# Manager – Quality Assurance

Location: Atlanta, GA
Reports to: CTO
Status: Full-time, exempt

### About the Company

BioCircuit Technologies is a medical device company developing novel implantable devices for nerve repair and electronic devices for treating of neuromuscular disease and injury.

### Position Summary

Plans and directs activities concerned with the development of new products and the application and maintenance of quality standards for design controls and design transfer. Leads department and projects where extensive experience is required. Provides input to regulatory activities and maintains compliance to applicable directives and standards.

### Key Job Responsibilities

- Develops and initiates 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.
- Establishes program 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 when applicable.
- Compiles and writes training material and conducts training sessions on quality assurance activities and data practices as well as changes in regulatory compliance requirements (as applicable).
- Conducts and / or coordinates new supplier and internal quality systems audits as Lead Auditor.
- Interacts with customers and suppliers routinely to ensure that product design and development compliance with applicable regulatory and internal / external standards are constantly maintained. Addresses all product development issues for current products.
- Regulatory Affairs Leadership back-up, participation in design meetings, FMEA (product & process), development plans, test plans and design transfer.
- Leads and mentors Engineering staff to ensure continuous improvement in processes, materials, and products.

### Problem Solving

- Possesses and applies comprehensive knowledge of quality assurance to the completion of significant assignments.
- Ability to multi-task product development projects with complex scheduling of key QA resources and deliverables.
- Possesses and applies a broad knowledge of principles, practices, and procedures of Quality Assurance to the completion of difficult assignments, including an understanding of industrial statistics.

## ACCOUNTABILITY/DECISION MAKING

- Works with minimum supervision, conferring with superior only on unusual matters.
- Has appreciable latitude for unreviewed action or decision to ensure continued company compliance with applicable regulatory directives and standards.

## SUPERVISORY RESPONSIBILITIES

- Supervisory responsibility as part of adherence to Quality Regulations and Good Laboratory and Data Practices. Additional supervisory responsibility as required (document control, quality control, etc.).

## EDUCATION

- REQUIRED: Four-year degree (Bachelor's in engineering or science).
- DESIRED: Post-graduate (Masters or higher) level in Quality, Organizational Development, or Engineering discipline.

## EXPERIENCE

- 5+ years in FDA/GMP/Quality Systems and/or ISO 13485 / QS 9001 environment.
- 3+ years experience in New Product Development (NPD) and design verification / validation methods.

## CERTIFICATES, LICENSES, REGISTRATIONS

- ASQC CQE certification preferred.
- Six Sigma experience, Yellow Belt or higher, preferred.

## 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 quickly 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 will lead to significant opportunity for continued growth and experience.

## CONTACT INFORMATION

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