



Job Title: Commercial & Regulatory Counsel

Department: Legal

Location: Boston

Reporting to: CFO

Job Summary:

Rhythm Pharmaceuticals, Inc. seeks an experienced and highly motivated individual to join its team in Boston, Massachusetts.

The Commercial & Regulatory Counsel will be the lead commercial and regulatory attorney supporting Rhythm's lead compound, setmelanotide – as well as providing support on issues relating to its development programs/pipelines. The attorney will report to the Chief Financial Officer with primary client responsibility for activities supporting the Chief Medical and Chief Commercial Officers.

Duties and Responsibilities:

- Act as the primary legal counsel to Rhythm's Medical and Commercial functions related to FDA/[EMA] laws and regulations, anti-kickback and bribery statutes, false claims acts, HIPAA/privacy and other relevant laws and regulations governing the commercialization of pharmaceutical products in both the US and subsequently in international jurisdictions
- Review promotional materials, grants, programs, contracts and other materials
- Develop the company's compliance function and provide appropriate guidance and training
- Review, analyze and advise on matters related to reimbursement activities, access services, patient support and assistance programs, government coding and reimbursement, payment and coverage decisions
- Coordinate external legal service delivery for contracts, SEC filings and other areas as needed
- Review and provide legal guidance on financial and other interactions with healthcare professionals, patients, or others in a position to influence healthcare decisions (e.g., payers, advocacy groups, distributors, etc.) to ensure compliance with applicable laws and regulations

Principal Responsibilities

- Advice and counsel clients in various therapeutic areas on FDA regulations, the Anti-Kickback Statute, False Claims Act and PhRMA Code in connection with product labeling, promotional activities, marketing strategies, sales training and compensation, speaker bureaus, and communications with FDA.
- Advice and counsel various internal clients with respect to projects, initiatives and communications regarding approved products and indications as well as those pending FDA approval.
- Review and provide guidance on promotional materials through Rhythm's Promotional Review Committee.
- Draft, review and negotiate commercial contracts, 3rd party vendor agreements, service agreements, consulting agreements and other corporate agreements.

Rhythm Pharmaceuticals, Inc
500 Boylston Street, 11th Floor
Boston, MA 02116
www.rhythmtx.com



Qualifications Required:

- 5+ years' experience as a practicing attorney, with at least 3 years' experience advising the pharmaceutical/biotech industry.
- Significant legal experience in fraud and abuse counseling and FDA issues, with a working understanding of the OIG's Guidance for the Pharmaceutical Industry, applicable regulations and laws relating to the development, sales and marketing of pharmaceutical products, the enforcement landscape from a U.S. Department of Justice, FDA and State perspective.
- The preferred candidate will have worked at a leading U.S. national law firm or had an in-house counsel position with a leading biotech/pharmaceutical company with significant marketed products.
- Expertise in counseling clients on best practices for Commercial and Regulatory functions.
- Government pricing experience a plus.
- Working knowledge/experience with GMP a plus.

Education

- BA/BS degree
- JD and licensed to practice law in the United States or be eligible for licensure as a registered in-house counsel.

Major Skills

- Knowledgeable of the laws and regulations affecting the pharmaceutical industry, including the Food Drug and Cosmetic Act, Anti-Kickback Statute, and False Claims Act.
- Excellent negotiation skills requiring effective interpersonal communication and oral and written communication skills.
- Ability to independently manage workload in a fast-paced environment. Ability to provide legal counsel to a wide variety of internal clients on legal and regulatory matters and interact effectively with employees at all levels of the organization.

This is not meant to be an exhaustive list of all responsibilities, duties, and skills required for this role. The role may be required to perform other related duties, as assigned.

(147)