Quality Assurance Engineer (Medical Devices)

Location: Atlanta, GA
Reports to: Quality Assurance Manager
Status: Full-time, exempt

About the Company

BioCircuit Technologies is a medical device company developing novel biomaterial-based devices for the surgical repair of nerve and other soft tissues.

Position Summary

As a Quality Assurance Engineer, you will play a critical role in ensuring the quality, safety, and reliability of our medical devices. You will execute activities concerned with the development of new products and the application and maintenance of quality standards for design controls and design transfer. You will work closely with our development, manufacturing, and regulatory team members to ensure that our products meet all regulatory requirements and exceed customer expectations.

Key Job Responsibilities

- Participates in the design, development, and maintenance of novel medical devices.
- Helps develop and maintain standards and methods for inspection, testing, and evaluation.
- Devises sampling procedures, including design and development of forms as well as instructions for recording, evaluating, and reporting quality/reliability data.
- Helps establish programs to evaluate precision and accuracy of production equipment and testing, measurement, and analytical equipment.
- Develops and implements methods and procedures for disposition of production materials and devises methods to assess compliance.
- Reviews measuring and testing of products developed under Good Laboratory and Data Practices as well as analyzes and tabulates data concerning materials, product, or process quality and reliability.
- Serves as Quality Assurance Unit in support of testing conducted in compliance with Good laboratory Practices (when applicable).
- Compiles and develops training material and conducts training sessions on quality assurance activities and data practices.
- Supports new supplier assessments and monitoring of suppliers already on the Approved Supplier List.
- Supports internal and external quality systems audits.
- Responsible for the timely investigation and closure of non-conformances, corrective and preventative actions, and supports post-commercialization activities such as complaint handling and customer service (as applicable).
- Contributor to related activities, including participation in design meetings, risk management, development plans, test plans and design transfer.

Problem Solving

- Possesses and applies a knowledge of principles, practices, and procedures of Quality Assurance to the completion of assignments, including a basic understanding of industrial statistics.
- Ability to multi-task product development projects, manufacturing, and post-commercialization support with complex deliverables.

ACCOUNTABILITY/DECISION MAKING

- Able to work independently with appropriate guidance.
- Maintains proactive awareness of company activities to ensure continued compliance with applicable directives and standards.

EDUCATION

- REQUIRED:
  - Previous working experience in Quality Assurance in a regulated environment (FDA/GMP/Quality Systems and/or ISO 13485 / QS 9001 environment)

    OR
  - Formal training or education in Quality Assurance for regulated environments
- DESIRED:
  - Four-year degree (Bachelor's in engineering or science)
  - 1 - 3 years experience specifically in the US medical device environment (21 CFR 820)
  - Experience/expertise with biomaterials especially biologics
  - Experience in New Product Development (NPD) and design verification / validation methods.

CERTIFICATES, LICENSES, REGISTRATIONS

- ASQ CQE and/or CQA certification(s) a plus but not required

TECHNICAL SKILLS

- Working knowledge of statistical methods and software for implementing statistics (e.g. MiniTab, StatGraphics, R, etc.)

COMMUNICATIONS SKILLS

- Ability to write routine reports and correspondence.
- Ability to communicate effectively before groups of customers or employees.

FURTHER DESCRIPTION

BioCircuit Technologies is a growing start-up company, where you will have the opportunity to receive exposure to all facets of medical device development and clinical translation (e.g., concept development, patent applications, grant proposals, partnerships with clinicians, presentations, etc.). Your successful performance in this dynamic work environment will lead to significant potential for continued growth and experience. If you are passionate about quality and have a proven track record of experience, we encourage you to apply for this exciting opportunity.

CONTACT INFORMATION

If you are interested in this position, please send your resume and cover letter to jobs@biocircuit.com