

## 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 and designs and develops forms and instructions for recording, evaluating, and reporting quality and 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 writes 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.
- Manages the quality system with respect to 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 knowledge of quality assurance to the completion of assignments.
- Ability to multi-task product development projects, manufacturing, and post-commercialization support with complex deliverables.
- 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.



**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)
  - 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**

- ASQC CQE certification a plus but not required

**TECHNICAL SKILLS**

- Ability to apply advanced mathematical concepts such as exponents, logarithms, quadratic equations, and permutations.
- Ability to apply mathematical operations to such tasks as frequency distribution, determination of test reliability and validity, analysis of variance, correlation techniques, sampling theory, and factor analysis.

**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](mailto:jobs@biocircuit.com)

