**Job Title:** Manufacturing Process Engineer/Sr. Process Engineer

**Departments:** Engineering

**Reports to:** Vice President Engineering

**Date:**  Oct 2020

**Purpose:**

Provide ongoing commercial process support, improvement, CI initiatives, equipment selection / support and scientific support to the portfolio of TM products that are in commercial and or transitioning into commercial across various industries. Support the portfolio of TM products and projects in accordance with cGMP, FDA, and DEA regulations and standards.

**Principal Responsibilities**:

* Lead Design Reviews and contribute to activities in the improvement of commercial mix, coat, slitting, converting, packaging, cartoning and serialization processes for transdermal, dissolvable films and other drug products.
* Assist and troubleshoot process / equipment issues that occur during commercial operations and product changeovers. Including utilization and adjustments of Vision System programs and tools.
* Based on QbD principles, plan and execute process studies for feasibility, development/characterization (DOEs), capability and qualification tied to changes on commercialized processes.
* Through CI activities enhance process conditions that increase quality, yield or reduce set-up and tear-down activities.
* Write specifications, R&D Mfg. instructions, protocols, SOPs, process development reports, etc.
* Support and follow all regulatory compliance aspects, including following the necessary change control processes.
* Lead, research and write equipment specifications with support from R&D
* Lead / support CI activities that increase efficiencies on commercial processes
* Support Quality in NCM and CAPA investigations
* Maintain accurate and complete records of development activities on commercialized processes.
* Support operations with qualification / PM, commercial manufacturing activities, etc.
* Interface and provide leadership to project teams, vendors and clients in all activities from re-development to on-going commercial production.
* Provide technical and/or scientific guidance to operations and internal teams when appropriate.
* Receive the hand-off of Developed Processes with robust control processes from Validation and R&D
* Design/re-design tooling, part and packaging equipment for use in various projects
* Other duties as assigned

**Job Qualifications**:

* Minimum of BS degree in science, engineering or related field, advanced degrees 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.
* Minimum 5 years hands-on experience in manufacturing process improvement / sustainability 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.
* Ability to review large amounts of data/information, identify trends, draw conclusions and support a position with text and data.
* Proven track record of planning and executing process re-development/ CI 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, USP and the regulatory requirements for pharmaceuticals preferred.
* Experience in rotary die cutting and pharmaceutical primary and secondary packaging
* Demonstrated experience drafting 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.

**Employee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**