Job Title
Lead Compliance Officer

FLSA Status
Exempt

Salary
Starting at $75,000 based on experience plus twice a year bonuses

Job Summary
Lead Compliance Officer within Epicur Pharma will report directly to the General Manager. This individual is responsible for ensuring operations are in alignment with the regulatory frameworks set forth by the Food and Drug Administration (FDA) and other applicable regulatory authorities. The Lead Compliance Officer acts as a key advisor and leader in ensuring the organization's adherence to ethical and legal standards, while also contributing to the overall effectiveness and efficiency of the business. This role is not just about adherence to standards; it's about leading with foresight, crafting and executing comprehensive compliance strategies that safeguard our commitment to quality, and regulatory conformance in every facet of our Epicur operations.

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

- Develops and implements compliances programs centered around CGMP operations.
- Conducts regular assessments and audits to evaluate compliance with applicable CGMP regulations for internal departments and 3rd Party Providers (i.e. Suppliers, Manufacturers, Contract Laboratories, etc.).
- Identify areas for improvement and collaborate with internal stakeholders to support compliance during strategic planning and decision-making processes.
- Provide companywide notifications when regulations and guidance, affecting 503B outsourcing facility operations, have been revised/updated.
- Assist in responses and information transfers with regulatory agencies.
- Analyzing regulatory developments and industry trends, providing insights and recommendations to enhance compliance strategy.
- Responds to inquiries, assist in inspections, and ensures timely and appropriate reporting.
- Champion the development and delivery of compliance training programs for employees, ensuring a thorough understanding of regulatory requirements.
- Collaborating with various departments (e.g., Legal, Quality, R&D) to address compliance issues and ensure a holistic approach to risk management.
- Perform internal audits of QMS ensuring adherence to applicable regulations and company policies.
- Ensures proper documentation of manufacturing processes and maintains accurate records to demonstrate compliance.

- Drives the implementation of corrective and preventive actions in response to compliance-related issues or identified areas for improvement.
- Develops and maintains effective relationships with internal stakeholders, external partners, and regulatory bodies.
- Collaborates with Quality Assurance and other departments to enhance the overall quality management system.
- Fosters a creative and collaborative work environment, encouraging teamwork, professional growth, and knowledge sharing among team members.
- Monitors and evaluates employee performance. Provides feedback as necessary.
- Partners with department leadership to evaluate department headcount needs, conducts interviews and selects qualified candidates.
- Performs other duties as assigned

Required Education and Experience

- Minimum of 8 years of experience in pharmaceutical, analytical testing, and/or related science field
- Minimum 3 years of experience in pharmaceutical compliance or quality assurance
- Bachelor's Degree in Biological Science, Chemistry, Biomedical Engineering, or relevant field, preferred
- Familiar with GxP, FDA, ICH, and OSHA requirements
- Familiar with 21 CFR Part 11
- Familiar with Microsoft Office applications (Word, Excel, etc.)
- Must be capable of wearing all protective wear as required. This includes, but not limited to, mask, gloves, gown, hairnet, safety goggles, etc.
- Must have strong organizational skills and exceptional attention to detail
- Must exhibit punctuality and low absenteeism
- Able to work independently and as part of a team
- Able to sit, stand, squat, kneel, reach and walk for prolonged periods of time
- May need to lift up to twenty-five (25) pounds on occasion

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 twenty-five (25) pounds on 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
Up to 20% Domestic Travel

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.