Title: Associate Director, Quality
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 an Associate Director to join the Quality team. The position will report directly to the CEO. The ideal candidate will be energetic, self-motivated, with a desire to succeed at the highest level, joining a team of employees dedicated to bringing our unique treatment to patients globally. The incumbent will lead the company's Quality function, which will include directing and overseeing quality assurance, quality control, quality engineering and document control activities for contract manufacturing and in-house production of all product lines. The individual will be responsible for directing activities and objectives related to compliance with global regulatory agencies. Additionally, this role will include managing a small team.

Key Responsibilities

- Provide leadership for the Quality function through development and implementation of the overall quality strategic plan
- Ensure the Quality System is in compliance with applicable standards and regulations for medical device products.
- Interface with regulatory agencies on compliance related issues.
- Direct the Quality System internal and external audit program and oversees the Corrective Action program. Responsible to recommend corrective action to the Quality System based upon internal or external quality reports.
- Direct activities related to process and product verification/validation.
- Oversee the document change control process
- Determine and implement sterility and biological test/validation requirements utilizing appropriate industry standards for new products.
- Interface with R&D to ensure that project teams are designing for patient safety (relating to FMEA and Hazard Analysis), Quality Systems compliance, and manufacturability in the development phases of the project.
- Coordinate and manage the qualification of internal and external manufacturing operations.
- Develop, refine, and document quality control test and inspection procedures.
- Support preparation of product approval applications (e.g., PMA, IND, NDA)
- Manage the product complaint handling process
- Report the performance of the Quality System to the Management Team.
- Represent company during ISO and/or FDA quality management system audits

- Interact / help manage relevant external vendors, mostly focused on external contract manufacturing partners

Qualifications

- BS degree in a scientific/engineering discipline required; advanced degree preferred.
- 10+ years of experience in a quality position with medical device experience; 4 years successful people management experience required
- Must be knowledgeable in the application of quality principals and industry guidance for Quality Systems
- Must be able to advise and/or teach others on the quality requirements of the company, including products, customer requirements and the interpretation of various industry guidelines
- Strong leadership and excellent communication skills essential
- Must be able to conduct an audit; must be able to be audited
- Must be familiar with statistical principals as they relate to statistical sampling plans
- Minimal travel required