

Job Description – Quality Engineer

Job Title: Quality Engineer
Company Name: Biomerics
Location: Brooklyn Park, MN
Position Type: Full Time
Pay: DOE

Company Description:

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 vascular access, electrophysiology, cardiac rhythm management, neuro vascular, structural heart, and cardiovascular markets.

Please explore our website for information about our offerings and capabilities.

Job Description:

Provide Quality Engineering support for Manufacturing Engineering, Operations and QC Inspection

JOB REQUIREMENTS:

- Bachelor's Degree/Technical Degree in Engineering or equivalent experience
- 5 – 10 years' experience in a Medical Device manufacturing/product development environment
- Working knowledge of FDA QSR's, ISO 13485, and ISO 14971 requirements
- Experience/knowledge with product/process verifications/validations
- Experience with PFMEA's and Risk Management
- Experience with Gauge R&R and/or Measurement System Analysis
- Must possess strong statistical analysis background to define valid sampling for OQ/PQ protocols
- Must possess a working knowledge of measurement techniques
- Must be able to manage and prioritize multiple projects/objectives
- Experience with Design of Experiments a plus
- Experience with Extrusion Operations a plus

JOB RESPONSIBILITIES:

- Collaborate with manufacturing engineers and technicians in the development of verification/validation protocols
- Participate on Manufacturing Engineering/Operations teams to assure customer product requirements as well as quality requirements are documented and addressed
- Collaborate with Supplier Quality to assure all new suppliers are qualified and that new materials are adequately qualified
- Assist with the development of inspection processes and equipment for extrusion operations
- Work with Manufacturing Engineering, Operations and QC Inspection in the development and qualification of extrusion processes
- Assure that design specifications are accurately translated into production/process specifications
- Other assignments as requested.