

Job Title: R&D Process Engineer/Sr. Process Engineer
Departments: Engineering
Reports to: Vice President Engineering
Date: July 2019

Purpose:

Provide ongoing scale up, process development, and scientific support to the portfolio of TM products, client projects and upcoming projects across various industries. Product types will include (but are not limited to) supplements, pharmaceutical, environmental, medical device, and nutraceutical. Scale up activities will be tailored towards transdermal, oral thin films, medical device and topical products.

Principal Responsibilities:

- Lead and contribute to activities in the development of commercial converting, packaging and serialization processes for transdermal, dissolvable films and other drug products.
- Based on QbD principles, plan and execute process studies for feasibility, development/characterization (DOEs), capability, qualification and validation.
- Establish optimum process conditions for product quality, throughput and yield.
- Write specifications, protocols, SOPs, process development reports, etc.
- Ensure regulatory compliance throughout all development activities
- Maintain accurate and complete records of development activities
- Support operations with equipment specification, qualification/PM, commercial manufacturing activities, etc.
- Interface and provide leadership to project teams, vendors and clients in all activities from development to commercial scale production.
- Provide technical and/or scientific guidance to operations and internal teams when appropriate.
- Other duties as assigned

Job Qualifications:

- Minimum of BS degree in science or engineering (mechanical/packaging) or related field, web-handling experience preferred.
- Minimum 10 years of direct industry experience (Senior)
- Bachelor's degree in an engineering or science related field with a minimum of 3 years of experience or an advanced degree with 0 years of experience.
- 3 - 5 years hands-on experience in manufacturing process development and scale-up within the pharmaceutical industry, preferably with transdermal and oral dissolvable thin film products, OR, experience with pressure sensitive adhesive processes for medical or other applications.
- Proven track record of planning and executing process development/scale-up projects, and an ability to meet aggressive timelines.
- Highly motivated individual who can work both independently and as part of a cross-functional team.
- Demonstrated problem-solving and analytical skills
- Strong technical writing and oral communication skills. Must be able to effectively communicate results or issues, verbally and in writing.
- Knowledge and experience with cGMP for pharmaceuticals and QbD principles preferred.

Preferred Qualifications:

- Knowledgeable and experienced with cGMP and the regulatory requirements for pharmaceuticals preferred.
- Demonstrated experience drafting URS, SOPs, master plans and additional protocols
- Proven scientific and technical ability to design and execute experimental studies as well as statistically analyze data, author and review protocols and reports.

Employee Signature: _____ **Date:** _____