



TOLMAR Inc.

### **Who We Are**

Located in Fort Collins, Colorado, TOLMAR specializes in the development, manufacturing and worldwide distribution of a wide variety of pharmaceutical products. TOLMAR offers a state-of-the-art facility, and a highly trained and seasoned staff with more than 20 years of specialty pharmaceutical experience.

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<b>Position Title:</b>	Process Development Engineer II
<b>Department:</b>	Operations
<b>Reports To:</b>	VP Operations

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### **Purpose and Scope**

Participates in the design and implementation of manufacturing processes, instrumentation and equipment from the laboratory through pilot plant and manufacturing scale-up. Assists the manufacturing operation in problem solving with regards to equipment and systems. Develops and recommends new process technologies to achieve cost effectiveness and improved product quality.

### **Essential Duties & Responsibilities**

- Assist with the planning/selection, design, implementation and validation of specialized equipment for pharmaceutical operations. Equipment includes but is not limited to: Steam Sterilizers/Lyophilization, Syringe fillers, Vial Filers, etc.
- Work “hands on” with formulation development personnel to refine formulations transferred from Research Group implementing changes when necessary to address practical considerations including processing, manufacturability and scale-up.
- Conduct process research, develop product/process optimization and/or improve procedures.
- Troubleshoot manufacturing problems.
- Provide technical support and technical training to manufacturing personnel.
- Interface with Quality, Regulatory and Business personnel.
- Prepare validation protocols and reports, writing of transfer packages, Standard Operating Procedures (SOP's) and government responses.
- Work with suppliers and contract manufacturers.
- Perform other related duties as assigned.

### **Knowledge, Skills & Abilities**

- Knowledge of pharmaceutical manufacturing process scale-up and validation.
- Familiarity with pharmaceutical manufacturing processes and systems in an Aseptic (sterile) environment.
- Familiarity with developing data-sets and documentation on formulation process, including setting specifications for transfer into pilot/manufacturing facilities
- Knowledge in Statistical Analysis.
- Working knowledge of spreadsheets and word processing.
- Effective written and oral communication skills, specifically in drafting regulatory responses.
- Ability to work with minimal supervision.
- Ability to analyze complex development problems, propose and implement creative solutions.
- Ability to work independently as well as in teams.
- Ability to manage multiple projects and prioritize/reprioritize work.

**Education & Experience**

- BS in scientific discipline, preferably chemical engineering or chemistry.
- Three or more year's experience in product and/or process development in the pharmaceutical manufacturing industry.

**Working Conditions**

- Working conditions are in an office, laboratory and pharmaceutical manufacturing environment. Work may require occasional weekend and/or evening work.

TOLMAR is an equal opportunity employer. Qualified candidates are asked to submit to post-offer background checks and drug screens.