

Job Title: Sr. R&D Process Engineer - Converting / R&D Process Engineer –
Converting

Department/Division: Engineering

Reports to: Sr. Director R&D Engineering

Grade:



Job Summary:

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, and topical products.

Duties/Responsibilities:

- Lead Design Reviews and contribute to activities in the development of commercial slitting, converting, packaging, cartoning 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 and qualification.
- Establish optimum process conditions for product quality, throughput and yield.
- Write specifications, R&D Mfg. instructions, protocols, SOPs, process development reports, etc.
- Follow Tapemark's applicable policies and procedures throughout all development activities.
- Support Manufacturing Engineers with equipment specifications
- Support Validation group with IQ, OQ and PQ
- Lead FMEA and Risk Assessments with support of Validation and Quality
- Maintain accurate and complete records of development activities.
- Support operations with qualification / PM, commercial manufacturing activities, etc.
- Interface and provide technical leadership to project teams, vendors and clients in all activities from development to validation scale production.
- Provide technical and/or scientific guidance to operations and internal teams when appropriate.
- Support the hand-off of Developed Processes with robust control processes to Validation and Manufacturing.
- Design/re-design tooling, part and packaging equipment for use in various projects
- Other duties as assigned.

Education and Experience:

- Minimum of BS degree in science or engineering, advanced degrees preferred.
- Prefer 5 years hands-on experience in manufacturing process development and scale-up within the pharmaceutical industry 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 Skills/Abilities:

- Knowledgeable and experienced with cGMP, cGLP, USP and the regulatory requirements for pharmaceuticals preferred.
- Demonstrated experience drafting R&D Manufacturing Records, 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.

The above job description does not constitute a contract of employment, and Tapemark may exercise its employment-at-will rights at any time.

Employee Signature

Date