Lead Process Engineer – CGMP Operations

FLSA Status
Exempt

JOB DESCRIPTION

Summary/Objective
The Lead Process Engineer provides technical discipline and leadership required to maintain, plan, and implement robust and capable processes for the manufacturing of drug products at Epicur Pharma. This individual exhibits a passion for driving processes and projects, and for achieving success through continuous innovation and execution to plan. Knows how to organize people, activities, and processes to get things done efficiently and effectively. This position is hands-on requiring implementation, gap analysis, and troubleshooting of both equipment and processes.

Essential Duties and Responsibilities include the following. Other duties may be assigned.

- Influences proper operating procedures during the manufacture of finished pharmaceuticals (Compliance with CFR's, Aseptic technique, etc.).
- Perform Gap Analysis and Remediation plans.
- Act as Subject Matter Expert for regulatory requirements and current industry guidelines relevant to supported processes.
- Process optimization by introducing process controls, technology, automation, and their effective implementation.
- Participate in validation activities and their documentation such as Validation Summary Report (VSR) as per GXP Regulations (GMP, GAMP).
- Lead in the development of equipment life cycle for tech transfer to manufacturing department.
    - User Requirements Specifications (URS), Functional Requirements Specifications (FRS), and Vendor Assessment
- Assists in the development and maintenance of process equipment, procedures, batch records, and training materials.
- Participate and/or oversee new equipment Factory Acceptance Test (FAT), Site Acceptance Test (SAT), and IQOQPQ.
- Able to write SOP (standard operating procedure) using equipment manuals and executing IQ/OQ/PQ protocols.
- Conducting research to develop new and improved processes for manufacturing.
    - Establishing safety procedures for individuals working with dangerous chemicals.
    - Designing and planning equipment layout.
    - Conducting tests and monitoring the process performance throughout production.
    - Troubleshooting problems associated with manufacturing processes.
- Schedule activities based on priorities and ensure all documentation is compliant with Good documentation practices.
- Use a systematic approach in solving problems through analysis of problem and evaluation of alternate solutions; uses logic, mathematics, or other problem-solving tools in data analysis or in generating solutions.
- Understand quality systems including Change Control, Deviations, CAPA’s and FMECA.
- Increase Safety Awareness and address any safety issues and concerns and ensures that equipment meets all relevant Health, Safety and Environment requirements.

Required Education and Experience

- Bachelor's degree in Mechanical, Electrical, Chemical, or Industrial Engineering.
- 5+ years of experience (pharmaceutical/FDA regulated facility preferred)
- Experience with Microsoft Office products, such as Excel, Word, and Outlook
- Familiarity with accepted engineering and scientific terms, principles and concepts required
- Ability to use and comprehend AutoCAD, electrical schematics, P&ID drawings
- Experience with GxP, FDA, ICH, NFPA and OSHA regulations and requirements
- Able to work both independently, within a team, and able to organize and lead a team
- Strong organizational skills
- Strong verbal and written communications skills and ability to communicate clearly and efficiently
- Able to sit, stand, squat, kneel, reach and walk for prolonged periods of time
- May need to lift up to fifty (50) pounds on seldom occasions

Competencies

- Work Independently
- Communication Proficiency
- Decision Making
- Problem Solving/Analysis
- Quality
- Results Driven
- Technical Capacity
- Thoroughness

Supervisory Responsibility

This position has no supervisory responsibilities.

Work Environment

This job operates primarily in a controlled laboratory environment. This position requires the use of standard office equipment, and frequent standing and walking.

Language Skills

Must be able to read, write, speak and understand English fluently and have the ability to read and interpret documents such as operating and maintenance instructions and procedure manuals.

Mathematical Skills

Uses addition, subtraction, multiplication and the division of numbers including decimals and fractions when checking of reports, forms, records and comparable data where interpretation is required involving basic skills knowledge.

Reasoning Ability

Must have the ability to solve practical problems and deal with a variety of concrete variables in situations where substantial standardization exists. Must be able to interpret instructions furnished in written, oral, and diagram or schedule form.

Physical Demands

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job.

- Able to sit and/or stand 8-10 hours or more per day as needed
- May need to lift up to fifty (50) pounds on seldom occasion

Position Type and Expected Hours of Work
This is a full-time position. Because of the nature of the business, work schedules may vary at times.

Travel
Minimal travel is expected for this position.

Disclaimer
The above job description is intended to describe the general nature and level of work being performed by employees assigned to this job. It is not designed to capture or illustrate a comprehensive list of all responsibilities, duties, and skills required of employees assigned to this job.

AAP/EEO Statement
Stokes Healthcare is an Equal Employment Opportunity and Affirmative Action Employer.