



Job Title: Director of Compliance / Compliance Officer
Date: October 2011
FLSA Exemption Status: Exempt

General Summary:

The Director of Compliance will develop and oversee Chelsea's compliance program. This role is responsible for ensuring that the Board of Directors, management and employees are in compliance with regulatory rules, company policies, as well as Chelsea's Standards of Conduct.

The Compliance Officer will focus on compliance as it relates to laws, regulations, and industry codes affecting pharmaceutical products, including FDA regulations, False Claims Act, Anti-Kickback Statute, OIG guidances, PhRMA and AdvaMed Codes, Medicare and Medicaid rebate and related price-reporting statutes. In addition, this position will provide oversight and ensure compliance to all functions and personnel representing Chelsea Therapeutics. The position is based in Chelsea's Charlotte, NC headquarters, and reports to the VP, Operations.

Principal Duties and Responsibilities:

- Works with Senior Management to develop Chelsea's Healthcare Compliance Program and day-to-day management of activities to prevent illegal, unethical, or improper conduct
- Develops an effective compliance training program, including the development of SOPs, management of SOP change control and implementation of training
- Oversight - Directs and/or conducts as needed compliance reviews of business operations and attends business programs and activities to ensure compliance
- Provides compliance program counsel, including: monitoring employee complaints and concerns, responding to alleged violations, initiating investigative procedures, and overseeing uniform handling of actual violations
- Reviews/approves all applicable Sales and Marketing, Clinical Operations, Medical Affairs, and Corporate Finance initiatives, including: promotional/sales, clinical/medical communications, financial relationships, etc.
- Risk Assessment - Identifies potential areas of compliance vulnerability and risk; implements corrective plans
- Knowledge expert and primary contact person for interactions with Center for Medicaid and Medicare (CMS), Food and Drug Administration (FDA) and Office of Inspector General (OIG)

Education and Work Experience:

A Bachelor's Degree is required; a JD is strongly desired; a minimum of 10 years of Pharmaceutical/healthcare industry experience in the area of compliance.

Specialized Knowledge and Skills:

Knowledge of federal fraud and abuse laws, including the ACCME guidelines, the Office of Inspector General reports, and the Food, Drug and Cosmetic Act and an understanding of the roles and authority of government agencies and industry cooperative groups including FDA, OIG, PhRMA and AdvaMed. Exceptional communication, both orally and in writing, as well as presentation abilities expected. Ability to maintain an independent and objective perspective while developing a strong partnership with key stakeholder groups.

Equipment and Applications:

Proficient with Microsoft Office.

Work Environment and Physical Demands:

General office environment with occasional travel as dictated by the business needs.

Disclaimer:

The above declarations are not intended to be an *all-inclusive* list of the duties and responsibilities, skills and abilities required for the position. Rather, they are intended only to describe the general nature of the job.