Clinical Research Scientist (GI Dynamics, Inc.):

Support ongoing and future clinical studies for GI Dynamics, a leading company in the development of surgical medical devices to treat diabetes. Responsible for trial start-up, conduct, and closeout activities on clinical trials of moderate to high complexity. Address site, CRA and vendor-related issues to deliver clinical projects on time and aligned with the company's stated objectives. Duties include:

1. Shepherd clinical studies to obtain regulatory approval of company's product;
2. Ensure all clinical studies are scientifically valid, meet all relevant regulatory requirements, and are conducted within ethical guidelines aligned with the functional and business evidence strategy;
3. Responsible for the STEP-1 Study for the US and assist with I-Step study in India;
4. Ensure the end result of the clinical studies provides a fair assessment of the safety and efficacy of the tested product(s); conduct the completion of evidence efforts in a timely matter and on budget with appropriate resources;
5. Accurately prepare regulatory submissions to ensure they comply with regulatory approvals;
6. Represent the company from a clinical research perspective within the country / region and collect feedback from local customers and authorities;
7. Build and maintain a strong network and close relationships with internal functions as well as external clinical sites and key stakeholders; and,
8. Responsible for additional functional projects that add value to the clinical portfolio, including new process improvements, system enhancements, and innovative resourcing.

25% travel required to clinical trial sites.

Minimum Requirements:

A Bachelor's degree or foreign equivalent in Pharmacology, Physiology, or a life sciences-related field followed by 5 years of post-baccalaureate experience in a medical scientist-related occupation.

Experience must include the following, which may have been gained concurrently:

1) 5 years of experience guiding clinical studies or trials related to endoscopic, implantable devices for treatment of obesity and Type-2 Diabetes;
2) 5 years of experience with Good Clinical Practice (GCP) and regulatory/compliance guidelines for clinical trials;
3) 5 years of experience with medical device or combination product trials and regulations;
4) 5 years of experience working with early medical device technologies within regulated environments in the US;
5) 5 years of experience using medical terminology; and,
6) 5 years of experience with clinical and outcomes research study design in the field of endoscopic gastroenterology.

Job site: 320 Congress Street, 3rd Floor, Boston MA 02210. Full-time.

JOB OPPORTUNITY QUALIFIES FOR EMPLOYEE INCENTIVE REFERRAL PROGRAM.

To apply, email cover letter and resume, referencing Req. #036806-403, to careers@gidynamics.com.

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