Job Title: Manufacturing Operator Department/Division: Production

Reports to: Production Supervisor or designee

Grade: 6



## Job Summary:

Responsible for assisting with production line set up, tear down, and routine operation of pharmaceutical manufacturing processes on commercial scale equipment. This includes following current Good Manufacturing Practices (cGMPs) and Tapemark standard operating procedures. It also includes documenting in manufacturing records using Good Documentation Practices (GDPs).

## **Duties/Responsibilities:**

- Demonstrate the necessary technical abilities related to the operation of commercial. equipment. This includes:
  - Gaining and applying the necessary technical aptitude related to mixing, coating, slitting, rotary converting, and packaging, as necessary.
  - Learning and retaining key technical concepts (as applicable) required for the converting. production lines. This includes web handling, tensions, gear ratios, splices, die stations, vision systems, pick-in-place systems, etc.
  - Learning and retaining the key technical concepts (as applicable) required for the mixing.
     and coating production lines. This includes order of additions, solvation, emulsions, coat.
     weights, % solids, assay, viscosity, etc.
  - Provide adequate support to the manufacturing line Lead. This includes monitoring the
    process, performing roll changes, in-process inspections, line set-up, line tear-down,
    applicable cleaning, and other production responsibilities as deemed necessary or as
    assigned.
  - Independently operating small presses (Webtron, Allied, Packaging Equipment)
- Perform necessary job functions, including assisting the Lead operator, per Tapemark. standards and policies to ensure the product Quality targets and specifications are met. This includes:
  - Documenting all manufacturing records in compliance with ALCOA and Good Documentation Practices (GDP).
  - An understanding of and compliance with Tapemark cGMP requirements. This includes, staying current with training and following proper gowning, safety, and controlled substance policies and procedures.
  - Demonstrate ability to read, comprehend, and accurately complete manufacturing documents such as Manufacturing Batch Records (MBRs), Set up diagrams (SUDs), Visual Standards, Control Charts, Summary Sheets, Reconciliation Forms, Logbooks, etc.
  - Performing proper line clearances and material returns as required.
  - Communicating issues and solutions in a professional manner, particularly during shift changeovers.
- Abides by, and contributes to, the Tapemark Continuous Improvement and Safety Initiatives. This includes:
  - Identifying and reporting potential safety hazards.
  - Ensuring safety equipment is functioning properly before using.
  - Following all safety policies and procedures.
  - Contributing to the safety culture by reporting close calls, performing safety and 6S audits routinely.
  - Participation in the continuous improvement and change processes. Identifying and

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submitting continuous improvement (CI) recommendations.

## Overall and other duties as assigned.

- Responsible for acting consistently with Tapemark core values of Excellence, Integrity and Community.
- Fosters team environment where other are treated professionally and respectfully.
- Maintain a positive attitude. Keeps self and team motivated.

## **Education and Experience:**

- High School diploma or GED. (Technical or Associates degree preferred)
- 0-3 years working in a cGMP production environment. (1+ years preferred)
- Strong ability to understand written and verbal instructions in English language required.

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	

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