Title: Quality Manager
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.

Key Responsibilities

- Provide leadership for the Quality function through implementation of the overall quality strategic plan
- Ensure the Quality Management System is in compliance with applicable standards and regulations for medical device products.
- Assist with regulatory agencies on compliance related issues
- Participate in the execution of Quality Deliverables though successful implementation of Design Controls such as Design & Development Plan, Specification Development and Verification Strategies, Field Assessment Plan, Test Methods, Design Change, Labeling, Clinical Reporting and Design & Usability Validation Plans; whether internal, co-developed or externally manufactured.
- Champion 100% compliance to Company Policy and SOP's. Devise and support the implementation of effective quality assurance, process controls, statistical analyses, and metrics that assure products meet or exceed internal quality as well as statutory requirements.
- Spearhead the execution of the Risk Management deliverables to ensure compliance to ISO 14971 and demonstrate a primary commitment to patient safety.
- Advocate product usability and design validation efforts for new product development and design change projects.
- Direct the Quality Management System internal and external audit program and oversees the Corrective Action program. Responsible to recommend corrective action to the Quality Management System based upon internal or external quality reports.
- Participate in activities related to process and product verification/validation.
- Oversee the document change control process
- Implement sterility and biological test/validation requirements utilizing appropriate industry standards.
- Coordinate and manage the qualification of external manufacturing operations.
- Participate in the development, refinement, and documentation of quality control test and inspection procedures.
- Support preparation of product approval applications (e.g., PMA, IND, NDA)
- Participate in the product complaint handling process
- Report the performance of the Quality Management System to the Senior Management Team.
- Take a lead role during ISO and/or FDA quality management system audits
- Assist in and/or completes the development of budgets and monitors spending.
- Maintain and enhances cross-functional team relationships.

- Work cross-functionally in identifying and resolving and implementing solutions to technical issues.

Qualifications and Requirements

- BS degree in a scientific/engineering discipline required; advanced degree preferred.
- 5+ years of experience in a quality position with medical device experience; 1 years successful people management experience required
- Must be knowledgeable in the application of ISO 13485:2016, quality principals and industry guidance for Quality Management Systems as well as previous working knowledge in the EU Medical Device Regulation, (MDR), Technical File.
- 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 may be required at times