

Associate Program Director, Commercial Regulatory (Promotional Materials Reviewer)

Job ID: 00412593

Job Function

Development

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

CORA is part of the broader PDR organization that interprets the needs of worldwide

health authorities and provides regulatory intelligence necessary to generate and present information that meets the needs of health authorities, patients, purchasers and prescribers for Roche's global Pharma Medicines Division, which includes all therapeutic areas and all phases of product development from early development to post-marketing. PDR is responsible for the timely submission of applications to health authorities for approval of new products and line extensions. PDR is committed to regulatory strategies that are the most innovative, ethical, and influential in the industry. CORA Program Directors chair moderate to higher complexity Promotional Review Committees (PRCs), for different products and product development phases, as business needs dictate. CORA Program Directors are responsible for leading and managing the assigned PRCs and their activities; providing strategic and operational leadership in the areas of advertising and promotion for Roche pharmaceutical products and devices. Associate Program Directors are expected to perform their responsibilities with increased independence.

Intact & Cross-Functional Teams:

- Participates in site, regional and/or global CORA departmental meetings

- Leads assigned PRCs
- As appropriate, participates as an ad hoc member in the Regulatory Affairs Functional Team (RAFT) for relevant products. Represents CORA and supports effective and efficient cross-functional PDR coordination, appropriate resources, and timely, thorough and compliant execution

Commercial Regulatory Affairs:

- Stays abreast of internal and external developments, trends and other dynamics relevant to the work of PD and PDR to maintain, at all times, a fully current view and perspective of internal/external influences and/or implications for Roche therapeutic areas and products. Continues to expand his/her knowledge base of laws, regulations and guidelines governing the development, licensure and marketing of drugs and biologics
- Obtains and applies in-depth knowledge of Roche and regulatory guidelines, procedures and best practices
- Maintains current awareness of evolving health authority interpretations; including advisory letters, enforcement letters and policy issues. Communicates significant changes or other relevant matters to internal partners and stakeholders
- Facilitates the timely development and approval of disease state and promotional materials by interpreting and applying regulations and guidelines from health authorities and Roche policies
- Manages the development of relevant correspondence with health authorities and interpretation of health authority comments, as well as serving as the primary Roche liaison with relevant personnel in marketing, advertising and communication offices within health authorities
- Chairs PRC meetings and effectively collaborates with cross-functional internal groups and external advertising agencies
- Participates in commercial meetings to provide a regulatory perspective on marketing strategies, implementation and promotion objectives
- Develops and implements effective strategies for health authority marketing, advertising and communications submissions

Who You Are

Qualifications & Experience:

- Bachelors Degree required (life sciences disciplines strongly preferred)
- Advanced Degree in related field is preferred
- Average of 5 or more years' work experience in the pharmaceutical, biotechnology or related industry. Previous regulatory affairs experience is preferred
- Average of 2 or more years' experience in advertising and promotion review with demonstrated competence in relevant regulations and guidelines governing drug promotion
- Demonstrated understanding of international regulations, processes and issues in drug/biologics development. Includes sound knowledge of ICH, FDA and other relevant guidelines; especially FDA regulations, guidelines and recent enforcement actions
- Familiar with competitive activity in the field
- Strong computer skills, including Microsoft Office Suite (Word, PowerPoint and Excel), Adobe Acrobat, relevant publishing and document management systems/software

- Fluent English and other language skills as needed

Genentech is an Equal Opportunity Employer.