



Position Title: Senior Director or Director of Compliance

Department: Legal

Reports To (title): Assistant General Counsel

Location: King of Prussia

Date: TBD

Exempt Non-Exempt

Summary of Position:

This role will be responsible for implementing Paratek's healthcare compliance programs to ensure the company's continued compliance with U.S. federal and state laws and regulations related to the promotion, sale and marketing of pharmaceutical products. Responsible for developing, implementing and oversight of healthcare compliance initiatives to ensure alignment with business goals and objectives, and adherence to applicable state and federal aggregate spend and compliance laws, regulations, and codes (such as the Anti-Kickback Statute, False Claims Act, OIG Guidance for Pharmaceutical Manufacturers, PhRMA Code & FDCA). Serves as a Compliance subject matter expert on application of Compliance regulations and requirements to key activities and processes, policies and procedures.

Position Responsibilities:

The roles and responsibilities will include the following:

- Assist the Chief Compliance Officer and Assistant General Counsel in driving the process of assessing, monitoring and mitigating healthcare compliance risks by developing, enhancing and executing programs and activities.
- Lead and oversee company-wide healthcare compliance training initiatives and programs including the training of a contract sales organization.
- Collaborate regularly with Legal, Regulatory, Clinical, Medical and Commercial colleagues and provides leadership for key Compliance initiatives, including compliance with State and Federal aggregate spend regulations.
- Develop and implement an annual Compliance auditing and monitoring plan to address Compliance risk areas.
- Monitor field commercial, medical affairs and managed markets transactions, activities, and processes to assess compliance with company policies and procedures and ensure that the company satisfies its legal and regulatory obligations and other requirements or guidelines.
- Perform reviews to assure that proposed business activities and engagements with healthcare professionals and healthcare organizations are consistent with company compliance guidance and that they conform to industry laws and regulations.
- Develop policies and procedures to evaluate business adherence to corporate compliance policies, as well as legal and regulatory requirements.

- Exhibit and maintain strong subject matter expertise in order to deliver timely and reliable advice to company-wide business partners regarding healthcare compliance issues
- Collect, analyze and prepare information used in the development of the annual compliance gap assessment and prepare any necessary presentations or reports to senior management and the Board of Directors
- Maintain clear and regular communications with the Board, Management Team and other stakeholders, as appropriate and assist with corrective action implementation as necessary

Candidate Requirements:

Skills and Competencies

- Excellent interpersonal skills
- Demonstrated negotiation capabilities and persuasion skills
- Unquestionable ethics and integrity
- Sound judgment, with an understanding of the intersection of legal, regulatory and business issues
- Strong intellect and solid business acumen, coupled with pragmatic and problem-solving skills
- Innovative, strategic and pro-active in anticipation of the future needs of the Company
- Proven “hands-on” approach with solid relationship-building and listening skills
- Ability to understand, simplify and clearly articulate complex issues
- Well organized and detail oriented with demonstrated ability to manage time, handle a variety of tasks and responsibilities, and meet timelines without supervision
- Possess the credibility and gravitas to be viewed as a trusted advisor

Minimum related experience required to perform job

- 8+ years of experience in the pharmaceutical industry with specific compliance related experience.
- Well-rounded, experienced compliance specialist who has played a key role as an engaged leader on matters relating to the marketing and promotion of pharmaceutical products and possesses an impressive track record of providing not only sound compliance advice, but also excellent business judgment concerning overall regulatory compliance and risk management
- Previous experience implementing infrastructure and processes to support the commercialization phase of a biopharmaceutical/biotech company

Education

- Undergraduate degree required

Additional Information:

Travel requirements (%): 10-20%