

DEA & DOH COMPLIANCE OFFICER

Status: Full Time, Employee
Location: Miramar, Florida - USA
Work Status: Will *not* consider sponsorship for work authorization
Job Number: 2009-365

Summary:

With minimal supervision, is responsible for overseeing and coordinating all aspects of compliance with the Drug Enforcement Administration (DEA) and the Florida Department of Health (FL DOH).

Essential Job Functions: *This is not intended as a comprehensive list; it is intended to provide a representative summary of the major duties and responsibilities. Incumbent(s) may not be required to perform all duties listed, and, may be required to perform additional, position-specific tasks.*

- Monitors internal DEA and FL DOH compliance programs at the operating level and ensures that the company maintains compliance with all DEA and FL DOH regulatory requirements. Identifies areas of vulnerability and proposes reconciliation procedures; takes prompt correction action when noncompliant acts or conditions are observed.
- Operates as a liaison between the company and DEA and FL DOH. Escorts DEA and FL DOH investigators during site inspections and responds to their concerns. Attends Agency meetings to ensure regulations and changes are well understood and brings that knowledge to the company in the form of training, task force implementation, and other measures to ensure compliance.
- Audits departments working with controlled substances and/or active ingredients that are regulated by permit and pedigree requirements of the Florida Department of Health and reviews departmental SOPs for applicable compliance.
- Responsible for writing and maintaining Regulatory Affairs SOPs pertaining to DEA and FL DOH. Assist other departments in writing SOPs for compliance with DEA and FL DOH.
- Maintains all DEA and FL DOH licenses and renewals.
- Responsible for regulatory compliance reporting, correspondence, and inquiries related to DEA and FL DOH.
- Completes and submits all DEA reports (ARCOS, Year-end, monthly submission of completed DEA Form 222 to DEA local office, etc.) in a timely manner. Completes registrant DEA validation for clients and customers prior to purchasing or shipping controlled substances. Reviews DEA Form 222 (Schedule II orders) for accuracy, and completes confirmation receipts for controlled substance shipments.
- Reviews all controlled substance inventories (initial, periodical and biennial) and verifies the accuracy of these inventories. Reviews reports relating to controlled substances such as weekly production schedules, suspicious order reports, and inventory adjustment reports.
- Obtains annual controlled material quotas, adjustments, and export permits.
- Maintains Power of Attorney authorization records of corporate officers authorized to sign DEA Order Form 222.
- Works with all applicable departments to ensure DEA clearance for employees, maintains a list of DEA approved employees and liaises with the Associate Director, Facilities regarding security access levels.

Supervisory Responsibilities:

This position requires no management abilities or experience in the supervision of technical and administrative personnel.

Required Knowledge and Skills:**Knowledge of:**

- Work experience in a pharmaceutical environment.
- Detailed understanding of Production and Warehouse practices and procedures
- Good understanding of legal and regulatory compliance regulations (DEA and FL DOH)
- Ability to follow and interpret DEA and FL DOH regulatory requirements and changes
- Ability to implement processes resulting in satisfactory audit practices
- Working knowledge of Microsoft Office Suite

Skills in:

- Strong organizational skills
- Communicating effectively both orally and in writing
- Problem solving skills ; ability to resolve issues effectively and efficiently
- Ability to work with under minimal supervision and rely on experience and good judgment to plan and accomplish assigned goals.
- Able to manage multiple tasks simultaneously, be responsive and adaptable to project/task change based on business requirements
- Strong interpersonal skills to interface with many levels of an organization.
- Ability to perform tasks of substantial variety and complexity and to serve as a resource in the resolution of problems and issues

Physical Requirements and Working Conditions:

While performing the duties of this job, the employee is regularly required to sit; use hands to finger, handle, or feel and reach with hands and arms. The incumbent is frequently required to talk or hear and occasionally required to stand and walk. The incumbent must occasionally lift and/or move up to 10 pounds. Specific vision abilities required by this job include depth perception and ability to adjust focus.

Minimum Qualifications:

Bachelor's of Arts or Science degree (B.A./B.S.) from four year college or university; and minimum of two to four years of related experience and/or training, with at least one year of regulatory experience with the DEA and FL DOH regulatory compliance activities, or equivalent substitution of education and experience.

For consideration, submit resume to: careers@avevadds.com

No phone calls please.

AVEVA Drug Delivery Systems, Inc. is an Equal Opportunity Employer