Portal Instruments

Medical Director

Reports to: CEO

DESCRIPTION

The Medical Director will report to the CEO and will provide medical and 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:

Medical Expertise

- Develop the medical affairs function within Portal Instruments
- Provide in-house medical guidance to the cross-functional teams with respect to drug delivery practices across therapeutic areas
- Facilitate strong relationship building with medical and clinical staff at pharma partner organizations
- Lead and participate in clinical discussions including clinical data interpretation, strategic guidance on evidence generation, clinical communications and developing changed in medical practice

Clinical Study Management

- Formulate and execute the clinical development plan including clinical trial strategy and the generation of evidence in support of the Portal portfolio ensuring 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, statistical analysis plan, informed consents, investigator brochure, websites, recruitment materials and other study related tools
- Serve as medical monitor for Portal clinical trials assessing issues related to protocol conduct and subject safety
- Coordinate the development, drafting, and submission of regulatory documents for approval including but not limited to: 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
- Drive the publication and presentation strategy including 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 appropriate clinical outcomes that Portal needs to demonstrate to advance the adoption of its drug delivery device
- Present at internal and external meetings (e.g., portfolio reviews, clinical advisory boards, investigator meetings, pre-study site selection visits and site initiation visits, Study Coordinator and CRA training, and internal and external medical/scientific meetings).
- Maintain awareness and keep program team informed of internal and external developments that may impact the investigational agent Clinical Development Plan, including attendance at major scientific conferences, participation in competitive intelligence activities, and periodic literature review.
- Maintain current knowledge of the external environment to ensure scientific innovations are considered and/or incorporated into clinical trial development strategy.
- Ability and willingness to travel 15-20% of the time.

Skills and Experience:

- MD or DO board certified/board eligible preferred
- Minimum of 3-5 years clinical practice experience post training

- 3 - 5 years progressive experience as medical professional in 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
- 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 fast-paced multidisciplinary team
- Excellent communication skills, both written and oral

Qualifications:

- Requires MD or DO

About Portal Instruments

Portal is transforming medicine by allowing chronic patients to self-inject their biological drugs with a needle-free device. This innovative drug delivery system replaces auto-injectors and is overwhelmingly patient preferred. Issued from MIT Research and easily connected to the cloud, the Portal device allows biopharmaceutical companies to augment their biological therapies and differentiate them from competitors. The device captures injection data in real time and transmit those via the cloud to all stakeholders for optimal care. Portal's business model is to partner with biopharmaceutical companies and co-develop drug/device combination products. The company has partnerships with Takeda Pharmaceuticals, LEO Pharma, Sanofi SA and 3M. It is currently at the pre-launch stage with pilot lines producing products for clinical evaluation. Come join us on this exciting journey of making chronic patient care and comfort a priority..

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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, creativity, accountability, teamwork, and openness while providing excellent leadership and development opportunities
- Portal Instruments is committed to challenging implicit bias and creating an equitable work environment. We are proud to be an equal opportunity employer. All qualified candidates will receive consideration without regard to race, ethnicity or national origin, sexual orientation, gender identity or expression, genetics, military service, age, family status, or disability.
- Portal offers 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

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.