POSITION: Manager, Regulatory Affairs, Ad / Promo

DATE: July 2021

REPORTS TO: SVP, Regulatory Affairs

FLSA STATUS: Exempt

DEPARTMENT: Regulatory

Accountability Objective:
The Regulatory Affairs Specialist, Ad / Promo position reports directly to the SVP of Regulatory and is responsible for the daily support or management of regulatory requirements for Impel's drug products, providing leadership on advertising and promotional materials, and developing and maintaining relationships with key client staff and regulatory bodies.

ESSENTIAL DUTIES AND RESPONSIBILITIES includes the following.

- Provide regulatory guidance for the development, review, implementation, and maintenance of promotional materials and other related activities with minimal oversight
- Chair promotional review committee meetings and effectively collaborate with cross-functional internal groups
- Responsibility and oversight of promotional material submissions under Form FDA 2253
- Manage the development of relevant correspondence with health authorities and interpretation of health authority comments, as well as serving as the primary liaison with relevant personnel in FDA's Office of Prescription Drug Promotion
- Maintain current awareness of evolving health authority interpretations, including advisory letters, enforcement letters and policy issues. Communicate significant changes or other relevant matters to internal partners and stakeholders.
- Manage, maintain, and continuously improve processes and systems (including a web-based platform) for review and approval of promotional materials
- Act as a key regulatory affairs expert within the Impel regulatory team, providing expertise on regulatory strategy, process, filing, and best practices
- Provide strategic and operational leadership for promotional, educational, and investigative communications
- Review and evaluate materials submitted by Impel to ensure that the content, quality, and format comply with applicable laws, regulations, and company policy
- Use extensive knowledge of US, EU and ICH regulatory requirements and the ability to apply knowledge both strategically and operationally to develop projects and marketed product regulatory issues to support Impel's corporate objectives
- Manage launch preparation of promotional material for TRUDHESA
- Maintain knowledge of changing regulatory requirements and advise teams as appropriate
- Represent the Impel Regulatory Affairs Team in meetings or workstreams; provide support for ancillary projects

EDUCATION, EXPERIENCE AND/OR SKILLS REQUIRED

- Bachelor's Degree
- At least 8 years of prior pharmaceutical regulatory affairs experience
- Knowledge of FDA advertising and promotion regulations and guidance
- Proactively monitors guidance, FDA current landscape and Federal Regulations
- Work collaboratively with medical, legal, and marketing personnel on advertising and promotional materials

CULTURAL COMPETENCIES

- **Collaborative**: Works together in an intersection of common goals by sharing knowledge, learning, and building consensus with others.
- **Flexibility**: Develops new or diverse strategies to achieve organizational goals. Able to lead in a changing and challenging work environment. Manages competing demands and unexpected events.
- **Ownership:** Demonstrates full ownership and takes accountability for the actions and execution of both self and the department.
- **Leadership**: Ability to be dynamic and visionary, and able to define clear and specific objectives, tasks, and responsibilities.
- **Initiative**: Measures self against a standard of excellence. Demonstrates persistence and overcomes obstacles, takes calculated risks to accomplish goals. Ability to work a demanding, primarily self-directed work schedule.
- **Professionalism**: Works well in a fast-paced environment; treats others with respect and consideration; accepts responsibility for own actions. Understands business implications of decisions, aligns work with strategic goals. Meets deadlines and commitments.
- **Communication Skills**: Clearly and persuasively communicates verbally and in writing. Listens and seeks clarification; manages difficult situations; maintains confidentiality.
- **Problem Solving**: Conducts appropriate analysis and makes clear, consistent, and timely decisions.
- **Detail minded**: Demonstrates accuracy and thoroughness; monitors own work to ensures quality and organization. Strong attention to detail while multitasking.

PHYSICAL DEMANDS

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. Must have demonstrated ability to multitask in high pressure, changing conditions. Sitting, standing, stooping, and lifting of packages/laboratory equipment up to 30 pounds may be required.

WORKING CONDITIONS

When based in the office or health clinic, expect a noise level typically moderate for offices.

PRIMARY LOCATION & TRAVEL

This position is not location specific with focus being on the right individual. We anticipate that on an ongoing basis this role will be a remote position although incumbent will need to participate in face-to-face meetings as needed. Travel up to 10% to meet the ongoing needs of the business.