

ReCor Medical

Ultrasound Denervation Therapies

Business Systems Manager – Clinical Research

Department: Clinical Affairs

Reporting to: Sr. Director, Clinical Data Management

Location: Palo Alto, CA / Remote optional

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 approximately US\$13 billion in the fiscal year ending December 2021 and has a market capitalization of app. US\$19 billion.

<http://www.omid.otsuka.com/en/> <http://www.otsuka.com/en/>

Position Summary

The Business Systems Manager is an experienced leader who understands how to lead and develop a team while juggling multiple critical business priorities. The role will be responsible for managing all clinical research systems such as Clinical Trial Management Systems (CTMS), electronic data capture (EDC), electronic trial master file, and RSTUDIO for reporting solutions.

The Business system manager leads the selection or development for new clinical solutions that may be off the shelf or home-grown solutions. The manager will evaluate solutions that support decentralized trials, including the use of wearable medical technologies (e.g., apple watch, cardiac patches).

Responsibilities and Duties

- Develop goals and strategies to ensure the clinical research business systems department runs smoothly and effectively
- Partner with business stakeholders to understand their processes and data requirements to develop robust solutions that met their objectives and specified outcomes.
- Lead systems implementation projects (e.g., requirements documentation, systems design, test documentation/execution, user guides, issue identification, and resolution).

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- Ensure systems used to make patient safety decisions or regulatory reports are validated per 21 CFR Part 11.
- Work with end-user groups to define project KPIs and metrics, and collaborate with business systems analysts to design, build, deploy and support solutions.
- Provide subject matter expertise for the clinical research-related process, systems, integrations, and identify impacts and triage issues due to bugs, functional changes, etc.
- Participate in vendor relationships, including evaluation and negotiation
- Drive continued automation and integration of our internal systems
- Contributes to, and applies, consistent standards through processes and work instructions.
- Acts independently to determine methods and procedures on new assignments
- Other duties as assigned

Requirements

- Bachelor's degree (or international equivalent) in computer science, mathematics, Life Sciences, or other appropriate disciplines
- At least eight years of Business Systems Analyst experience, coupled with 5+ years of management experience with at least 2 years managing direct reports.
- Knowledgeable in GCP, CDISC standards, clinical trial guidelines & Data Management Best Practices.
- Experience with clinical research technologies such as Clinical Trial Management Systems (CTMS), electronic data capture (EDC), electronic trial master file, and RSTUDIO for reporting solutions

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