

## **JOB DESCRIPTION**

The nature of *LIN-ZHI INTERNATIONAL*'s business dictates that personnel must remain flexible with the ability to accept responsibilities within their educational and training levels. These may be different from those stated on their 'Terms of Employment'.

### **JOB TITLE:**

DEA Compliance Analyst

### **RESPONSIBLE TO:**

General Counsel

### **GENERAL DUTIES:**

- Knowledgeable on all matters of DEA as it pertains to research, manufacturing, and distribution of controlled substances, including licensing, procurement, movement of material, production, shipment, and destruction
  - Facilitate external audits and site inspections from governmental agencies, represent the company by serving as the point of contact for federal and state regulatory agencies, and facilitate and/or respond to forms, warning letters, or administrative actions from agencies
  - Oversee and renew DEA registrations, inventory records, and security documentation
  - Maintain state and federal licenses
  - Track regulatory changes affecting controlled substances and labeling requirements
  - Lead and participate in LZI quality management system internal audits to ensure compliance with established regulations, standards, and requirements for DEA compliance
  - Coordinate with Quality Assurance and Regulatory on Standard Operating Procedure (SOP) compliance, change controls, and deviation reports
  - Document and file compliance records and ensure timely reporting
  - Collaborate with legal counsel to ensure LZI compliance with all applicable laws and regulations
- \* Additional duties may be added as the need arises

### **SPECIFIC DUTIES:**

- DEA Registration, Licensing, and Regulatory Maintenance:
  - Maintain compliance with all DEA and California State registrations
  - Assist registrants and compliance with schedule-specific controlled substances requirements
  - Remain current on DEA registrations in order to address organizational business needs
  - Responsible for submitting Schedule I and II quota applications to DEA when applicable; maintain organized DEA files on related activities
  - Request controlled substance confirmation from the DEA
  - Prepare and track chemical preparation exemption applications for products

## JOB DESCRIPTION

### **SPECIFIC DUTIES, continued:**

- DEA Registration, Licensing, & Regulatory Maintenance: (continued)
  - Liaise with DEA, Procurement, and Shipping regarding import/export of controlled substances and complete required paperwork
  - Interpret DEA requirements and identify and resolve gaps between the requirements and current company practices
  
- Ordering, Receiving, and Distribution:
  - Coordinate for DEA-related activities involving scheduled controlled substances at the site
  - Review internal orders containing controlled substances to ensure full compliance with regulatory guidelines and internal requirements
  - Maintain comprehensive and accurate records for all controlled substance orders, including receipts, invoices, and shipping documents
  - Hold Power of Attorney to sign DEA 222 Forms, responsible for completing, maintaining, and tracking all DEA 222 forms
  - Review and release daily customer orders through Suspicious Order Monitoring System (SOMs) and ensure compliance with Suspicious Orders Reporting (SORS)
  - Maintain Know Your Customer (KYC) information
  - Coordinate all movement of controlled substances from manufacturing through analytical testing
  
- Inventory, Recordkeeping, and Reporting:
  - Conduct biennial inventories (twice a year) of controlled substances
  - Perform cycle counts and maintain inventory accuracy
  - Prepare and submit the Automation of Reports and Consolidated Orders System (ARCOS) quarterly reporting via the DEA website
  - Maintain organized, audit-ready documentation and ensure corrective actions are tracked and completed
  - Assist in preparing documentation for DEA reporting (e.g., diversion, theft/loss, inventory discrepancies, etc.)
  - Support collection and verification of records for compliance reports, audits, and policy reviews
  
- Security, Storage, and Facility Controls:
  - Work with the Facility to maintain and upgrade security systems required for controlled substance storage
  - Ensure proper handling, storage, and access controls for all scheduled substances on-site
  - Coordinate controlled substance destruction with Regulatory, Quality Control (QC), and Quality Assurance (QA)
  - Create all destruction reports and coordinate pick-ups for controlled substance destruction with reverse distributors

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### **SPECIFIC DUTIES, continued:**

- Audits, Inspections, and Regulatory Readiness:
  - Assist in preparing the business for audits, inspections, or reviews from regulatory agencies
  - Coordinate and document internal DEA compliance audits and issue audit reports to management upon completion
  - Maintain audit-ready documentation and ensure timely completion of corrective actions
- Training, Processes, and Personnel Compliance:
  - Develop, update, and train staff on policies for ordering, handling, storing, and shipping controlled substances
  - Identify opportunities for process improvement in controlled substance workflow
  - Maintain compliance documentation system, including annual trainings, licenses, and personnel records
  - Track employee policy acknowledgments and training completion
  - Work with Human Resources to administer annual employment screening questionnaires and periodic background checks for applicable positions

\* Additional duties may be added as the need arises

### **QUALIFICATION & EXPERIENCE REQUIREMENTS:**

- B.S. in biology (or related)
- 2+ years of relevant work experience in a related industry
- 3-5 years of DEA compliance and training experience, including ARCOS and 222 Forms
- Strong knowledge of DEA and FDA regulations (21 CFR regulations), Chemical Diversion and Trafficking Act (CDTA), and the Controlled Substances Act (CSA) regarding handling, storage, distribution, and destruction of controlled substances
- Experience with DEA Manufacturing and Research Schedule I-V licensing and compliance
- Experience responding to DEA inspections, audits, and Research Advisory Panel of California (RAPC) requests
- Knowledgeable of manufacturing and production processes
- Expertise with DEA regulations and controlled substance ordering processes
- Proficiency in the following software applications: MS Office Suite (Word, Excel, and PowerPoint) and Adobe Acrobat Professional
- The ability to master new applications upon request
- Strong work ethic, focused, able to prioritize workload with minimal supervision, detail-oriented, organization skills, able to multi-task and follow-up on open tasks; importantly, ability to execute on job functions in a timely manner

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### **QUALIFICATION & EXPERIENCE REQUIREMENTS, continued:**

- Excellent writing and verbal communication skills
- Excellent documentation and attention to detail, organizational, and analytical skills
- Maintain a good working relationship with various internal departments
- Must pass comprehensive background screening

### **GENERAL ON THE JOB TRAINING REQUIREMENTS:**

- Team time management
- Prioritizing tasks to meet deadlines
- Multitasking abilities

*Lin-Zhi International, Inc.* is committed to building a diverse and inclusive work environment that reflects the society and communities in which we are located. We are committed to diversity and actively seek out applicants from groups facing systemic inequities in the biotech world.

*Lin-Zhi International, Inc.* is an equal opportunity employer. We enthusiastically welcome and accept our responsibility to make employment decisions without regard to race, gender, sex, sexual orientation, gender identity, age, religious creed, color, national origin, religion, marital status, medical condition as defined under State law, disability, genetic information, military service, pregnancy, childbirth, and related medical conditions or any other classification protected by federal, state, and/or local laws and ordinances.