GI Dynamics Career Opportunity

Title: Sr. Manager/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 a Sr. Manager/Associate Director of the Quality team. This individual will direct and oversee quality assurance, quality control, quality engineering and document control activities for contract manufacturing and in-house production of all product lines. This individual will also be expected to establish and direct activities and objectives related to compliance with regulatory agencies throughout the world. This position is directly responsible for all work needed to implement and maintain Quality function responsibilities for medical device products.

Key Responsibilities

- Provide leadership for the Quality function through development and implementation of the overall quality strategic plan.
- Assures that the Quality System is in compliance with applicable standards and regulations for medical device products.
- Interface with regulatory agencies on compliance-related issues.
- Directs 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.
- Directs activities related to process and product verification/validation.
- Oversees 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 appliances (e.g., PMA, IDE, CE)
- Manage the product complaint handling process.
- Report the performance of the Quality System to the Management Team.
- Supervise Quality Engineers.

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Qualifications

- BS degree in a scientific/engineering discipline required; advanced degree preferred.
- 10+ years of experience in a quality role with medical device experience; 4+ years in a management position.
- 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.
- Must have leadership and strong communication skills.
- 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 (ISO and MDR certified preferred).

Physical Requirements

- Minimal travel may be required.

GI Dynamics is an equal opportunity employer and will not discriminate against any employee or applicant based on age, color, disability, gender, national origin, race, religion, sexual orientation, veteran status, or any classification protected by federal, state, or local law.

GI Dynamics does not accept unsolicited resumes from any source other than directly from a candidate.