Job Title: New Product Development (NPD) Quality Engineer (QE)
Job Number: 411-42401-BIO
Company Name: Biomerics
Location: Salt Lake City, UT
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 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.

Job Description:
The candidate will create, execute, and teach advanced design quality practices. The candidate will be responsible for supporting Business Development & Engineering/R&D via meetings with prospective customers and developing a technical relationship with other engineers. The candidate will report to the VP of Quality and must be able to function with little supervision.

Roles and Responsibilities Include:
- Functioning as a subject matter expert for:
  - Quality Engineering – Quality by Design (i.e. proactive risk mitigation through HFE analysis).
  - Design Assurance – Working with NPD Engineers to control product development through a phase-gate approach.
  - Supplier Qualification – Working with NPD team to research and qualify new suppliers.
  - Risk Management – Leading NPD team(s) in creation of dFMEA, pFMEA, and RMR compliant with ISO-14971.
- Maintaining and improving the Quality Management System.
- CAPA ownership and/or support.
- Interacting effectively with customers, suppliers, and internal resources.
- Managing projects and/or providing project support from the Quality function.
- Facilitating the identification of project risks, developing mitigation actions, and managing mitigation plan(s).
- Performing root cause analysis and corrective actions.
- Effectively employing problem solving tools/methodology.
- Other responsibilities as assigned.

Requirements:
- A Bachelor’s degree in related engineering or technical field (e.g. Mechanical, Chemical, Material Science, Plastics, etc.) (Required).
- A minimum of 3+ years related work experience in the medical device field (Required).
- The ability to perform statistical analysis using k-factors, PpK, or capability indices as well as sample plan creation and analysis (Required).
- Six Sigma Green/Black Belt (Preferred).
- Experience working through all aspects of medical device design/development including (Required):
  o Design verification & validation.
  o Process validation.
  o Technology transfer.
- An understanding of design for manufacturability and assembly / design for six sigma (DFMA/DFSS) (Required).
- Experience with test method development & validation (e.g. measurement/test system development, gage R&R, etc.) (Required).
- Experience and understanding of design for plastics injection and the mold fabrication processes (Required).
- Experience and understanding of the design for profile extrusion processes.
- An understanding of design of experiments (Required).
- Experience and understanding of lean manufacturing (Required).

If you believe that your skills and talents match our needs, please email your resume to csr@biomerics.com. Be sure to include your name and the job number in the subject line.