ReCor Medical
Ultrasound Denervation Therapies

Principal Manufacturing Engineer

Department: Operations
Reporting to: Director of Manufacturing 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.otsuka.com/en/

Position Summary

This is a hands-on position which will plan and execute commercial control and readiness activities for our manufacturing. Position reports to the Director of Manufacturing Engineering.

Responsibilities and Duties

Duties & responsibilities include, but are not limited to:

- Manage multi discipline groups for project execution and implementation
- Authoring validation, qualification protocols and reports
- Hands on development, qualification and implementation of new production systems integrating mechanics, electronics, and software
- Identify and drive production capacity improvements
- Identify, manage, and qualify alternate supply sources or new vendors
- Hands on investigation and root cause analysis

- Define process corners and product process targeting from characterization results
- Characterize NPI product performances and yield including bench correlation to meet product cost targets
- Supports the regulatory submission process in compliance with all ISO, EN MDD and FDA regulations and requirements

Requirements:

- Must have experience in a regulated environment such as medical devices
- Bachelor of Science degree in Engineering or related field with a proven track record of transitioning products from NPI to volume production.
- 8+ years of experiences with NPI; specifically, in product engineering and assembly with focus on yield, cost and manufacturing process improvements.
- Experience with complex data analysis using JMP, MiniTab, or other yield tools.
- Experience with solid modeling using Solidworks or other modeling software.
- Proven record of product engineering leadership resulting in quantifiable improvements in quality, yield, cost or process.
- Self-motivated, action oriented and result oriented.
- Deep understanding of medical device processes and assembly knowledge to drive product yield and performance.