

Position Title

Process Development Engineer II

Company Profile

TOLMAR is a northern Colorado based pharmaceutical research, development, manufacturing and commercial operations company. TOLMAR develops and manufactures both proprietary and generic pharmaceutical products with specific focus in therapeutic areas of dental, dermatology, and oncology products.

TOLMAR provides our customers with a competitive and sustainable combination of product development and commercial services. Our strengths include a proven development, clinical, regulatory and manufacturing infrastructure with highly trained and experienced staff.

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, lyophilizer, syringe fillers, vial fillers, 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.
- Knowledge of pharmaceutical manufacturing processes and systems in an Aseptic (sterile) environment; including experience with lyophilizers.
- Knowledge of 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.
- Excellent professional written and verbal communication and interpersonal skills.
- Ability to analyze complex development problems, propose and implement creative solutions.
- Ability to work independently with minimal supervision as well as cooperatively on a team

- Ability to manage multiple projects and prioritize/reprioritize work.

Education & Experience

- B.S. in a scientific discipline, chemical or mechanical engineering preferred.
- Three or more year's experience in product and/or process development in the pharmaceutical manufacturing industry to include experience with lyophilizers.

Working Conditions

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

Apply online at www.tolmar.com or send resume and cover sheet to resumes@tolmar.com

NOTE: For consideration you must submit a resume or application and meet minimum requirements. All offers are contingent upon an employment reference check and drug screen. Candidates within a 50 mile radius of the hiring zip code may receive first consideration.

TOLMAR offers equal opportunity employment to all qualified employees and applicants for employment without regard to race, creed, color, sex, national origin, age, disability or veteran status.