



## Job Description – Engineer II

**Job Title:** Engineer II

**Company Name:** Biomerics

**Location:** Salt Lake City, UT

**Position Type:** Full Time, (M-F, 7AM – 3PM)

**Pay:** Salary

### **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.

### **Position Summary:**

Responsible for New Product Development (NPD) and New Product Introduction (NPI) project support. Must work through all aspects of medical device design/development including design V&V and process validation / technology transfer. Supports Business Development through meetings with prospective customers and develops the technical relationship with other engineers.

### **Roles and Responsibilities include:**

#### **Project Management**

The Engineer II is responsible for managing the execution of projects regardless of scale; may manage project managers within assigned project.

Works within the constraints of: budget, schedule and scope while managing risk and ensuring adherence to established processes and methodologies.

- Interact with customers, suppliers, and internal resources.
- Demonstrates advanced knowledge of project and program management principals
- Uses project management tools to manage large and complex projects
- Defines and manages scope, time and resources of large scale, complex projects or a program
- Facilitates identification of project or program risks, develops and assigns responsibility for mitigation actions; manages mitigation plan
- Synthesizes critical information and communicates business implications to stakeholders

#### **Design Verification/Validation:**

Must have experience developing designs, testing via phase-gate analysis (Concept, Feasibility, Verification) using a risk-based approach (dFMEA) compliant with 21CFR/ISO14971.

Desired Skills:

- Subject matter expert in a directly applicable sub-field (injection molding, extrusion, electro-mechanical, etc.)
- Proficient in solid 3-D modeling skills (SolidWorks 2010-2013)
  - o Understands design for manufacturability and assembly / design for six sigma (DFMA/DFSS)
- Able to author/co-author risk assessments & failure mode element analysis (RA/FMEA) per ISO14971

**Process Validation:**

Must have experience with medical process validation.

- Capable of supporting validation definition and execution (IQ, OQ, PQ), test method definition, root cause analysis, gage R&R and measurement systems analysis (MSA).
- Familiar with root cause analysis and structured problem solving.

Preferred Skills:

- Design for plastics injection-mold fabrication processes.
  - o Develop and design plastic parts, insert molded parts and assemblies.
  - o Able to conduct design review(s) of hot/cold runner injection molds.
- Design for profile extrusion processes.
  - o Develop and design single, co-extruded and braided profiles.
- Ability to perform statistical analysis to ensure quality output of molded/extruded components.
  - o Establish the parameters for an optimal molding environment.

**Requirements:**

- Bachelor's degree in related field required (Mechanical, Materials Science, Plastics, etc.)
- A minimum of 5+ years related work experience in the medical device field required.
- Ability to lead team toward operational objectives with aptitude to contribute to strategic goal-setting for department/business unit.
- Preferred: PMP certification
- Preferred: Six Sigma Green/Black Belt or ASQ CQE certification
- Ability to perform statistical analysis using k-factors, Ppk, and DOEs along with root cause analysis.

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