**Company:** Lungpacer Medical USA Inc.

**Address:** 260 Sierra Drive, Suite 116
Exton, PA 19341

**Position:** **Senior Clinical Operations Manager**

Lungpacer Medical USA Inc., a subsidiary of Lungpacer Medical Inc. - a British Columbia Corporation, is developing a novel therapeutic solution for preserving the integrity and strength of the diaphragm muscle in critically ill patients who require mechanical ventilation, is seeking to hire experienced and highly motivated **Senior Clinical Operations Manager**.

As a member of the **Clinical Compliance** Team, the individual in this position is responsible for providing operational support for clinical related activities, under direction of Lungpacer Medical's Director of Clinical Compliance. The role includes the development and implementation of clinical research projects, creation and management of study timelines, budgets, reports and communication materials, assistance with oversight of Clinical Research Organizations (CROs) and other vendors, and the preparation, review and approval of various study related documents and plans.

**Responsibilities**

- Support the Director of Clinical Compliance in assisting the Clinical team execute and deliver clinical studies in accordance with clinical development plans/strategy and timelines.
- Develop and maintain clinical timelines using Microsoft Project.
- Manage and maintain the Project team tracker. Prepare and maintain project organograms.
- Assist with the development and maintenance of the project and risk management plans.
- Manage the overall study budget, track invoices and facilitate clinical study and vendor (CRO and CRA) payments.
- Assist with execution of clinical studies including the management, of vendors including CROs, review of work orders and review of invoices.
- Interface with Clinical Affairs staff to ensure engagement and coordination of activities for clinical studies.
- Proactively identify areas of risk and contribute to the risk management plan.
- Monitor and track progress of clinical study activities. Assis the Director of Clinical Compliance in preparing reports on the progress of assigned clinical trials including enrollment, budget and timelines.
- Track and forward regulatory documents to the CRO for the clinical Trial Master File.
- Review study-related plans generated by CROs and vendors to ensure documentation is in accordance with GCP regulatory requirements and consistent with the protocol.
- As needed, contribute to the writing and review of clinical documents including the protocol, consent form, investigator brochures, monitoring plan, clinical trial reports and annual IRB/EC reports.

- Support the Clinical team with start-up activities including but not limited to investigational site contracts, investigational site and ethics committee/IRB submissions (working collaboratively with clinical site managers and external resources such as legal counsel).
- Provide support to the VP of Regulatory Affairs for regulatory submissions, filings and strategy, including regulatory reporting of safety events to appropriate regulatory authorities.
- Provide support to the Quality department during audits and corrective action resolution and reporting (CAPA) related to clinical trials activities.
- Prepare clinical documents for DCO and route them through to final execution.
- Assist the Clinical Affairs team in the planning and conduct of Investigator Meetings, Study Coordinator meetings, etc.
- Assist the Director of Clinical Compliance in the drafting and preparation of new department SOPs, review, and training of the clinical team, CRAs and CRO. Prepare process flowcharts as needed.
- Support the preparation of Clinical related information for Board of Directors and other stakeholders under the direction of the Director of Clinical Compliance.

**Qualifications & Required Skills**

- Bachelor's degree is required. Scientific/health care background preferred, but not required.
- Minimum of 7 years in in clinical trial research and project management.
- Thorough working knowledge of FDA and ICH GCP guidelines.
- Experience managing CROs, budgets, and timelines.
- Strong verbal and written communication skills.
- Ability to organize and manage multiple priorities in a fast-paced environment.
- Ability to work independently.
- Strong interpersonal skills to interact with investigators, vendors, CRO, field and in-house individuals at all levels of the organization.

The primary location of work will be at our facility in Exton, PA. The position may require some travel.

Qualified candidates may send a letter of interest and resumé to hr@lungpacer.com by **March 25, 2019**. Please quote **Senior Clinical Operations Manager** in your e-mail subject box.

*We thank all interested applicants. However, only those under consideration will be contacted. No Phone Calls, please.*