Associate Director, Regulatory Advertising Promotion

Biogen
Weston, MA

Job Description Essential Functions:

• Actively contribute to the development and implementation of regulatory strategy for promotional labeling and other communications including social media, press releases and talking points

• Coordinate all aspects of AP regulatory submissions including promotional materials and pre-use submissions for subpart E&H products as needed

• Provide regulatory representation to early stage programs, including review of DSMR materials as needed

• Prepare and deliver effective presentations for external and internal audiences. • Represent Regulatory Ad-Promo on global regulatory teams • Supervise and mentor direct reports if applicable

• Participate in industry groups

• Comment on draft guidance’s issued by FDA

• Represent Ad-Promo on cross-functional teams

• Actively contribute to the development and implementation of regulatory training programs for cross-functional partners

Additional Functions:

• Contribute to organizational effectiveness.

• Maintains optimism and energy in the face of change and adversity.

• Effectively serve as a role model within regulatory and cross-functionally.

• Ability to impact industry and agency organizations

Qualifications: Minimum 8+ years pharmaceutical/Biotechnology industry experience, 6+ years regulatory advertising and promotion experience, Alzheimer’s and/or Neurology experience preferred. • Ability to work both independently with minimal direction and within teams to attain group goals. • Demonstrate excellent communication skills. • Demonstrate effective cross-cultural awareness and capabilities.
• Demonstrate strong organizational skills, including the ability to prioritize workload. • Strong interpersonal skills and the ability to deal effectively with a variety of staff including commercial, medical, scientific, and clinical development staff. • Knowledge and understanding of applicable regulations. • Experience in interpretation of regulations, guidelines, policy statement related to product labeling, promotions and other communications. • Direct experience with regulatory agencies • Computer literate. • Sensitivity for a multicultural/multinational environment • People • Global Advertising and Promotion experience, a plus

Additional Information This role is based in Weston, MA and reports into the Director Regulatory Advertising Promotion