Title: Director, Clinical Affairs
Location: Boston, MA

Company Information

GI Dynamics® Inc. is committed to alleviate the symptoms of type 2 diabetes and obesity for patients fighting these global epidemics worldwide. The company's revolutionary **EndoBarrier® is the first endoscopically delivered device therapy for the treatment of type 2 diabetes and obesity. EndoBarrier is aimed to bridge the gap between pharmaceuticals and surgery by providing an alternate treatment option to help reduce HbA1c and weight for individuals who are underserved by drugs and injections, but for whom surgery is not an option.**

Position Overview

GI Dynamics is seeking a Director of Clinical Affairs to manage various aspects of the clinical department for assigned project(s). This includes contributing to the strategic and operational leadership relative to the direction, planning, execution, and interpretation of all programs and the data collection activities. As a management team member, works to establish and approve methods for design and implementation of clinical, projects, including protocols, data collection systems and final reports, clinical activities. Responsible for selection, management of vendors in support of department. Contribute to meeting clinical budget. Also has operational responsibility for training, labelling, package design, etc. related to US and OUS clinical trials. Monitors adherence to protocols requirements. Interacts with various inside/outside groups to facilitate all programs. May select, develop, and evaluate personnel to ensure the efficient operation of the function. This job contributes to and supports the company's research and development, efforts to create high value medical devices to address unmet clinical needs.

Key Responsibilities

- **Develops global clinical affairs strategies, in collaboration with management, regulatory affairs, marketing, research & development, reimbursement and outcomes planning, and obtain approvals by the most effective method possible.**
- **Develop and execute Clinical Affairs Strategy to generate data for both regulatory and marketing purposes**
- **Travels to clinical sites for training and clinical trials oversite**
- **Enroll and manage KOL / physician-clinician engagement and lead the management of all Clinical Affairs investments and required support**
- **Execute studies in the US, and OUS in full compliance with all applicable GCP requirements, and local and international regulations and standards.**
- **Negotiates contracts and budgets with sites, CRO's and vendors.**
- **Responsible for data collection, analysis, and presentation to company management**
- **Responsible for preparing data for publication, white papers, presentations, etc.**
- **Manages team to prepare protocols for projects; reviews final study conduct documents such as study manuals, study plans, study tools, etc.**
- **Develops staffing plans according to needs.**

- **Initiate investigator and coordinator meetings.**
- **Participate in Risk management and R&D DRs representing clinical affairs**
- **Provides oversight of individual clinical trials to ensure full compliance with GCP and that safety concerns and/or adverse events are identified and appropriate responses to such concerns are executed.**
- **Provides advice to the customer complaint reportability team of adverse events and other clinical trial issues to regulatory agencies.**
- **Determines membership criteria and identifies potential members for clinical events committees and data monitoring committees. Reviews and approves trigger plans for CEC and DMC.**
- **Reviews and approves Clinical Risk Benefit Analyses.**
- **Reviews and approves study corrective action plans. Prepares for and participates in internal/external study-related audits.**
- **Develops and maintains Clinical Investigation, conduct infrastructure – drafting and/or reviewing of SOPs, DOPs, and Work Instructions.**
- Demonstrates thorough knowledge of and coaches' others in the **appropriate application of clinical research conduct, laws, regulations, standards, and compliance with applicable SOPs and policies**

Qualifications

- Bachelor's degree in related field and 15+ years' clinical experience, preferably in medical device **industry.**
- Master's degree (MBA, MSN, MS) or Doctorate highly desirable
- **Extensive knowledge of FDA requirements, hospital, and health care environments**
- 5+ years' experience in direct management of clinical teams required
- **Excellent written and verbal communication skills required**
- **Experience interacting with physicians, clinicians, and patients**
- **Possesses excellent leadership skills and ability to be very flexible, adaptable, and to work under pressure.**
- **Self-motivated and self-directed; conscientious approach to work assignments; enjoys the challenges of multitasking and working at a fast pace while staying flexible to shift tasks frequently**
- **Excellent interpersonal and negotiating skills; ability to adapt to changing work priorities; and ability to maintain good working relationships while dealing appropriately with sensitive and confidential matters and with a wide variety of personal and telephone contacts**
- **Demonstrated record of success and leadership**