Duties

- Ensure compliance with all procedures and all applicable regulatory agency requirements
- Leads cross-functional teams to achieve consensus for deliverables associated with quality issues
- Provide Quality Engineering support for project development or sustained manufacturing activities, such as product transfers from development to production, design or process change, and validation
- Interact with customers and suppliers to resolve NCMR and CAPA investigations and in support of manufacturing
- Identifies continuous improvement and collaboration opportunities, promoting development and implementation of quality data and reports for improvement and optimization

ReCor Medical

Ultrasound Denervation Therapies

- Interface with suppliers to ensure components and product meets specifications
- Maintain inspection procedures for the inspection of incoming materials, in-process materials and finished goods
- Select appropriate inspection, test and measurement equipment, fixtures, and gauges
- Develop quality systems and procedures as needed
- Review and document procedure changes for quality requirements and compliance with the quality system
- Audit the work of others through review of labeling, documentation (MPI's, LHR's, etc.) and lot history records and provide final quality approval
- Audit support for internal and external audits
- Other duties as assigned

Requirements

- 5-8 years in Quality Assurance/Quality Engineering from medical device industry
- Bachelor's degree in an engineering discipline or equivalent
- Regulations experience in any: FDA 21 CFR Part 820, ISO 13485, ISO 14971
- Working knowledge of design controls, risk management, process validation, and statistical techniques.
- Strong written and verbal communication skills and ability to collaborate effectively
- Proficient in the use of Microsoft Office Suite

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