**Role Description**

**Job Title**: SDM Manufacturing Engineer – P01

**Job Role:** The successful candidate will be responsible for performing daily manufacturing activities in the manufacture of clinical supplies and of development batches. Additionally, the colleague will contribute to the development of manufacturing capabilities by supporting novel process development and process understanding studies associated with solid dose manufacturing processes. The candidate will be required to learn a wide variety of support activities in support of process development and manufacture of clinical supplies. This work will focus on supporting standard solid dose processing techniques as well as working with continuous manufacturing processes and associated Process Control, Process Analytical Technologies, Data capture and analysis.

The successful candidate will support the manufacture and development of solid dosage forms for clinical supplies.

Demonstration of teamwork within the operation unit when interfacing with various groups (Operations, Quality, Tech Support) is a requirement.

**Organisational Relationships**:

**Department**: Drug Product Manufacturing Group, Drug Product Supply, Pharmaceutical Sciences Small Molecule (PSSM)

**Reports to**: Manufacturing projects lead

**Liaises with:** Key stakeholders in DPS, DPD, PGS, ARD, GO, Quality, Safety and external subject matter experts.

**Resources controlled**: Role will operate as an individual contributor at a local level supporting the Manufacturing and Technical Service groups. Work impact is at department level. Individual will become a recognized SME on certain equipment, manufacturing processes and work processes.

**Requirements:**

* Educated to degree level in Chemical, bio-medical, bio-engineering, mechanical engineering or equivalent.
* Excellent verbal and written communication skills. Demonstrated competency using Microsoft Word, Microsoft Excel, Microsoft Outlook, and additional software. Strong interpersonal skills and accountability in day-to-day interactions with an operational focus on business goals, customers and process requirements is required. Proven ability to deliver technical reports and presentations.
* Suitable understanding of engineering and manufacturing operations including; processing, instruments, controls and mechanical aspects of pharmaceutical manufacturing equipment and associated services is preferred.
* Experienced with data visualization software (i.e. Spotfire, Pivision, or Tableau) is preferred.
* Role requires a Sandwich site presence and may require travel to other sites for extended periods (weeks). The job requires the operation of manufacturing equipment in the Sandwich SDM area. Flexible core hours may be required as needed for manufacturing needs.
* Demonstrated communication and influencing skills with multiple stakeholders, influencing major decision makers using a variety of communication tools.
* Ability to independently interpret internal/external business challenges and best practices to recommend technical improvements.
* Ability to trouble shoot and problem solve issues associated with solid dose manufacturing.
* Knowledge of GMP and associated compliance and quality management. Ability to independently author GMP documentation, Quality records and SOP’s.

**Job Description:**

* Responsible for manufacture of clinical and development batches of solid dosage forms using conventional or novel processes. (primary activity)
  + Includes equipment setup, manufacturing, equipment strip down and cleaning
  + Perform in-process operational checks associated with clinical manufacturing (examples include Solid Fraction Determination and Disintegration testing).
* Support for completing and controlling GMP documentation such as (Batch Records, Logbooks, SOP’s etc).
* Support troubleshooting / manufacturing support during manufacturing operations.
* Contribute to providing “hands-on” training for SDM Manufacturing Technicians.
* Support the Development of operational processes/systems and associated standard operation procedures.
* Make recommendations for continuous improvement opportunities with regard to safety, quality, and efficiency.
* Support continuous improvement initiatives throughout the manufacturing workstream and act as a change agent to incorporate improvements.
* Coordinate the required PM/Cal activities for the process rooms and equipment with the associated groups (Tech Support, GPO, SDM Scheduler).
* Assist with ordering associated tooling, spare parts, and change parts.
* Ensure all operations are executed according to Pfizer and OSHA safety standards.
* Responsible for contributing to departmental technical/GMP/safety training initiatives.
* Responsible for identifying and supporting the resolution of quality concerns and contributing to the subsequent investigational reports within the quality system (QTS).
* Responsible for providing detailed post manufacturing feedback.
* Present to partner lines during pre and post manufacturing including critical manufacturing information.
* Responsible for creating equipment recipes and providing batch record feedback to drug product manufacturing leads.
* May support writing of development batch records, electronic batch record review, and authoring working batch record.
* May support additional batch manufacturing processes as needed.
* Utilize Pivision, Spotfire, and other software tools to create relevant dashboards and knowledge management tools.
* May require support for cleaning validation activities including CVPA, CVEA, Generation of CV Swab Documentation, Generation of CV batch records and swab documentation.