

**Siegfried USA, LLC
Pennsville, NJ
Job Description – Page 1 of 2**

Job Title: Lead Production Engineer
Local Title: Production Engineer – Physical Operations
Department: Operations
Reports to: Physical Operations Building Owner
FLSA Status: Exempt
Grade Level : 6D
Approved by: Tracy Renschler
Approved on: May 10, 2019

The employer reserves the right to amend or change this job description.

SUMMARY:

The Lead Production Engineer – Physical Operations is responsible for the day-to-day operations of Physical Operations area. The role is accountable for meeting production schedules and ensuring compliance with all regulatory requirements. In addition, Production Engineer will focus on optimization of processes within the assigned area and overall performance of the assigned area.

ESSENTIAL DUTIES, RESPONSIBILITIES AND ACCOUNTABILITIES:

- Executes daily operations for Physical Operations area.
- Manages the equipment and manpower requirements on a daily & weekly basis.
- Ensures that Building is kept in accordance with cGMP and Security standards.
- Review and approve batch log records (BLRs, DLRs, CLRs, etc.) pertinent to area.
- Reviews batch log records (BLRs, DLRs, CLRs, etc) prior to submitting to Compliance.
- Troubleshoots problems with production, equipment and procedures.
- Writes/approves LOTO permits to support maintenance work.
- Performs timely investigations and writes deviation reports.
- Communicates directly with all supporting departments (e.g. QA, QC, maintenance, equipment engineering, process engineering).
- Reviews and approves validation documents (Process Validation and Equipment Qualification).
- Manages implementation and adherence to all applicable SHE compliance and regulatory regulations.
- Provides shift supervisor with direction and priority for area operations.
- Ensures training for area is adequate/assists with operator training.
- Perform visual equipment inspection and swabbing to support equipment cleaning process
- Writing/updating SOPs and other documents as needed.
- Coaches and mentors operators on an as needed basis in regards to process operations, filling out documentation, housekeeping and safety.
- Backup for Building Owner/ as necessary.
- Ensures that the personal moral, ethical, legal, and behavioral conduct is in compliance with the Siegfried Code of Conduct.

SUPERVISION:

- No direct reports but is responsible for providing role model leadership and direction and assuming accountability to ensure safety, quality and production goals are met and for the general success of the assigned area.

EDUCATION AND EXPERIENCE:

- Advanced Degree Preferred or Bachelor Degree in Chemistry or Engineering or equivalent degree.
- 4 – 7 plus years of experience preferably in a pharmaceutical batch plant or chemical plant.
- In-depth knowledge of process engineering and cGMP regulations required.
- Strong leadership and mentoring capabilities are a must.
- Strong troubleshooting ability.
- Spray Drying and/or Milling and Blending Experience a plus.

Job Description: Lead Production Engineer - Physical Operations

OTHER REQUIREMENTS:

- Must have demonstrated leadership skills and be a team player.
- Must be able to manage projects and prioritize appropriately.
- Must have good attention to detail when reviewing documentation.
- Must have demonstrated ability to manage indirectly and thru influence.
- Solid knowledge of FDA/OSHA/DEA requirements is preferred.
- Must be able to work efficiently with people of all levels and cultures.
- Must be a team player and must be a self-starter and initiator.

Siegfried USA will explore and provide reasonable accommodations to assist any qualified individual with a disability in performing the essential functions of his/her job. Please speak with HR should you require an accommodation or have any questions.

By the Incumbent

By the Direct Supervisor

Name of Incumbent

Name of Direct Supervisor

Date

Date