Senior Director, Regulatory Affairs Advertising and Promotion

Do you want to be part of building a fully integrated biopharmaceutical company together with a team of highly skilled colleagues who are passionate about developing best-in-class therapeutics that address significant unmet medical needs? Then Ascendis Pharma is committed to support your personal development on our journey towards becoming a leading rare disease company.

Ascendis Pharma is looking to hire an experienced Senior Director, Regulatory Affairs Advertising and Promotion to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Senior Director, Regulatory Affairs Advertising and Promotion will be responsible for providing strategic guidance on the development and implementation of advertising and promotional materials for pre-launch and commercial programs. This position will ensure that promotional and other product and disease-related materials are compliant with applicable regulations, guidelines, corporate polices and business objectives. He/she will also ensure effective communication and constructive working relationships with regulatory authorities and internal/external collaborators. The position is based in Palo Alto and will report to the Senior Director, Regulatory Affairs.

Key Responsibilities

- Provide commercial regulatory knowledge, guidance, and risk assessments to cross-functional teams developing advertising and promotional materials, as well as senior management, that are aligned with corporate commercialization efforts
- Collaborate with cross-functional teams, including field sales team, in creating and reviewing promotional materials to ensure compliance with related corporate and regulatory requirements while meeting strategic promotional objectives
- Conduct Regulatory promotional labeling and marketing compliance reviews of Clinical, Medical Affairs, Corporate Communications and Commercial materials and communications (e.g., marketing materials, disease education, institutional promotion, press releases, websites, social media, speaker presentations, talking points) to ensure promotional, scientific, medical and corporate external communications are compliant with applicable regulations, guidelines, corporate polices and business objectives.
- Serve as the primary contact to the US FDA Office of Prescription Drug Promotion (OPDP).
- Lead OPDP meetings and negotiations and ensure timely submission of promotional materials to OPDP.
- Serve as the Regulatory lead on the Promotional Review Committee (PRC)
- Ensure that changes in product labeling are appropriately implemented and reflected in current promotions and advertising
- Work collaboratively with the commercial team and any associated compliance functions to ensure that approved materials are used within the intended guidelines and duration of use.

- Identify potential areas of regulatory compliance vulnerability and risk; develop/implement corrective action plans for resolution of problematic issues and provide general guidance on how to avoid or deal with similar situations in the future.
- Participate in training of sales and marketing personnel on promotion, marketing, labeling and advertising regulations.
- Collaborate and provide input to other stakeholders to develop policies and SOPs to support the company's Commercial and Medical Affairs activities.

Knowledge, Skills and Experience

- 8+ years required of regulatory pharmaceutical industry experience and extensive experience (at least 5 years) in advertising and promotion regulatory affairs including participation on PRCs, or equivalent experience
- Outstanding interpersonal and communication (written and verbal) skills
- Attention to detail and highly organized
- Thorough understanding of regulatory requirements for compliant advertising and promotional materials.
- History of providing creative solutions to Commercial and Medical Affairs teams exhibiting superior judgment and a balanced, realistic understanding of issues
- Fluency in English as business language
- US regulatory experience required

Education Minimum requirements

- BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph D, PharmD) preferred
- Ability to travel up to 20% of the time domestically and internationally

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write "Senior Director, Regulatory Affairs Advertising and Promotion job description" in the subject field.