MEDICAL DEVICE DEVELOPMENT ENGINEER

SUMMARY

The Product Development Engineer position is responsible for developing and launching new 510K products—specifically glucometer devices—and line extensions complying with all necessary requirements with regulations relevant to the market served. This includes US FDA regulations as required by the QS regulations and the CFR part 820 for medical devices, ISO 13485: 2003 and the Canadian Medical Devices Regulations and European Community Medical Device Directives 93/42/EEC of June 14, 1993 (MDD) requirements.

RESPONSIBILITIES

- Plans and executes the development and launch of new 510K medical device products that broaden current portfolio and build new capabilities for the Company.
- Plans and executes the development and launch of new line extensions to current product line.
- Provides team and technical leadership in the execution of assigned projects, and meets commitments.
- Utilizes best practices associated with design control and product development and is responsible to meet Regulatory requirements.
- Provides overall life cycle management support for medical devices designed, produced and serviced by the Company.
- Provides technical support to Quality Improvement, and Manufacturing Cost Reduction projects, and to Complaint resolution.
- Executes technical tasks (protocols, investigations, data analyses, reports, test method development, design changes, etc.) to meet project commitments.
- Participates in periodic technical review of the device performance and develops required design changes to resolve any operational issues. Provides compatibility solutions that demonstrate understanding of business objectives and cost implications.
- Qualifies and manages suppliers and R&D contractors.
- Ensures sterilization, documentation, testing, and manufacturing requirements are met.

- Ensures that the new R&D lab has the capabilities to support projects and meet Good Laboratory Practices (GLP).
- Ensures that the new R&D lab meets safety and environmental requirements.
- Always demonstrates the highest level of safe work practices in the execution of responsibilities
- Completes other activities as necessary to ensure that devices continue to meet performance and compliance requirements.

REQUIREMENTS

- B.S. Mechanical, Electrical, Chemical or Biomedical Engineering; related Engineering technical degrees considered
- Minimum of 3 years of related industry experience.
- Preference is given to applicants with glucometer development experience.
- Related experience includes and is not limited to having developed and launched 510K medical devices, created and maintained design history files, worked with solutions packaging, and secured CE mark approvals.
- Has experience with CAD systems, FEA, Six Sigma, ANDA, ISO/CE Mark, GLP, GMP, GDP, USP testing, and high volume manufacturing processes.