ReCor Medical
Ultrasound Denervation Therapies

Clinical Safety Associate
Department: Medical Affairs
Reporting to: Sr. Manager, Clinical Safety
Location: Palo Alto
Workplace Type: Hybrid

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 safely and effectively. Join us on our journey and make a meaningful impact on the lives of people around the globe.

Position Summary
The Clinical Safety Associate will be a member of the team responsible for Clinical Safety for a Global Clinical Trial program. This position will work under the direction of the Manager, Clinical Safety.

The Clinical Safety Associate will be responsible for the processing of adverse events and product experiences reported within clinical studies; will ensure that the review of events is performed in a timely manner and communicated to internal stakeholders; and will ensure the timely reporting of all applicable events to regulatory authorities.

Responsibilities and Duties
- Processing of all clinical adverse events to include timely review, assessment, coding, and reporting as required
- Ability to work collaboratively with study clinical site managers and clinical research associates to ensure comprehensive information is available for full review, coding, and reporting
- Familiar with medical terminology and MedDRA coding
- Safety event narrative writing as required
- Assist with preparation of materials for DSMB as needed
- Assist with preparation of materials for CEC as needed
- Assist with preparation of safety data for annual, interim, and final reports of clinical information.
- Participate in vigilance safety assessment and reporting consistent with applicable regulations
- Provide administrative support for overall clinical study start-up process
- Support clinical procedure training as needed
- Quality-focused. Ensure protocol compliance, facilitation of data collection and source document verification and compliance.
- Continuously evaluate, recommend, and implement quality improvements as needed.

- Independent and proactive personality; able to think critically and create customer-based solutions.
- Position requires cross-functional collaboration with Clinical Affairs, Biostatistics & Data Management, R&D, and Quality

Requirements

- Minimum of a Bachelors' degree health-related, RN, or other scientific discipline
- Preferred 1-2 years cardiovascular device industry
- Preferred 1-2 years clinical trial experience
- Working knowledge of clinical trial and regulatory process required including FDA; ICH and ISO regulatory rules.
- Working knowledge of medical terminology
- Strong verbal and written communication skills.
- Proficient in MS Office and database navigation skills
- Self-motivated with excellent time management skills

Salary range: $93K - $117K (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 >=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.