



Job Description – Quality Engineer I

Job Title: Quality Engineer I

Company Name: Biomerics

Location: Salt Lake City, UT

Position Type: Full Time, Employee

Pay: Salary

Company Overview:

Biomerics is a world class contract manufacturer and innovative polymer solutions provider for the medical device and biotech industries. As a vertically integrated company, we specialize in the design, development, and production of medical devices for diagnostic and interventional procedures. We are focused on next-generation solutions for the vascular access, electrophysiology, cardiac rhythm management, neurovascular, structural heart, and cardiovascular markets.

Please explore [our website](#) for more information about our offerings and capabilities.

Position Summary:

This position supports manufacturing to ensure compliance with applicable standards in manufacturing of medical components, devices, and biocompatible materials. The Quality Engineer is responsible for product disposition, complaint handling, root cause investigations, identifying and implementing process improvements, and functioning as a Quality Management System expert.

Job Responsibilities:

- Quality System maintenance and improvement
- CAPA ownership and/or support
- Interact effectively with customers, suppliers, and internal resources
- Manage projects and/or provide project support from the Quality function
- Facilitate identification of process risks, develop mitigation actions;
- Perform root cause analysis, corrective actions. Effectively employ problem solving tools/methodology
- Other responsibilities as assigned

Desired Skills

- Root cause analysis
- Understanding of statistical sampling and analysis
- Understands Design of Experiments
- Lean manufacturing
- Six Sigma

Qualifications

- Bachelor's degree in related engineering or technical field (Mechanical, Chemical, Material Science, Plastics, etc.) or 5+ years technical experience
- Working understanding of ISO13485, ISO14971, ISO9001, ISO17025 & GLP, 21 CFR 820
- Ability to perform statistical analysis using k-factors, Pp_k , or capability indices. Sample plan creation and analysis.
- Preferred: 1+ years related experience in the medical device field

If you believe that your skills and talents match our needs, please email your resume to csr@biomerics.com.