

## **SCIENTIFIC PROTEIN LABORATORIES LLC**

POSITION TITLE: Senior Quality Assurance Compliance Specialist  
DEPARTMENT: Quality Assurance (760)  
REPORTS TO: Manager, QA  
CLASSIFICATION: Exempt Level 7

### **PRIMARY OBJECTIVE OF POSITION:**

Develops and oversees execution of written procedures designed to ensure current Good Manufacturing Practice (cGMP) compliance in such areas as record review and retention; sampling and evaluating incoming raw materials; sampling and evaluating facility water, air, and other specified utility systems. Prepares and maintains trend reports. Conducts deviation/discrepancy investigations and prepares written reports of investigation findings. Provide technical support and guidance for contract manufacturing. Back up the QA manager, including release of API.

### **DUTIES AND RESPONSIBILITIES:**

1. Be able to back up QA manager duties including: releasing API, and coordinate documentation for shipment
2. Provide technical support and guidance for contract manufacturing.
3. Samples and inspects or develops and oversees execution sampling and inspection of incoming raw materials. Physically releases materials subsequent to approval. Maintains raw material specifications, reports, and technical information files. Coordinates the auditing and qualification of new raw material vendors.
4. Ability to perform all duties of the QA Compliance Technician position. Assigns batch/raw material/environmental monitoring review duties in the absence of a QA management. Updates and maintains computer databases of environmental and water monitoring data.
5. Issues reports generated from these databases.
6. Provides technical support for the preparation of Standard Operating Procedures (SOPs) covering all QA operations.
7. Develops and oversees execution for supporting documentation (Manufacturing Instructions, etc.) for contract and protocol-based manufacturing campaigns.
8. Reviews or coordinates the review of completed batch manufacturing records for the API for completeness and compliance with stated process parameters prior to product release. Prepares deviation/discrepancy reports and assures completeness of each report and supporting documentation. Conducts investigations into the impact of deviation/discrepancy events as required.
9. Prepares and assigns duties as needed to prepare the Annual Product Review.
10. Reviews Process MI's and SOP's and makes recommendations for improvements.

11. Coordinates and performs QA Audits of SPL Manufacturing / Quality Control testing as well as outside laboratory audits.
12. Works closely with QA Manager and QA Management to provide technical support during all customer and Regulatory audits.
13. Works closely with Regulatory to provide technical support for DMF information.
14. Works closely with Purchasing, Manufacturing, Sales and Customer Service to coordinate product releasing and shipping.
15. Monitors and maintains all product and customer specifications for conformance.
16. Maintains integrity and security of all QA documentation.
17. Actively participates in the Change Control process.
18. Performs other duties as assigned.

**JOB STANDARDS:**

- A. **Education:** Bachelor's Degree in Microbiology, Chemistry, Medical Microbiology or related scientific discipline preferred.
- B. **Experience:** Five (5) years work experience in a cGMP pharmaceutical manufacturing or QC testing environment with two of those years in Quality Assurance.
- C. **Standards:** Must be able to write and complete reports as assigned; must be able to perform routine to moderate mathematical calculations. Demonstrated proficiency in the use of computer spreadsheets and word processing/databases. Able to work with no direct supervision. Good attendance, good communication skills and good interpersonal skills are necessary. Good organizational skills are required. Because this position requires working in a cGMP regulated environment, additional but critical components required for this position are reliability and accuracy in documentation.
- D. **Work Environment:** This position is mostly office environment, some manufacturing and QC laboratory testing exposure. Demonstrated proficiency in math, reading computer and writing skills, attention to detail essential. Use of dust masks, respirators, and protective clothing/equipment may be required to handle a variety of chemicals and raw materials. Must be able to schedule time effectively. Extended hours and/or some weekend hours may be required.
- E. **Physical Standards:** Job requires stranding, sitting, walking, reaching, bending, twisting, and squatting. Use of the hand for fine manipulation and simple grasping also required. Fine manipulation and frequent lifting of 1-20 pounds and occasional lifting of 21-75 pounds required. Good vision, speech, and hearing are required.

Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Department Approval: \_\_\_\_\_ Date: \_\_\_\_\_

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