Director of Clinical Affairs

Reports to: Vice President, Research and Development, BioPorto Diagnostics Inc.

About the Role

Facilitates and develops relationships with the medical/scientific community by communicating product-concept and disease-related information to investigators and institutions. Provides information on research developments and changes in standards of care and medical treatment, giving perspective to activities associated with new product development. Manages the clinical trials on behalf of BioPorto directly and/or works with a clinical research organization for registrational trials. Additionally, manages the Investigator Initiated Study (IIS) process and program and is accountable for all clinical research at BioPorto.

Specialized and in-depth comprehensive knowledge and experience in clinical affairs. Duties are varied and complex often involving research, analysis and solution development. Provides direction on issues of expertise and serves in a leadership capacity in setting strategic direction for trials. Executes the experimental design and liaises with Principal Investigators. Requires the regular use of originality and ingenuity. Employs positive motivation techniques in supporting clinical trial sites to hit their enrollment objectives. Possesses and applies a broad knowledge of principles, practices and procedures in the field of clinical affairs. Is generally assigned more complex and difficult assignments that are broad in nature. Typically works with greater discretion and latitude. As the team grows and develops, recruits and trains personnel for support of the trials. Determines when to in-source or out-source the trials and is accountable for the trial budgets.

Responsible for maintaining and continuously improving the quality system and achieving quality objectives through daily actions. Responsible for appropriate and accurate documentation of activities.

About BioPorto

BioPorto is an in vitro diagnostics company focused on saving lives and improving the quality of life with actionable biomarkers — tools designed to help clinicians make changes in patient management. The Company uses its expertise in antibodies and assay development, as well as its platform for assay development, to create a pipeline of novel and compelling products that focus on conditions where there is a significant unmet medical need, and where the Company's tests can help improve clinical and economic outcomes for patients, providers, and the healthcare ecosystem.

The Company's flagship product is The NGAL Test, which has been designed to aid in the risk assessment of Acute Kidney Injury (AKI), a common clinical syndrome that can have severe consequences, including significant morbidity and mortality if not identified and treated early. With the aid of The NGAL Test, physicians can identify patients potentially at risk of AKI more rapidly than is possible with the current standard of care measurements, enabling earlier intervention and more tailored patient management strategies.

Knowledge, Skills, Attribute

- Doctorate degree requirement and 5+ years of previous related medical/scientific/clinical experience
- Hands-on experience with sponsoring and leading the execution of clinical trials for submission purposes
- Direct experience in managing Contract Research Organization (CRO) relationships
- In-depth knowledge of GCP Regulation including knowledge of ISO 14155:2020 - Clinical investigation of medical devices for human subjects
- Working knowledge of TMF (Trial Master File) structure and maintenance
- Knowledge of Clinical trials - Regulation EU No 536/2014 is a plus
- Ability to develop and maintain collegial relationships predominantly with specialists and generalists within respective fields, as well as nurses and other hospital professionals
- Ability to lead, direct, influence and empower multi-discipline teams and individuals
- Ability to successfully interface with senior management (within and external to the company)
- Collaborative - superior ability to engage the right people to produce the best results
- Capacity to manage conflict
- Superior oral communication skills, ability to tailor messages to different audiences while presenting complex material in a clear and consistent manner
- Excellent written communication skills
- Ability to prioritize work
- Strong analytical and problem-solving skills; Strong judgment and decision-making skills
- Ability to think strategically
- Ability to develop and maintain deep relationships with thought leaders and healthcare professionals
- Ability to analyze data and trends and summarize for purposes of FDA submission
- Excellent project management skills
- Proficient in Microsoft Office including Word, Excel, Power Point and Customer Relationship Management Systems (CRM), specifically Salesforce.

Travel

Home office based. Ability and desire to travel on a frequent basis (potentially up to 30%) and with short or minimal notice. This may include weekend and evening hours.

Work Environment, Expected Hours

Professionalism and the ability to represent in office, hospital, and business locations, including familiarity with appropriate safety and credentialing, is expected in this job role.

This is a full-time position.

Other Duties

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.

EEO Statement

BioPorto is an equal-opportunity employer. All qualified applications will receive consideration for employment without regard to sex, sexual orientation, gender identity or expression, race, color, religion, national origin, ancestry, genetic information, citizenship, age, disability, pregnancy, genetics, veteran status, or any other protected status under applicable federal, state, or local law.