Portal Instruments

Clinical Affairs Lead

R&D: Quality & Regulatory | Cambridge, MA
Reports to: VP Quality and Regulatory

DESCRIPTION

The Clinical Affairs Lead will report to the VP Quality & Regulatory and will provide clinical leadership and guidance to the organization with a patient-centric focus on drug delivery, patient education and training at Portal Instruments, from a clinician's perspective.

This role will plan and execute successful clinical studies in support of corporate objectives, demonstrating proficiency in all areas of clinical study development and execution with an ability to build and direct effective multi-disciplinary project teams.

Role and Responsibilities:

Clinical Oversight

- Develop an understanding of competitive landscapes for assigned products and therapeutic areas;
- Develop and implement standardized processes and operating procedures for conducting clinical research;
- Ensure research activities comply with local regulatory requirements, Portal SOPs, GCPs and that audit readiness is maintained throughout trail conduct.
- Oversee development and management of clinical database;
- Drive quality efforts to proactively identify and manage risks to trial quality and ensure inspection readiness

Clinical Study Management

- Oversee the planning and execution of clinical studies to ensure that deliverables are completed on time and within budget
- Develop and manage study related documents and materials such as study protocol, investigational plans, case report forms, study manuals, monitoring plan, informed consents, investigator brochure, websites, recruitment materials and other study related tools
- Coordinate the development, drafting, and submission of clinical reports, clinical study data, and Summary of Safety and Effectiveness Data. Support and provide data reviews of abstracts, manuscripts, presentations, Instructions for Use, and other materials that include study data;

- Orchestrate the publishing of research papers in peer-reviewed journals, based on the results of the clinical trials;
- Lead the evaluation, selection, and oversight of CROs and other external vendors to ensure successful clinical trial implementation and execution
- Develop and manage overall study budgets; negotiation of budgets with clinical sites, vendors, and consultants
- Ensure that internal and external clinical study teams fulfill their responsibilities in accordance with corporate standards, regulations, and good clinical practice;
- Oversee appropriate reporting and documentation of adverse events and protocol deviations per investigational plan requirements;
- Conduct on-site clinical monitoring/quality activities as needed;

Other

- Participate on cross functional core project team to ensure clinical deliverables are aligned with corporate objectives;
- Support regulatory submission activities globally where clinical study data is needed to show product safety and efficacy, including drafting of Clinical Evaluation Reports
- Apply critical thinking in identifying the right clinical outcomes that Portal needs to demonstrate to advance the adoption of its drug delivery device
- Ability and willingness to travel 15-20% of the time.

Skills and Experience:

- Bachelor's Degree Nursing. Current and valid Registered Nurse license.
- 3 - 5 years progressive experience as clinical research coordinator in an academic medical center or the biotech/pharmaceutical/medical device industry
- Knowledge of IRB procedures through all phases of study development
- Experience in drug delivery technology will be favorably considered
- Clinical experience in Gastroenterology and Dermatological diseases a plus
- Ability to work in a fast pace, cross-functional, start-up environment
- Multi-dimensional Clinical operations background with capability of devising plans for operational challenges such as site activation, patient enrollment, monitoring oversight, protocol deviation management, data cleaning, clinical supply management.
- Outstanding verbal and written communication skills including clinical authoring experience including protocols and investigator brochures
- Thorough knowledge of FDA and ICH GCP guidelines to ensure the appropriate conduct of clinical studies globally

- Excellent organizational as well as problem-solving skills as well as the ability to work independently
- Proven track record of effective leadership in the context of a multi-disciplinary team in the biotech or pharmaceutical industry
- Strong interpersonal and team skills to work both independently and collaboratively as part of a multidisciplinary team
- Excellent communication skills, both written and oral

Qualifications:

- Requires Bachelor's degree in Nursing
- Nursing license, such as RN
- Master's degree a plus

About Portal Instruments

Portal Instruments is a Series B funded medical device company focused on advanced drug delivery and backed by powerful strategic partners and venture investors. We are developing and commercializing a highly innovative needle-free drug delivery platform technology to transform the administration of medicines and improve the patient experience for chronic diseases. Portal's needle-free delivery technology enables the injection of high viscosity biologic drugs without the pain, anxiety and troublesome handling of needles. Our needle-free breakthrough technology is precise, reliable and comfortable to use. Additional real time tracking and reporting set a new standard for interactivity between patient and care teams to improve outcomes. Come join us on this exciting journey of making chronic patient care and comfort a priority.

Working at Portal Instruments

- Portal Instruments is looking for unique individuals who want to make a difference in the lives of patients and how medicines are delivered today
- Portal Instruments offers employees the opportunity to work in a fast-paced start-up that values innovation, intellectual rigor, accountability, teamwork, and openness while providing excellent leadership and development opportunities
- Portal Instruments is an equal opportunity employer offering a competitive salary, a comprehensive benefits package, including stock options, a 401(k) retirement plan, a health and dental plan and a chance to make a difference in the lives of thousands of patients.

Portal Instruments

To Apply: Please submit a resume and cover letter to: careers@portalinstruments.com, and please reference the position that you are applying for. You will be contacted if your background meets Portal's needs.

Disclaimer: The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not to be construed as an exhaustive list of all responsibilities, duties, and skills required of personnel so classified. All personnel may be required to perform duties outside of their normal responsibilities from time to time, as needed.